

Thoracolumbar Spine Fractures
- WFNS Spine Committee Recommendations -

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Aims and Scope

Neurospine provides spine clinicians and researchers with peer-reviewed articles on basic and clinical investigation of spine and spinal cord to enhance patient management, education, clinical or experimental research, and professionalism. The journal will consider submissions in areas on craniocervical to lumbosacral spine including the followings: neuroscience and pain research, bone and mineral research, disc and joint research, bio and industrial technology, pathophysiology, risk factors, symptomatology, imaging, treatment, rehabilitation of spine, spinal cord and peripheral nerve diseases. Specifically, basic and technology researches include the most influential research papers from all fields of science and technology, revolutionizing what physicians and researchers practicing the art of spinal neurosurgery worldwide know. Thus, we welcome valuable basic and translational technology research articles to introduce cutting-edge research of fundamental sciences and technology in clinical spinal neurosurgery. Clinical or basic research articles, review articles, case reports, technical notes, and letters to the editor written in English will be accepted.

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Introduction



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Introduction to Thoracolumbar Spine Fractures: WFNS Spine Committee Recommendations

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World Federation of Neurosurgical Societies (WFNS) Spine Committee is focused on giving a new horizon in light of research and available recent past data. With the increasing advances and day to day variations in surgical approaches, it has become extremely important to develop new guidelines and recommendations. After developing and publishing guidelines about cervical trauma,¹ spinal cord injury,² lumbar spinal stenosis,³ and cervical spondylotic myelopathy,⁴ the WFNS Spine Committee has developed recommendations regarding thoracolumbar (TL) spine trauma. This was achieved after a gross literature search between 2010 and 2020 and then holding a consensus meeting. It is an honour for me to be part of this work done during the chairmanship of Prof Zileli, Prof Fornari, and myself.

Up-to-date information was reviewed to reach an agreement in the World Federation of Neurosurgical Societies (WFNS) Spine Committee meeting. The first meeting was conducted live in Peshawar in December 2019, and the second meeting was a virtual meeting on June 12, 2020.

Both meetings aimed to analyze a preformulated questionnaire through preliminary literature review statements based on the current evidence levels to generate recommendations through a comprehensive voting session. Delphi method was utilized to administer the questionnaire to preserve a high degree of validity. The consensus was achieved when the sum for disagreement or agreement was $\geq 66\%$. Each consensus point was clearly defined, with evidence strength, recommendation grade, and consensus level provided.

The 6 papers you will find in the following pages are guidelines for almost all aspects of the TL fracture. The annual incidence of TL fractures is about 30/100,000 inhabitants, including osteoporotic fractures. There is a trend towards increasing fractures in developed countries, especially due to low velocity falls in the elderly population. The mortality rate after the spinal injury decreases in developed countries due to improvements in motor vehicle safety and traffic regulations.⁵

The TL spine is the most frequently injured spinal region in blunt trauma. The potential risk of concomitant injury to the spinal cord, chronic pain, and life-long disability presents a significant burden on patients and the health service. Due to the range of injury classification systems and varied treatment efficacy, literature on the indications for nonoperative treatment of TL fractures is conflicting.

The WFNS Spine Committee was able to formulate numerous key recommendations to guide clinical practice. Although compression-type fractures and stable burst fractures can

be managed conservatively, if there is significant vertebral body damage, kyphotic angulation, neurological deficit, spinal canal compromise, surgical treatment may be indicated. AO type B, C fractures are preferably treated surgically. Both new AO and Thoracolumbar Injury Classification and Severity Scale are reliable classifications of traumatic TL fractures and are widely used. Recent literature has shown that modified AO classification, despite being more complex, can be helpful in the management of TL fractures.⁶

Regarding the radiographic evaluation of TL fracture, the committee recommends that anteroposterior/lateral standard radiographs may be obtained if a computed tomography (CT) scan/magnetic resonance imaging (MRI) scan is not available. CT retains an important role in assessing trauma but cannot reliably demonstrate the disco-ligamentous complex. Hence MRI may be considered. MRI is the most commonly used advanced imaging method and is the method of choice in disco-ligamentous and spinal cord abnormalities and other pathologies associated with spinal trauma.⁷

Surgical treatment of TL fractures can be a better option over the nonoperative approach, especially for those who cannot tolerate months in an orthosis or cast, such as those with multiple extremity injuries, skin lesions, obesity, and so forth. AO type B and C fractures preferably should not be treated conservatively.⁸ AO type A2, A3, and A4 can be treated conservatively if there is no significant vertebral body collapse, significant kyphotic angulation or canal compromise with neurological impairment. There is no clinical evidence that Bracing for conservative treatment of TL fractures will improve the outcome.⁹

Moreover, fracture-dislocations and cases with significant instability (score ≥ 5 of Thoracolumbar Injury Classification and Severity Score classification) preferably should be operated. Surgical decompression and stabilization may be considered for burst fractures with neurological deficits, although there is not enough scientific evidence to support that. Burst fractures without neurological deficits can be treated either with conservative or surgical techniques.

In most cases, short segment posterolateral pedicle screw fixation is sufficient for burst fractures. Incorporating the fracture level screw is preferable for burst fractures of TL junction.

Long-segment fixation is a better option at TL junction burst fracture if fracture level screw cannot be incorporated.¹⁰

Long-segment screws are sufficient, and fusion is not needed. There is no difference between the anterior and posterior approaches regarding the clinical outcome in TL burst fractures. Minimally invasive techniques may be considered in the treat-

ment of TL burst fractures as the evidence suggests equivalent clinical outcomes. Compared to fusion surgery, nonfusion surgery for TL burst fractures has advantages of reduced bleeding, surgical time and donor site complications.¹¹

There is no statistical data suggesting the progression of regional kyphosis after nonfusion surgery.

Anterior vertebral body height loss of more than 50% may lead to progression of the kyphotic deformity. Detection of injury of the posterior longitudinal ligament complex is important as it significantly influence the outcome. Burst fractures with sagittal-transverse canal diameter ratio < 0.40 are highly associated with neurological injury and outcome.¹² The most common reason for posttraumatic kyphosis is untreated, unstable burst fractures. For treatment of posttraumatic kyphosis, the global sagittal balance has to be taken into consideration, and there is no proven definite kyphosis angle for indication of surgery. Posterior surgery can achieve satisfactory kyphosis correction with less blood loss and complications.

Future research is necessary to tackle the relative scarcity of evidence pertaining to patients with TL fractures. WFNS Spine Committee will continue to endeavour to teach, train, guide and inspire spine surgeons worldwide.

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Editorial



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Looking for the Optimum Treatment of Thoracolumbar Spine Fractures

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The World Federation of Neurosurgical Societies (WFNS) Spine Committee has recently created several consensus meetings using Delphi method and has published new recommendations on specific spinal disorders, such as cervical spondylotic myelopathy, ossification of the posterior longitudinal ligament, lumbar spinal stenosis, cervical spine trauma, and spinal cord injury.¹⁻⁵ Though controversy still exists in the optimum treatment of the spinal disorders, a continued high-level research and better reporting of outcomes, however, is necessary to make an optimal management and to work toward more standardized treatments for various spinal disorders.

In the current special issue of the *Neurospine*, readers will find up-to-date recommendations of the WFNS Spine Committee for the thoracolumbar spine fractures. Six review articles have focused on the epidemiology, classification and radiological diagnosis, outcome factors, indications for nonsurgical treatment, surgical techniques, and posttraumatic kyphosis of the thoracolumbar spine fractures by performing a systemic literature search of the last 10 years, reporting evidence, and producing the recommendations of the WFNS Spine Committee through 2 consensus meetings.

The thoracolumbar spine represents the transitional zone from a rigid segment to a mobile segment, making it very vulnerable to traumatic lesions. Fractures of the thoracolumbar spine are the most frequently injured part of the spine, representing 90% of all spinal injuries, followed by cervical and lastly by lumbosacral spine.⁶⁻⁸ The average annual incidence of thoracolumbar spine fractures was 30.4 per 100,000 inhabitants and the most frequent etiology was traffic accidents and fell from heights in a Swedish study.⁹ Among patients younger than 60 years of age, the annual incidence was 13 per 100,000 and was twice as high in men as in women, the incidence, however, increased steeply with age and in patients 60 years or older, it was higher in women than in men. Lifelong disability following thoracolumbar spine fractures may produce a significant economic burden on relevant society and healthcare funding.

Despite tremendous improvements in spinal imaging and management techniques over the last several decades, there has been still a lack of consensus or no standard guidelines for indications of nonsurgical or surgical treatment, optimal surgical approach and technique, fusion levels, amount of kyphosis correction and factors affecting the clinical outcome of the thoracolumbar spine fractures.

I wish the recommendations of the WFNS Spine Committee in these 6 review articles will be quite helpful to readers in better understanding and improving their treatment strategy for the thoracolumbar spine fractures.



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In the conclusion of this editorial, as one of the valued members of the WFNS Spine Committee, I'd like to cherish our friendship and proudly express my deep gratitude to all members of the Spine Committee for their outstanding collaboration and tremendous contributions to the committee and the outcomes.

CONFLICT OF INTEREST

The author has nothing to disclose.

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Title: Girl Before a Mirror
Artist: Pablo Picasso
Year: 1933
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Review Article

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INTRODUCTION

The thoracolumbar spine is the most often fractured part of the spine.¹ Wang et al.¹ in 2012, recorded that 54.9% of patients had injuries in the thoracolumbar spine in a comprehensive series of 3,142 patients at high-risk spinal fractures. The thoracolumbar junction is marked by significant biomechanical strain due to its location between the rigid thoracic and dynamic lumbar spines.² For more than 8 decades, trauma and spine surgeons have been perplexed by a broadly agreed thoracolumbar fracture classification. Persistent occurrences refer to the seriousness of an injury.³ A description of spine fractures is essential to create a common language for diagnostic purposes.⁴ To promote the creation of a globally accepted treatment algorithm

Classification and Radiological Diagnosis of Thoracolumbar Spine Fractures: WFNS Spine Committee Recommendations

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The aim of this review to determine recommendations for classification and radiological diagnosis of thoracolumbar spine fractures. Recommendation was made through a literature review of the last 10 years. The statements created by the authors were discussed and voted on during 2 consensus meetings organized by the WFNS (World Federation Neurosurgical Societies) Spine Committee. The literature review was yielded 256 abstracts, of which 32 were chosen for full-text analysis. Thirteen papers evaluated the reliability of a classification system by our expert members and were also chosen in this guideline analysis. This literature review-based recommendation provides the classification and radiologic diagnosis in thoracolumbar spine fractures that can elucidate the management decision-making in clinical practice.

Keywords: Thoracolumbar spine fracture, Classifications, Therapy recommendation, Radiological diagnosis

and to make treatment guidelines for a wide variety of thoracolumbar injuries.⁵ Encouraging constant communication between practicing doctors in order to develop a common terminology for identifying an injury configuration when a patient requires surgery, and directing care with a comparative assessment of the type and severity of injury.⁵ This clinical guideline was developed to enhance patient care by recommending a description and diagnosis for thoracolumbar spine fractures.⁶

MATERIALS AND METHODS

The guidelines for thoracolumbar spine fracture classification were proposed by World Federation of Neurosurgical Societies (WFNS) members following a study of the literature on the

classification and radiological analysis of thoracolumbar spine fractures. We conducted a review of the literature from 2010 to 2020 using the keywords “thoracolumbar fracture and classification” and “thoracolumbar fracture and radiology”; PubMed and MEDLINE reported 1,057 findings. Additionally, we conducted a manual search and discovered 15 journals. We excluded articles written in non-English languages, case notes, and low-quality case series. Then, for this analysis, we reviewed 32 papers. Fig. 1 depicts the flowchart of the literature findings. The WFNS Spine Committee reviewed current evidence on the recognition and radiological evaluation of thoracolumbar fractures in order to reach consensus at 2 consensus meetings. The first meeting was held in Peshawar in December 2019 with the attendance and involvement of WFNS Spine Committee members. On June 12, 2020, a virtual meeting was held.

Both meetings were designed to discuss a preformulated survey from detailed literature reviews and comments about the current state of evidence in order to elicit recommendations in a thorough polling session.

To ensure a high degree of validity, we administered the questionnaire using the Delphi system. To achieve consensus, participants individually voted on their degree of agreement or disagreement on each item using a Likert-type scale ranging from 1 to 5 (1 = firmly oppose, 2 = disagree, 3 = fairly agree, 4 = agree, 5 = strongly agree). The results are expressed as a percentage of

respondents who responded with a 1 or 2 (disagreement) or a 3, 4, or 5 for each object (agreement). Consensus was reached as the total of the points of dispute or compromise reached 66%. Each consensus point was established in detail, including the strength of the proof, the recommendation score, and the consensus standard.

RESULTS

The literature search yielded 2,028 abstracts, 32 of which were selected for full-text review. Our task force participants tested the effectiveness of a classification scheme in 13 articles, which were all included in this research guideline.

DISCUSSION

1. Thoracolumbar Spine Fractures Classifications

1) Goal of classification

The classification of thoracolumbar fractures aims to promote better coordination between treating doctors, to provide a standard vocabulary for describing injury configurations, and to provide a consistent measure of the injury’s form and severity. Additionally, the designation would serve as a clear guide for management, regardless of whether the patient requires surgery.⁴

Finally, the classification’s primary objective is to facilitate the

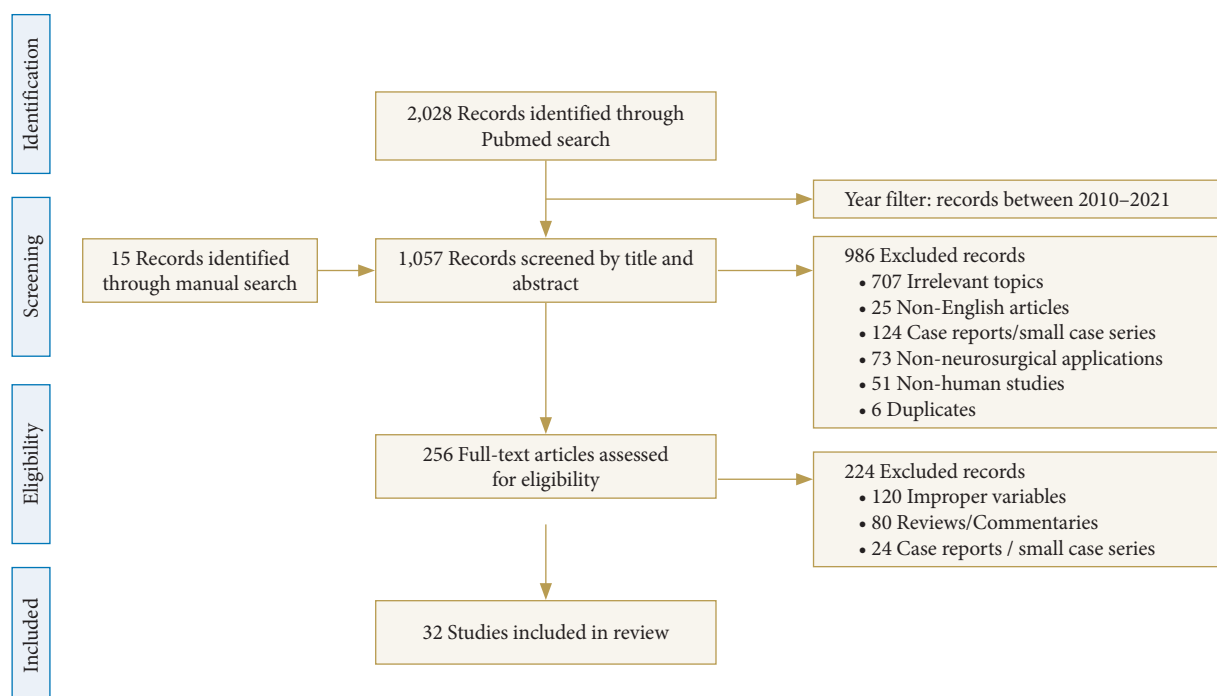


Fig. 1. Flowchart of the literature search we used.

implementation of a globally agreed therapeutic algorithm that can offer treatment guidelines for a broad range of thoracolumbar injuries.⁷

2) Requirements for an ideal classification

A reasonable spinal fracture classification system should be detailed, intuitive, and easy to use. Additionally, the definition must be consistent in describing the injury to be tested using a variety of techniques. Additionally, it must forecast the result and have a moderate to fair degree of reliability.³

The majority of current classifications do not meet the above requirements. While others are oversimplified, some are much too inclusive and nuanced for everyday use. In a functional level, these classifications fail to correctly indicate whether an injury is stable or unstable.³

3) History and evolution of classification system

The definition of thoracolumbar fractures dates all the way back to 1929, when Boehler proposed his accident types. He described 5 distinct categories of thoracolumbar injuries by fusing anatomical details of the fracture with information about the cause of injury.^{8,9}

Watson-Jones suggested a new classification scheme based on Boehler's study in 1938.¹⁰ Watson-Jones was the first to emphasize the importance of maintaining the continuity of the posterior ligamentous complex (PLC) for spinal cohesion, as well as the principles of anatomic reduction and radiographic orientation.⁸ Nicoll¹¹ sought to better characterize equilibrium in 1949 by using an anatomical classification. In contrast to his contemporaries, Nicoll believed that the main determinant of equilibrium was the integrity of interspinous ligament (ISL).¹²

Holdsworth extended Nicoll's scheme to include the whole spine more than 25 years later. It was a breakthrough when the "panel idea" was introduced.¹³ Holdsworth divided the spine into 2 major columns; anterior and posterior.¹² This definition emphasized the integrity of the ISL and emphasized the importance of the posterior column in maintaining spinal stabilization.⁸ In 1968, Kelly and Whitesides¹⁴ worked to improve Holdsworth's classification system. They asserted that burst fractures are intrinsically fragile.⁸

With the introduction of computed tomography (CT) technology in the early 1980s, it became essential to revise previous classification schemes. Denis¹⁵ updated Holdsworth's "column principle" in 1983 by substituting 3 columns for two. The middle column consisted of the vertebral body's posterior portion, which included the annulus fibrosus and the posterior longitu-

dinal ligament.

McAfee et al.¹⁶ improved and extended the Denis scale in order to further describe the enigmatic property of uncertainty. This classification scheme places a focus on the PLC as the primary determinant of fracture stability. McAfee suggested that the failure of the middle column could be calculated and that this aspect affected injury stability.

Ferguson and Allen¹⁷ rejected the "panel definition" in 1984 and suggested a classification scheme based on injury function and loss patterns that included anterior and posterior spinal "elements." Their suggested classification scheme for thoracolumbar injuries was an extension to their more commonly accepted cervical injury classification, which is a strictly mechanical classification.⁸

The Arbeitsgemeinschaft für Osteosynthesefragen (AO) classification scheme was established in 1994 as a result of a multicenter review involving over 1,445 thoracolumbar injuries. Initially, the AO classification was extended to extremity fractures, with injuries classified on a progressive severity scale ranging from type A to type C. As was the case with Ferguson and Allen,¹⁷ the severity of injury is determined by a variety of factors, including technical integrity and the likelihood of neurologic injury.¹⁸

A1 was the least severe fracture, while C3 was the most severe. There were a total of 53 distinct trends. Magerl et al.¹⁸ abandoned Denis's 3-column theory in favor of Holdsworth's 2-column theory while establishing the AO classification. The AO classification attempted to provide a systematic scheme that encompassed all fractures. Nonetheless, the scheme proved to be confusing beyond the most elementary classification stage and exhibited only modest inter- and intraobserver reliability.^{19,20} Additionally, the AO classification lacked a concrete description of stability and failed to characterize neurologic deficits. The AO classification and magnetic resonance imaging (MRI) results of instability based on posterior ligamentous integrity had a low correlation.²¹

The thoracolumbar injury classification and severity score (TLICS) was established in 2002 by the Spine Trauma Study Group to help determine which considerations to include when performing surgery on thoracolumbar injuries. Additionally, this multinational community of spine surgeons sought to find commonalities in care algorithms perceived to be driven by the thoracolumbar injury characteristics. The TLICS was developed as an injury severity scale with the aim of informing treatment and predicting outcome. In general, TLICS could be used to systematically classify accidents and guide care, following the

requirements for a classification system.²²

The TLICS is focused on 3 main characteristics of injury: the cause of injury, the PLC's dignity, and neurologic condition. An analysis of imaging research, including plain radiographs, CT, and MRI, is used to conclude the cause of damage and the state of the PLC. It was the first to use data from MRI. A cumulative score is derived from the severity scores assigned to these 3 groups and can be used to coordinate care.⁸

While TLICS remains the most robust grading scale to date, further work should be done to improve the system's accuracy and validity.¹ One significant criticism leveled at this designation is that its authenticity has never been independently checked by a panel other than the creators.^{19,23}

In 2012, the AOSpine Knowledge Forum Trauma committee revised the classification scheme and created a single classification system for spinal column trauma. The upper cervical spine, the subaxial cervical spine, the thoracolumbar spine, and the sacrum are also included. The morphological component of the system is focusing on the hierarchical AO fracture classification system, which divides fractures into 3 major groups (A, B, and C), each of which has many subtypes depending on the severity of the injury. Neurologic status at the time of initial admission is often graded using a simple and understandable procedure that is consistent in all spine areas. To improve the granularity of the underlying patient status and to integrate critical additional clinical facts, a system of supplementary modifiers was developed by consensus of the world's largest multispecialty spine society through a series of consensus-based confirmation studies led by the AOSpine Trauma Knowledge Forum. In addition to the basic alphanumeric injury description scheme, patient-specific modifiers take into account important injury and disease features that can affect the choice of operative versus conservative care and outcome. These are critical factors when treating trauma patients, as modifiers assist in coordination between surgeons and help to consolidate care habits. Validation tests conducted on the subaxial cervical spine and thoracolumbar spine suggest their inter- and intraobserver reliability.^{7,24}

4) Recent literature thoracolumbar fracture classifications

The TLICS classification, established in 2002 by the Spine Trauma Study Group, was widely used by physicians and radiologists to classify thoracolumbar fractures in order to develop an effective therapeutic approach.²⁵ This has been the most often used classification method for patients with thoracolumbar injuries until recently.⁶ TLICS attempted to quantify the severity of injuries and aid in the development of care guidelines²⁶ as

well as serve as the best possible measure of surgical versus non-surgical management.⁴

Initial research with TLICS demonstrated a high degree of reliability and variability in accident classification and recovery plans. However, some of the experiments were written by the TLICS system's developers.^{22,23,27} Both subgroups' interrater kappa statistics were within the spectrum of modest to significant reproducibility (0.45–0.74). It possesses an adequate degree of reliability and validation for classifying thoracolumbar fractures and prescribing effective therapeutic measures,²⁸ and reliable when used by experts.²⁶

TLICS also has some problems, despite its high reliability and validity. Worldwide implementation is restricted due to the understanding of its creators' treatment prejudices and the fact that they do not correctly reflect widely recognized treatment algorithms in many parts of the world.^{27,29,30}

The PLC score was the least reliable component²⁶ since it necessitates the use of an MRI that is restricted in functional emergency applications. The condition of the PLC is indeterminate. Neurological scoring can be impossible during spinal shock. Additionally, there is a need to determine the indirect radiographic parameters of an unstable spine.³ TLICS does not prescribe surgical stabilization in cases of rotational damage (score of 3), with intact PLC and neurology. However, this kind of injury is classified as more unstable than distraction injuries in the AO classification (type C).⁸

Additionally, there is a question for burst fractures. For instance, an L1 fracture with compression and burst fracture injury (1 and 1), an intact PLC (0 point), and a normal neurologic status (0 points). At the TLICS level 2, the classification takes into account nonoperative management. However, the analysis of Joaquim and Patel²⁷ shows that this situation results in a 20% reduction of height with a 19° kyphotic angulation. Additionally, considering the availability of 3 randomized trials, there is confusion about the optimal treatment of patients with moderate incidence burst fractures (TLICS score 4, the integrity of the PLC is indeterminate).⁶

Some other recent classification system for TL fractures is the Latest AOSpine Thoracolumbar Classification System, which was revealed in 2012. Verheyden et al.² discuss how this classification scheme establishes accurate terms for spinal criteria and therapeutic mechanisms, which is essential for clinical consultation and medication recommendations. Additionally, they demonstrate that the device can aid in successful diagnosis by accurately assessing the fracture morphology. In the other hand, this diagnostic scheme highlights critical morphological modi-

fiers for decision-making, such as sagittal or coronal symmetry disruption, the extent of vertebral body destruction, spinal canal stenosis, and intervertebral disc lesion.

Gamanagatti et al.⁴ argue that this is the most comprehensive and realistic classification scheme available, reflecting a progressive progression of morphological injury that allows for the determination of the degree of instability. Additionally, the categorization is precise and scientifically relevant; a higher level implies greater seriousness, and therefore greater uncertainty, as well as the style of management and prognosis. This system is straightforward, convenient, and easy to use due to a basic algorithm designed for radiologists/clinicians.⁴ Additionally, the inter- and intraobserver reliability of this classification scheme has been shown. It means that the case presentations were interpreted consistently.³¹

Furthermore, there is a reasonable recommendation for therapy. Following a study of the most recent trials with the highest level of data, it was determined that the clinical guidelines in this classification scheme were beneficial for everyday practice. However, morphological modifiers could be discussed in future research to determine their impact on daily decision-making and result. Additionally, more differentiated evidence-based therapy algorithms should be available on this framework in the future.²

Despite favorable reviews of the current AOSpine Thoracolumbar Classification System and its morphological modifiers, some condemn the system for being too inclusive, nuanced, and inefficient for normal clinical practice. Additionally, it made no recommendations for therapy, and their reproducibility is a major issue.^{3,7} Finally, Table 1 summarizes the 2 most recent and widely used thoracolumbar fracture classification schemes. The description of thoracolumbar fractures is recommended at the conclusion of the article.

2. Radiological Diagnosis of Thoracolumbar Spine Fractures

1) Radiological evaluation

Anteroposterior and lateral radiographs are also common and necessary radiographic examinations. The above examination should include spinal orientation, any rotation or translation, kyphosis, vertebral height loss, and widened interpedicular or interspinous distances.³²

CT is also a vital modality for evaluating thoracolumbar fractures, especially in emergency situations. It contains additional information about the fracture and the degree of canal compromise. However, about 25% of burst fractures are mistaken as stress fractures based solely on radiographs.³²

Table 1. Comparison of TLICS and the new AOSpine classification systems for thoracolumbar fractures

Features	TLICS	New AO
Correct terminology	±	+
Accurate morphology diagnosis	-	++
PLC injury determination	±	+
Burst fracture determination	±	+
Assessment of severity	+	++
Recommendation for therapy	++	+
Inter-/intraobserver reliability	+	+
Validity in the interpretation	+	+
Ease of use in clinical practice	Easy	Complex

TLICS, thoracolumbar injury classification and severity score; AO, Arbeitsgemeinschaft für Osteosynthesefragen; PLC, posterior ligamentous complex; ±, fair; +, strong; -, none; ++, very strong.

MRI may also be used to evaluate thoracolumbar fractures, but it is not recommended in emergency situations. In these cases, MRI provides useful knowledge about nonbony structures and soft tissues, especially about spinal cord or root injury. It can detect and quantify cord edema and hemorrhage, as well as epidural hematoma. Additionally, it can test intervertebral disc and PLC damage and detect the existence of noncontiguous injuries (23,8%) by evaluating the whole spine.³²

2) Radiological factors on diagnosis of thoracolumbar spine fractures

Numerous radiological influences influence thoracolumbar fracture diagnosis, medical considerations, and outcome. Both of these factors can occur individually or in combination with other factors, depending on the mechanism of the trauma.

(1) Vertebral body height

In the event of a vertebral body fracture, the height of the vertebral body can decrease. It is most often found in the anterior portion of the vertebral body and is graded as A1–4 by the AOSpine classification.³³

Numerous calculations may be used to quantify it. The first equation is the most straightforward. The anterior vertebral body compression percentage (AVBC) is specified as the ratio of the anterior vertebral body height (AVH) to the posterior vertebral body height (PVH).³⁴

$$AVBC = \frac{AVH}{PVH} \times 100\%$$

The second equation is used to calculate the loss of AVH. It is calculated by dividing the difference between the mean height

of the anterior vertebral body above and below the broken vertebrae by the height of the anterior vertebral body inside the fractured vertebrae (Fig. 2). The equation as follows:

$$\% \text{ of vertebral height loss} = \frac{\left(\frac{A+C}{2} - B\right)}{\frac{A+C}{2}} \times 100$$

These calculations have clinical significance in determining the kyphotic lesion. If the AVH decreases by more than 50%, the resulting segment is kyphotic.³⁵

(2) PLC and interspinous distance

The PLC is a group of spine components comprised of the supraspinous ligament, the ISL, the facet capsule ligament, and the ligament flavum.³⁶ This complex works in conjunction with the surrounding fascia and muscles to withstand bending and

compressive stresses, thus stabilizing the spine by preventing repetitive motion. In a case of thoracolumbar fracturing, disruption of PLC integrity results in instability and kyphotic deformity.³⁷⁻⁴⁰ It is critical in determining stabilization and subsequent medication selection.

PLC evaluation is critical because its deficiency has a direct effect on the seriousness of the fracture.⁴¹ More than 3.5 mm of vertebral translation is strongly associated with PLC damage. Variations of up to 7 mm in the interspinous gap are possible. However, technically, an expansion of the interspinous gap of more than 20% indicates an unstable PLC that requires surgical care. However, it should be checked by an MRI evaluation.^{42,43} The interspinous distance equation is depicted in Fig. 3³⁵:

$$\text{Interspinous widening \%} = \frac{\left(B - \frac{A+C}{2}\right)}{\frac{A+C}{2}} \times 100$$

Take note that the PLC injury is very unpredictable, and the associated brain injury necessitates surgery.⁴⁴ Due to the critical

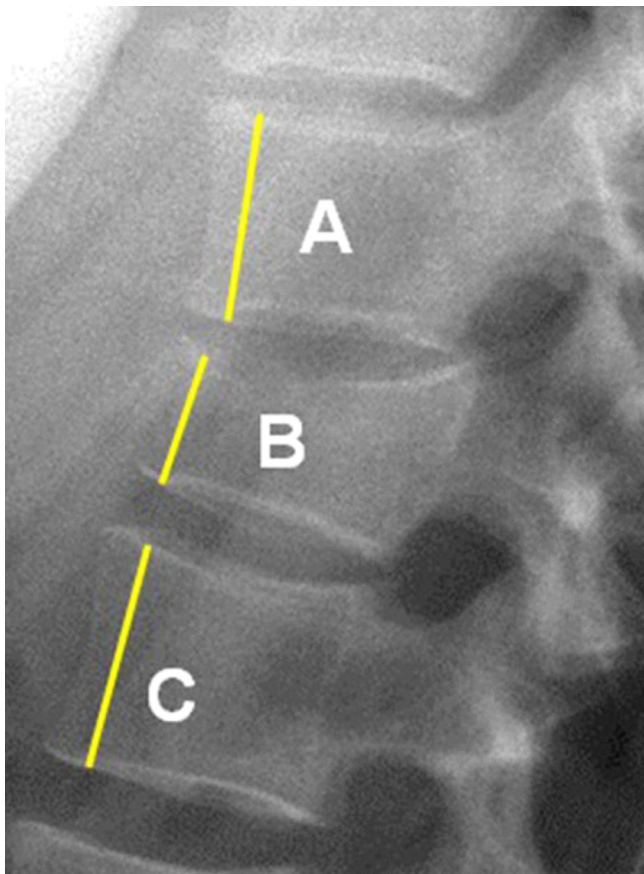


Fig. 2. Measurements used in the calculation of anterior vertebral body height loss. Measure from the lateral x-ray film the height of the most anterior corpus vertebra (straight line): (A) the height of normal superior vertebra; (B) the height of the fractured vertebral body; (C) the height of the normal inferior vertebra. Reprinted from Ruiz Santiago et al., *Quant Imaging Med Surg* 2016;6:772-84.³⁵

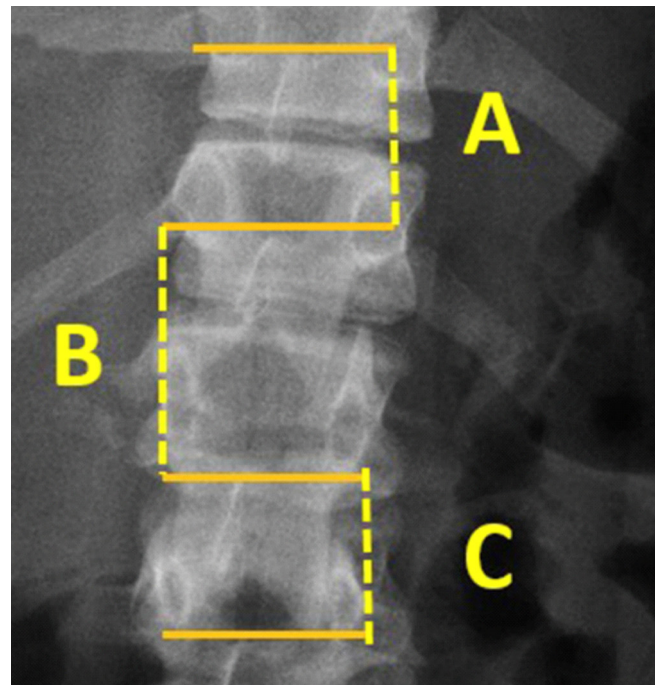


Fig. 3. Measurements used in the calculation of interspinous distance in anteroposterior x-ray film, Make a horizontal straight line right on the upper edge of each spinous process, then the distance between the adjacent horizontal lines is the interspinous process distance: (A) Interspinous distance of normal superior vertebra; (B) Interspinous distance of a fractured vertebra; (C) Interspinous distance of normal inferior vertebra. Reprinted from Ruiz Santiago et al., *Quant Imaging Med Surg* 2016;6:772-84.³⁵

nature of the PLC evaluation, PCL integrity can necessitate a shift in care from conservative to surgical management.^{32,45}

CT scan findings are correlated with clinical neurological findings about the extent and degree of spinal cord trauma, as well as the presence and severity of PLC injury in this situation.^{32,45} Apart from CT scans, such radiological observations, such as vertebral body translation on simple x-ray, are also accurate indicators of PLC damage (AO type C). Without vertebral body fracture, focal kyphosis is also a good indicator of PLC injury. Disruption of the PLC portion is also the most accurate predictor of PLC injury on T1 sagittal segment MRI.⁴⁴ Moreover, there is a chance of development of kyphosis if a PLC lesion is discovered in conjunction with a burst fracture, whether complete or incomplete.³⁴

(3) Facet joints/pedicles

The stiffness of the facet joints and pedicles also has an impact on the treatment options for thoracolumbar injuries. Bilateral facet joint-pedicle dislocation-fracture is synonymous with thoracolumbar AO type B2 damage.³³

(4) Intervertebral disc space

Most often, anterior disc space expansion occurs with or without avulsion and/or shear chip fracturing of the anterior endplate. It is associated with disability caused by hyperextension (AO type B3 on thoracolumbar fractures classification). Increased disc space width signals an unstable injury that can necessitate surgical intervention.^{33,44,45}

(5) Spinal canal diameter

Details regarding the degree of canal stenosis should be used in burst fractures. Since the degree of stenosis in neurological injury differs between vertebral stages, it can be expressed as a percentage. However, a sagittal-to-transverse diameter ratio of 0.40 is strongly correlated with neurological damage.⁴⁶

The spinal canal diameter ratio can be easily determined using CT scan axial cuts. Given that B is the spinal canal diameter ratio at the level of injury, A and C are the spinal canal diameter ratios of surrounding tissues vertebrae, respectively, above and below the level of injury.⁴⁶ The equation as it follows (Fig. 4).³⁵

$$\text{Canal narrowing percent} = \frac{\frac{A+C}{2} - B}{\frac{A+C}{2}} \times 100\%$$

(6) Displacement - dislocation

Vertebral displacement or dislocation is a form of thoracolumbar fracture that is extremely unstable. Since it involves the whole vertebral column, it is graded as the most severe level of damage on the AOSpine classification of thoraco-lumbar fractures (AO Spine type C – translational injuries). Indeed, surgical intervention is needed.^{4,33}

(7) Spinal lordosis - kyphosis

This may be the product of incomplete correction, which results in kyphosis progressing late. Kyphosis resulted in constant back pain, and its correction improved clinical symptoms in posttraumatic kyphosis.^{46,47}

In spinal surgery, it is necessary to restore the usual range of thoracolumbar curvature in order to prevent further improper

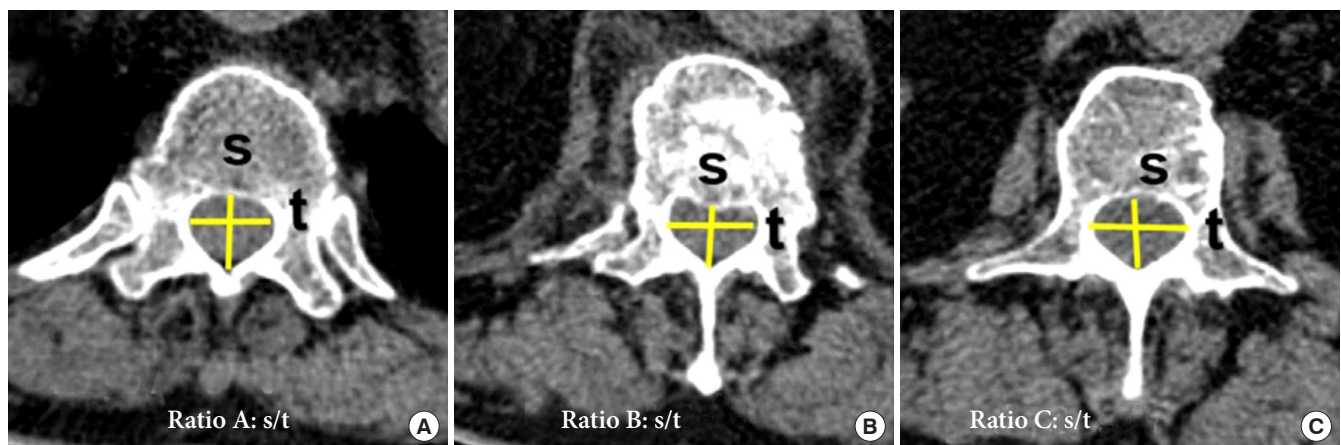


Fig. 4. Measurements used in the calculation of canal narrowing percent in axial computed tomography scan of the vertebral body. The ratio of each spinal canal is the division of the sagittal diameter (s) by the transverse diameter (t). (A) Canal ratio of the normal superior vertebra; (B) Canal ratio of the fractured vertebra; (C) Canal ratio of the normal inferior vertebra. Reprinted from Ruiz Santiago et al., *Quant Imaging Med Surg* 2016;6:772-84.³⁵

Table 2. Review statements: radiological factors which affect the clinical symptoms

1. A decrease in anterior vertebral height of more than 50% should be considered as a risk in its course of causing kyphotic development.
2. Widening the distance between spinous processes by more than 20% can be a sign of posterior ligamentous complex instability and should be confirmed by magnetic resonance imaging.
3. In burst fractures, the degree of stenosis of the canal should be measured. A sagittal-transverse diameter ratio < 0.40 may be associated with neurological injury.
4. A Cobb angle of $> 10.5^\circ$ immediately after surgery may lead to unfavorable radiological results. Besides, loss of Cobb angle correction $\geq 20^\circ$ can be associated with severe back pain.

loading of the spine, which may result in another secondary complication.⁴⁸ As a result, the surgery's objective is to achieve a fair adjustment and appropriate alignment. Cobb's 7° are the desired practical result. Cobb's 20° correction deficiency has a clear association with extreme back pain.⁴⁹ Cobb's angle greater than 10.5° immediately after operation was significantly correlated with an adverse radiographic result, which is associated with a worse clinical outcome.⁵⁰

(8) Statements about radiological diagnosis of thoracolumbar spine fractures

As a result of the preceding examination, multiple radiological causes may be identified with the diagnosis of thoracolumbar fractures and can be considered when planning surgery and assessing the surgical outcome. A reduction of more than 50% of the AVH results in the onset or development of kyphotic. PLC evaluation is critical because its deficiency has a direct effect on the seriousness of the fracture. Widening of the interspinous gap by 20% or more is considered a symptom of an unhealthy PLC and should be checked via MRI. Stable disc lesions include those depicted in AO type B-3.1 and those caused by hyperextension damage with an anterior subluxation. Details regarding the degree of canal stenosis should be used in burst fractures. A ratio of sagittal-to-transverse diameters of 0.40 is strongly correlated with neurological damage. Cobb's angle greater than 10.5° directly after operation is associated with adverse radiological effects and a weak clinical result. Cobb's 20° correction deficiency has a clear association with extreme back pain. Table 2 contains a summary of the study.

CONCLUSION

Besides being critical for physician-physician communication, terminology and clinical algorithms may also determine the therapy, so it is crucial to examine fracture anatomy carefully. The current AO and TLICS classifications for thoracolumbar fractures have demonstrated their validity and utility in

clinical practice. The AOSpine classification scheme for thoracolumbar spinal injuries is complicated. Nonetheless, it contains the majority of details on the degree of vertebral body injury, canal stenosis, intervertebral disk lesion, and neurological trauma.

Numerous radiological considerations have an impact on the diagnosis, the need of treatment, and the kind of surgery that can be done. As a result, the option of x-ray, CT scan, or MRI imaging is highly dependent on the nature of the observation. The radiological evaluation would determine whether or not the surgical objectives were met.

WFNS SPINE COMMITTEE RECOMMENDATIONS

Classification of Thoracolumbar Fractures

- Both the current AO and TLICS classifications are valid and can be used in clinical practice for traumatic thoracolumbar fractures.
- Recent research indicates that, considering its complexity, the current AO classification could be more useful in treating thoracolumbar fractures.

Radiological Diagnosis of Thoracolumbar Fractures

- If a CT scan/MRI scan is not available, anteroposterior and normal lateral radiographs may be obtained.
- Although CT is still critical for trauma evaluation, it cannot accurately demonstrate the disco-ligamentous complex; therefore, MRI should be considered.
- MRI is the most often used advanced imaging technique. It is the preferred treatment for discoligamentous disorders, spinal cord abnormalities, and other pathologies involved with spinal trauma.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Review Article

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Surgical Techniques for Thoracolumbar Spine Fractures: WFNS Spine Committee Recommendations

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To formulate the specific guidelines for the recommendation of thoracolumbar fracture regarding surgical techniques and nonfusion surgery. WFNS (World Federation of Neurosurgical Societies) Spine Committee organized 2 consensus meeting. For nonfusion surgery and thoracolumbar fracture, a systematic literature search in PubMed and Google Scholar database was done from 2010 to 2020. The search was further refined by excluding the articles which were duplicate, not in English or were based on animal or cadaveric subjects. After thorough shortlisting, only 50 articles were selected for full review in this consensus meeting. To generate a consensus, the levels of agreement or disagreement on each item were voted independently in a blind fashion through a Likert-type scale from 1 to 5. The consensus was achieved when the sum for disagreement or agreement was $\geq 66\%$. Each consensus point was clearly defined with evidence strength, recommendation grade, and consensus level provided. A magnitude of prospective papers were analyzed to formulate consensus on various surgical techniques that can be employed to address different types of thoracolumbar fractures. Surgical treatment of thoracolumbar fractures can be a better option over the nonoperative approach, especially for those who cannot tolerate months in an orthosis or cast, such as those with multiple extremity injuries, skin lesions, obesity, and so forth. It generally allows early mobilization, less hospital stay, reduced pulmonary complications, and better correction of sagittal balance. Current available literature fails to demonstrate any statistically significant benefit of fusion surgery over nonfusion in thoracolumbar fractures.



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Keywords: Thoracolumbar fracture, Burst fracture, Spine trauma, Spinal fusion, Nonfusion surgery

INTRODUCTION

Traumatic fractures of the thoracolumbar spine, especially the thoracolumbar junction (T10–L2), are the most common fractures of the spinal column. One of the major contributing factors is the significant biomechanical stress acting on this junction between a mobile lumbar spine and a semirigid thoracic spine. The outcome can be devastating, ranging from complete paraplegia to incomplete weakness, persistent fracture site

pain, and deformity.^{1,2}

Patients with majority of thoracolumbar fractures may require surgical intervention, depending upon the degree of spinal instability. Over the past 75 years, many classification systems have been developed to quantify the degree of spinal instability and neurological compromise accurately, thereby aiding the decision-making process. Denis 3 column model was one of the easiest and most reproducible classifications and became the foundation of further advancement in fracture de-

scriptions.³ This was replaced by a much more complex AOSpine classification introduced by Magerl et al. in 1993.⁴ However, a recent study reported that the AO system (and the Denis) had only moderate reliability and repeatability among spine surgeons.⁵ The AO classification was later modified and was deemed essential for accurate diagnosis through proper assessment of the fracture morphology.^{6,7} Vaccaro et al.⁸ have proposed a novel thoracolumbar injury classification and severity score, which is relatively easy to reproduce and helps demarcate surgical patients from nonsurgical ones. This chapter will discuss the various surgical techniques that could be employed to address unstable thoracolumbar fractures.

MATERIALS AND METHODS

World Federation of Neurosurgical Societies (WFNS) Spine Committee organized 2 consensus meetings to formulate the recommendations for thoracolumbar fracture regarding surgical techniques.

A systematic literature search in PubMed and Google Scholar database was done from 2010 to 2020 with the keywords “thoracolumbar fractures” and “thoracolumbar spine fractures fixation technique.”

Up-to-date information on thoracolumbar fractures was re-

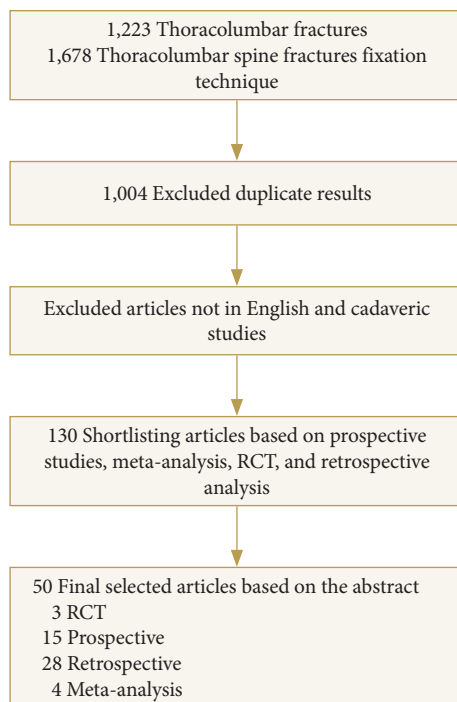


Fig. 1. Flowchart of literature search of thoracolumbar fracture and surgical techniques. RCT, randomized controlled trials.

viewed to reach an agreement in a consensus meeting of the WFNS Spine Committee. The first meeting was conducted in Peshawar in December 2019 with WFNS Spine Committee members’ presence and participation. The second meeting was a virtual meeting via the internet on June 12, 2020.

Both meetings aimed to analyze a preformulated questionnaire through preliminary literature review statements based on the current evidence levels to generate recommendations through a comprehensive voting session.

We utilized the Delphi method to administer the questionnaire to preserve a high degree of validity. To generate a consensus, the levels of agreement or disagreement on each item were voted independently in a blind fashion through a Likert-type scale from 1 to 5. The consensus was achieved when the sum for disagreement or agreement was $\geq 66\%$. Each consensus point was clearly defined with evidence strength, recommendation grade, and consensus level provided.

RESULTS

A systematic literature search in PubMed and Google Scholar database was done from 2010 to 2020 with the keywords “thoracolumbar fractures” and “thoracolumbar spine fractures fixation technique.” The search yielded 1,223 and 1,678 results respectively. Most of the results were duplicated between 2 databases. The search was further refined by excluding the articles which were duplicate, not in English, or were based on animal or cadaveric subjects. The results included case reports, case se-

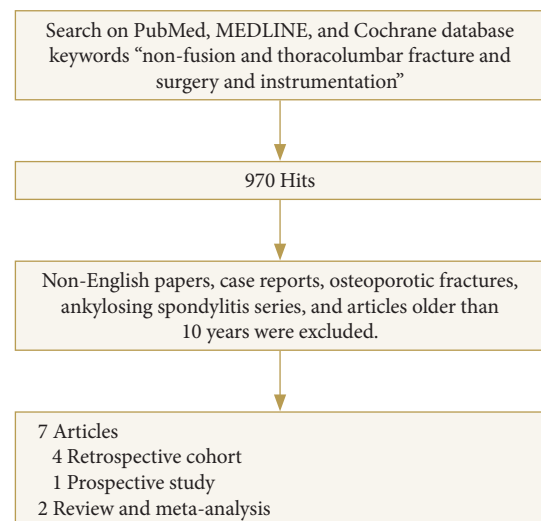


Fig. 2. Flowchart of literature search of thoracolumbar fracture and nonfusion surgery.

ries, prospective and retrospective studies, randomized studies, systematic reviews, and meta-analysis, shortlisting the count to 130. After reading the abstract, only 50 articles were selected for full review in this consensus meeting (Fig. 1).

Another search was performed using keywords “thoracolumbar fracture and nonfusion.” The same criteria were used. There were 566 results in PubMed and MEDLINE. We removed osteoporotic and ankylosing spondylitis fractures, non-English language papers, case reports, and low-quality case series. Seven papers were analyzed for this review. A flowchart of the literature search is shown in (Fig. 2).

DISCUSSION

1. Compression Fractures

Majority of compression fractures are stable and require a short period of bed rest and immobilization.

2. Burst Fractures

Burst fractures are the most common fracture requiring surgical intervention. These can be considered stable if posterior ligaments and facets are intact. Before embarking on a surgical procedure, the major question that needs answering is whether the fracture requires surgical intervention or not. In order to identify surgical indications, multiple classifications systems have been proposed to further characterize these fractures. The Thoracolumbar Injury Classification and Severity Score (TLICS) is the most commonly used score that serves the basis for guiding further treatment plan. Patients with a total score greater than 4 indicate instability and require surgical intervention where as those with a score < 4 are managed conservatively. Relative surgical indications include patients with TLICS score of less than 4 if they have intractable pain not responding to medical management or if the patient wants early mobilization. Similarly, AO classification which is much more extensive also works on a point-based system with surgery indicated for patients with score more than 5.

Main principles of thoracolumbar burst fracture surgery are; neural decompression, improve stability, and correction of kyphosis. Thoracolumbar fractures with 25°–30° kyphosis, progressive neurological deficits, loss of vertebral height more than 50%, and compression of the canal more than 50% should be treated surgically.⁹ Unstable thoracolumbar fractures cause sagittal imbalance due to progressive kyphosis when they have not been treated.^{9,10}

1) Burst fracture: posterior approach and variations

One of the most common and easy procedures to perform is posterior transpedicular screw fixation. It remains the most popular technique today, although not entirely free of complications, including instrumentation failure, pseudarthrosis, infection, and the need for late instrumentation removal.¹¹ One of the dilemmas to overcome in such circumstances is to identify the number of levels that require fusion. For many years thoracolumbar junction fractures have been conventionally treated with long constructs with 4 screws proximal and distal to fracture level. Long-segments posterior fixation imparts greater stability and support with less chances of implant failure but at the cost of sacrificing motion segments. In addition, it is unclear how these constructs of variable length affect adjacent or nearby segments.¹² Long-segment fixations are known to cause increased movement in adjacent disc spaces leading to raised intradiscal pressure. These biomechanical effects are known to hasten disc degeneration process.¹³ To overcome the limitations of long-segment fixation, many authors have put forward a short-segment fixation technique incorporating the pedicle of fractured vertebrae well over a decade ago.¹⁴ Parker et al.¹⁵ explained that a load-sharing score of 6 or less is sufficient to be treated by short-segment pedicle screw fixation. However, Lee et al.¹⁶ reported that in his study of 47 patients, short-segment pedicle screw fixation was ineffective with a load-sharing score of 7 or more. Kim et al.¹⁷ also reported significant differences in the loss of correction angle between long-segment and short-segment posterior fixations, indicating that short-segment posterior instrumentation is insufficient in cases with a load-sharing score of 7 points or above.

However, Altay et al.¹⁸ recommended that short-segment fixation provides adequate fixation with no loss of height or correction loss. Due to the ongoing dilemma and the possibility of implant failure with a large load-sharing score, a newer technique to incorporate fracture segment into the construct was introduced. Park et al.¹⁹ in their study of 45 patients, compared short-segment fixation and intermediate screw with long-segment fixation. A follow-up of 5 years was carried out to assess the degree of correction loss, implant failure, and revision surgery. His results showed that there was no significant difference in outcome between the 2 groups. Hence the use of intermediate screw has been shown to add strength to short-segment fusion. Recent biomechanical studies confide with the results showing the placement of intermediate screw at fracture level increases the stiffness of the construct and protects the anterior column during loading.²⁰ Similar results have been demonstrated

by Chung and Rhym²¹ who reported that easy indirect reduction of fractured vertebrae and improved segmental stability could be achieved by inserting the pedicle screw at the level of the fractured vertebra. Jeong et al.²² compared the clinical and radiological results between short-segment and long-segment pedicle fixation while inserting the pedicle screws at the level of the fractured vertebra in the thoracolumbar burst fracture and obtained similar results. Mahar et al.¹⁴ also reported that segmental fixation with additional screws at the level of the fracture increases constructs stiffness and shields the fractured vertebral body from anterior loads (Fig. 3A, B).

One of the major limitations to all these techniques is the lack of level 1 evidence. All the aforementioned papers and studies are small prospective trials or retrospective analysis. Only a handful of randomized controlled trials have been conducted and that too of a very small sample size. Those worth special mentioning are by Li et al.²³ in 2016 who performed percutaneous pedicle screw fixation in 32 patients with 19 of them having an additional screw in fractured vertebra. His results concluded that an intermediate screw helped in better correction of kyphosis and a stronger construct. The other randomized controlled trial is by Lyu et al.²⁴ in 2016 who compared 3 different techniques, 3-level percutaneous fixation, 2-level

percutaneous fixation, and 3-level open fixation, respectively. His results showed 3-level percutaneous fixation to be the most effective technique in terms of operating time and blood loss. However, the efficacy of either technique was statistically same. (Fig. 4A, B).

With the available recent research, we can safely conclude that short-segment fixation with the incorporation of the fracture segment provides a stable construct even in a setting of high load-sharing score. In circumstances where anatomical boundaries are disrupted and fracture segment cannot be used, a long-segment fixation may be considered.

Recent trials for pedicle screw fixation technique are summarized in Table 1.

2) Burst fracture: use of monoaxial screws and crosslinks

The introduction of polyaxial screws has significantly incre-



Fig. 3. (A) D12 burst fracture. (B) Traditional long constructs for junctional fractures.

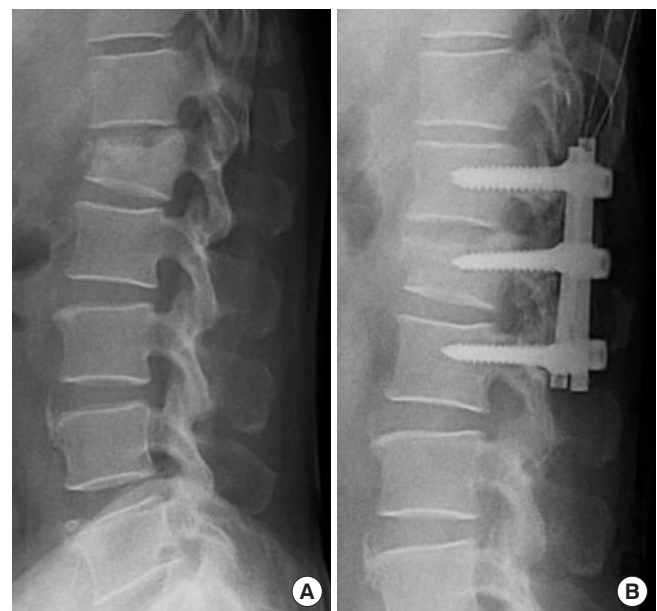


Fig. 4. (A) Burst fracture of thoracolumbar junction. (B) Short-segment fixation with an additional screw in fractured vertebrae.

Table 1. Recent trials for pedicle screw fixation technique

Study	Year of publication	Research type	No. of patients	Comparison made	Results
Park et al. ¹⁹	2016	Retrospective	45	2-Level vs. 3-level fixation	Results are similar
Li et al. ²³	2016	Prospective	32	Short-segment percutaneous screw vs. short segment with screw in fractured vertebrae	Short segment with screw in fractured vertebra is better
Lyu et al. ²⁴	2016	Randomized controlled trials	90	3-Level percutaneous fixation vs 2 level percutaneous fixation vs 3 level Open fixation	3-Level percutaneous fixation is superior to open technique

ased the ease of rod placement, particularly in long constructs. However, monoaxial screws that had initially phased away are now being reinvestigated due to their beneficiary effects in reducing burst fracture segments. Yao et al.²⁵ compared short-segment fixation using both monoaxial and polyaxial screws. He concluded that monoaxial screws at the fracture level have a flick-up effect on the central vertebral body contributing to the restoration of loss height. Similarly, Xue and Zhao²⁶ used monoaxial screws with distraction and compression to reduce collapsed endplate. He concluded that satisfactory fracture reduction and correction of segmental kyphosis could be achieved and maintained with the use of monoaxial pedicle screw fixation, including the fractured vertebra (Figs. 5, 6).

Although not frequently used, the addition of crosslinks, particularly in short-segment fixation, has been biomechanically proven to increase the strength of the construct.²⁷ An experimental study with cadaveric models has shown that crosslinks, when added to short-segment posterior fixation, improve stiffness and decrease motion in axial rotation.²⁸ Despite these studies, there is a lack of level 1 or 2 evidence to suggest the use of crosslinks and its current use is largely dependent on the surgeon's preference.

3) Burst fracture: nonfusion surgery

Unstable thoracolumbar burst fractures need to be treated

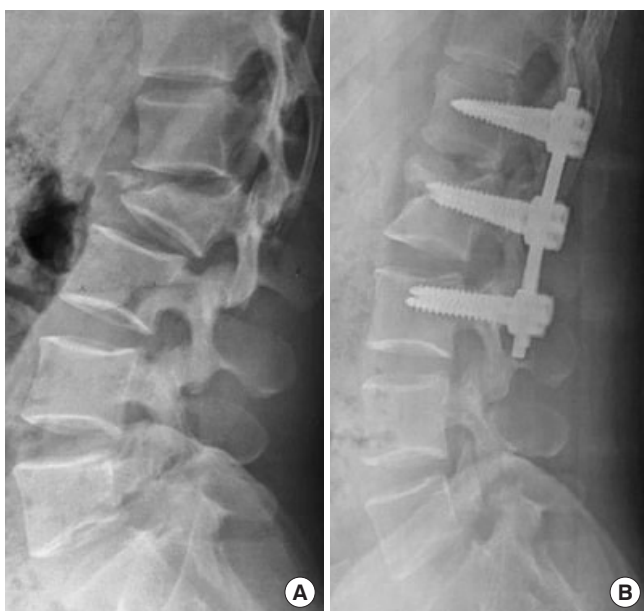


Fig. 5. (A) Burst fracture of junction with significant loss of height and kyphosis. (B) Use of monoaxial screws for distraction and restoration of lost vertebral height.

surgically. However, the ideal surgery is still controversial. Long term of clinical and radiological results of posterior surgeries have been published.^{29,30}

Fusion surgery is an effective method used in the treatment of thoracolumbar fractures. Necessity of fusion surgery is controversial due to complications like pseudoarthrosis and adjacent segment.³¹ Articles on the effectiveness of nonfusion surgeries in thoracolumbar fractures have been published, in the last decade.^{16,32}

Anterior, posterior, and combined surgeries are the treatment options of thoracolumbar fractures. Posterior only surgery has good clinical and radiological results. Instrumentation levels for the treatment of thoracolumbar fractures is also another topic that has been discussed. The main advantage of short-segment instrumentation is the preservation of segmental motion.³³⁻³⁵ Intermediate screws (screw inserted in the fractured vertebra) strengthen the construct and they are more effective in correction of kyphosis.^{34,36}

Recent discussion is whether fusion is necessary for the treat-

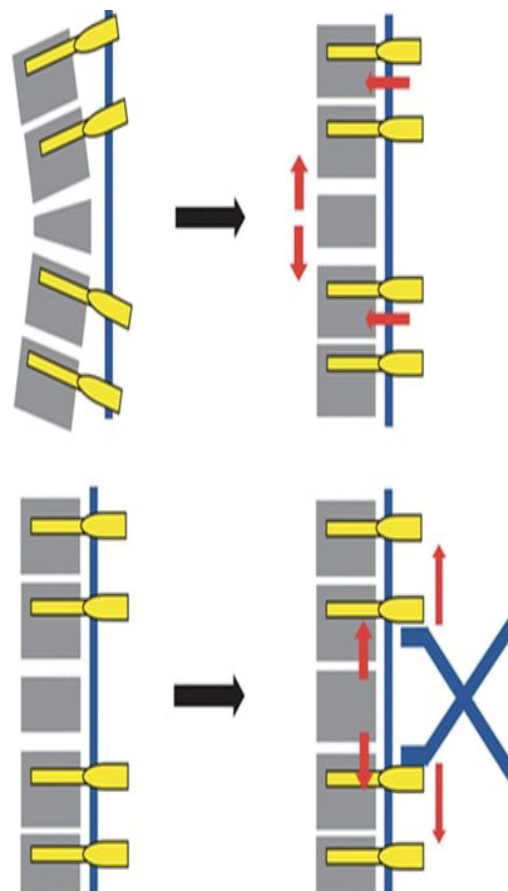


Fig. 6. Distraction/compression method for height restoration using monoaxial screws.

ment of thoracolumbar fractures.^{32,37} Some papers report better radiological correction with fusion surgeries compared to nonfusion surgeries.^{38,39} Other studies suggest that the loss in correction of kyphosis is less in patients who have undergone fusion surgery than nonfusion surgery, but difference is statistically insignificant.⁴⁰

4) *Burst fracture: fusion surgery*

The important advantage of fusion surgery is that the incidence of implant failure reduces when fusion is achieved.¹⁰ Despite this main advantage, fusion surgery decreases the segmental motion. It increases stress forces at the adjacent segment.^{9,15,41,42} Even in patients in which fusion is achieved, kyphosis may increase over time due to the decrease of the height of the disc. Screw breakage may occur due to the increase of kyphosis.⁴³ It has been reported that screw fractures do not make a clinical difference.^{44,45}

Qian et al.⁴⁶ reported that the posterolateral fusion was an effective measure to prevent implant failure in burst fractures, but Sanderson et al.⁴⁵ and Dai et al.⁴⁷ recommended that routine fusion was unnecessary in the operative management of these fractures. Singh et al.⁴⁸ performed a prospective study where 66 patients with thoracolumbar fractures underwent posterior instrumentation with fusion. These patients were followed both clinically and radiologically for up to 12 months. Their results showed that they had less loss of the postoperative correction achieved for all radiological parameters on the final follow-up as compared to the available literature.⁴⁹ Hwang et al.¹⁰ reported that in the patient group who underwent fusion surgery, there were infection, bleeding, pain, and wound healing problems in the iliac donor site. Excessive muscle dissection and bone removal for fusion increase bleeding in fusion surgery.^{31,40} Lan et al. have reported is no difference in postoperative clinical scores in the patient group with fusion and nonfusion surgery.³¹

Studies have shown that nonfusion surgeries have less surgery time and reduce bleeding for the the treatment of thoracolumbar fractures.^{10,31,40} Chou et al.⁴⁴ have reported that thoracolumbar fractures that have been operated with nonfusion short-segment instrumentation have less bleeding, shorter surgical time, fewer bone graft donor site complications, and motion segment preservation. Hwang et al.¹⁰ compared thoracolumbar fractures patients that were treated with short-segment instrumentation with fusion and nonfusion and reported less bleeding and less surgical time in nonfusion surgery group compared to fusion surgery group. They also discussed the advantage of segmental motion preservation and less adjacent segment dis-

ease. Lee et al. showed less bleeding and minimal tissue damage with percutaneous short-segment instrumentation.¹⁶

One of the disadvantages of nonfusion surgery is the need of the implant removal at the end of the first year to prevent implant failure.^{10,37} Kim et al.³² reported that they have removed the screws at the end of an average of 10 months. Sanderson et al.⁴⁵ reported 14% screw fractures who underwent nonfusion short-segment instrumentation. They did not recommend removing the screws. Chou et al.⁴⁴ compared the patients that have been treated with nonfusion instrumentation with and without screw removal. They have reported that there was no functional or radiological difference between the 2 groups.

(1) *Radiological results of nonfusion surgery*

Wang et al.³⁷ stated that the patients in the nonfusion group obtained better radiological results than the fusion group and showed that segmental mobility decreased in the fusion group. Hwang et al.⁵⁰ reported that kyphosis correction was more effective in the fusion group. Chou et al.⁵¹ compared fusion and nonfusion short-segment instrumentation for thoracolumbar fractures. They concluded that there was no significant increase in kyphosis between the 2 groups and suggested that the loss of correction that occurred in the follow-up was due to the decrease in the disc height because of the degeneration of the damaged disc rather than the vertebral height loss.^{37,50} Kim et al.³² published the results of thoracolumbar fractures patients who underwent nonfusion short-segment instrumentation in patients without the disc and facet injury and had no loss of correction.

(2) *Clinical results of nonfusion surgery*

There are many studies that have compared fusion and nonfusion short-segment instrumentation for thoracolumbar fractures. In all of these studies, no clinical or radiological difference was reported between the fusion and nonfusion groups.^{37,40,45,47} Chou et al.⁴⁴ have compared fusion and nonfusion short-segment instrumentation groups and reported that there was no visual analogue scale (VAS) and low back outcome score difference between the 2 groups. Hwang et al. have compared fusion and nonfusion groups and they have reported that there was no clinically and radiologically significant difference in the correction of kyphosis. They also reported that there was loss of correction in the nonfusion group, but there was no clinically significant difference compared to the fusion group.¹⁰

We summarized the 7 papers on nonfusion surgery for thoracolumbar fracture at Table 2.

Table 2. Summary of the reviewed papers on nonfusion surgery

Study	Study design	Evidence level	No. of patients	Main target of the study	Conclusion
Lan et al., ³¹ 2017	Systemic review and meta-analysis	5	445	Comparing fusion and nonfusion for the treatment of thoracolumbar burst fractures	Nonfusion surgery has less blood loss, shorter operation time, better segmental motion and lower donor site pain
Chou et al., ⁴⁴ 2014	Prospective	2	22	Nonfusion surgery for thoracolumbar burst fracture	Regional segmental motion could be preserved without fusion
Hwang et al., ¹⁰ 2012	Retrospective	4	46	Comparison of posterior fixation alone and fixation with fusion	No significant differences in the kyphosis correction and clinical outcomes between the 2 groups
Chou et al., ⁵¹ 2016	Retrospective	4	69	The effect of removal of the implants after fixation of thoracolumbar burst fractures without fusion	The radiological and functional outcomes of both implant removal and retention were similar
Diniz et al., ⁴⁰ 2017	Systemic review and meta-analysis	5	220	Necessarity of fusion for thoracolumbar burst fracture treated with spinal fixation	Arthrodesis did not improve clinical outcomes. Fusion was associated with increased surgical time and higher intraoperative bleeding
Kim et al., ³² 2011	Retrospective	4	23	To evaluate the results of posterior stabilization of thoracolumbar fracture using nonfusion method	Nonfusion method is one of the most effective methods for thoracolumbar fractures, especially in young patients
Lee et al., ¹⁶ 2013	Retrospective	4	59	The effect of percutaneous short-segment instrumentation without fusion for the treatment of thoracolumbar burst fracture	Percutaneous pedicle fixation without bone graft provided earlier pain relief and functional improvement

5) Burst fracture: anterior surgery

The anterior column supports about 80% of the axial load of an intact spine. When the anterior column is substantially injured, the anterior column support is reduced, leaving most of the stress transmitted by the posterior implant and the bony elements. Anterior surgery for such type of burst fractures was introduced in the 1980s when computed tomography (CT) scans demonstrated fracture fragments inside the spinal canal.⁵² Using an anterior transthoracic or transabdominal approach, the surgeon can directly visualize the fracture fragment and remove it completely without any traction on the spinal cord or risk of dural injury. If the defect is significant, it can be bridged with an artificial cage or bone graft to restore the height of the anterior column. Such forms of implants are usually supplemented with lateral body screw placement or posterior transpedicular screws. These techniques are as effective as posterior approaches in neurologically intact patients or even better in terms of restoration of vertebral body height and maintain sagittal balance with comparable outcomes.⁵³ Other studies have shown that degree of neurological recovery is equal to or greater than 80% and significantly correlated with the quality of neural decompression.⁵⁴

The principle of ligamentotaxis is based on the distraction that allows intracanalicular bony fragments to be pushed back into the vertebral body. But this requires the presence of an intact posterior longitudinal ligament. Biomechanically, the anterior approach may seem to be a better option when posterior elements have been injured and the ligamentotaxis cannot be utilized.⁵⁵ An isolated posterior approach is likely to cause iatrogenic injury to the spine or dura in these circumstances. But some surgeons have modified their posterior approach to address these pathologies by combining laminectomy and then unilateral pediclectomy.⁵⁶ As previously mentioned, current anterior approaches are considered as safe as posterior approaches. Kaneda et al.⁵² performed a study on 150 patients with a burst fracture of the thoracolumbar spine with neurological deficits. These patients were subsequently managed with a single-stage anterior spinal decompression, strut grafting, and anterior spinal instrumentation. At an average follow-up of 8 years, radiographs showed successful fusion of the injured spinal segment in 140 patients (93%) with a neurological recovery of 95%. Not many studies have compared anterior with posterior approaches. A meta-analysis by Zhu et al.⁵⁷ compared anterior and posterior surgeries and found no significant differences

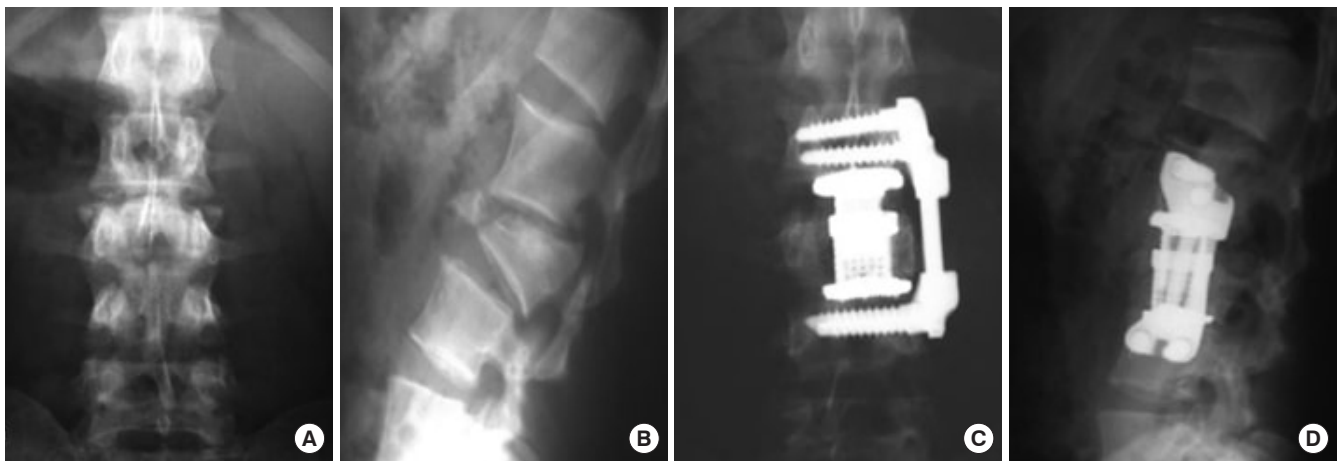


Fig. 7. (A) L1 burst fracture anteroposterior view. (B) L1 burst fracture lateral view. (C) Anterolateral approach with cage placement anteroposterior view. (D) Anterolateral cage placement lateral view.

between the two. However, the anterior approach was associated with more blood loss. Wood compared the 2 approaches in 38 patients and followed them for 2 years. He reported similar patient outcomes between the 2 approaches and that anterior fusion and instrumentation for thoracolumbar burst fractures might present fewer complications³² (Fig. 7A–D).

One of the major drawbacks of the anterior approach is its technical difficulty.⁵⁸ Not many surgeons are comfortable with the anterior approach, which might explain their tendency to shy away from these procedures and improvise on traditional posterior approaches. In addition to this, the procedure may be complicated in obese individuals with the possibility of significant blood loss. These parameters should be borne in mind while planning such operations.⁵⁹

6) Minimally invasive techniques

Conventional open techniques that are being employed to address thoracolumbar fractures are often criticized due to associated blood loss and higher infection rates.⁶⁰ In a systematic review conducted by Verlaan et al.⁶¹ blood loss of up to 1,000 mL has been documented in conventional open procedures with an average infection rate of 0.7% in anterior and 3% in posterior approaches. In addition to these, open procedures are also associated with significant approach-related morbidity. The anterior procedures are associated with significant perioperative pain, shoulder discomfort, and ventilation problems.⁶² Similarly posterior midline approaches lead to extensive retraction and muscle ischemia. These have been known to cause paraspinal muscle scarring, atrophy, and decreased muscle strength.⁶³ The clinical effect of this muscle morbidity can be a

significant postoperative pain and functional impairment in the long term.

In order to overcome these limitations, minimally invasive surgery (MIS) are being employed. Although there are no randomized controlled trials to document the safety and results of MIS techniques, most of the available literature suggests these procedures to be safe and effective.

(1) Anterior endoscopic decompression

For anterior approaches, an endoscope is most commonly used instrument. Endoscopic surgery requires appropriate training and experience. Since most injuries occur at the thoracolumbar junction, knowledge about the attachment and manipulation of the diaphragm is of extreme importance. The procedure is not only surgeon dependent but also requires endoscope-friendly instruments. Anterior endoscopic decompression assisted with posterior stabilization has been used to treat burst fractures⁶⁴ A large trial with 371 patients was conducted by Khoo et al.⁶⁵ in Germany, who did thoracoendoscopic decompression of burst fractures. In 35% of patients, a stand-alone anterior thoracoscopic reconstruction was performed. He reported a steep learning curve with a mean operating time of 300 minutes which was reduced to half after the 50th case. The risk of major complications in his series was 1%.

Similarly, Le Huec et al.⁶⁶ performed video endoscopic decompression and cage placement in 50 patients with thoracic fractures. He achieved good results with better kyphosis correction and neural decompression. Simultaneous anterior and posterior procedures were performed in 20 patients. Although no complications were reported in any of the cases, a long-term

follow-up was lacking. Compared to conventional open techniques, reduced blood loss, perioperative pain, reduced time to mobilization, and hospital stay have been noted.⁶⁷

(2) Percutaneous screw fixation

Percutaneous pedicle screw fixation can be used as a stand-alone procedure or an adjunct to anterior approaches in many circumstances. A systemic review by Phan et al.⁶⁸ in 2017 compared 279 patients undergoing percutaneous pedicle screw fixation with 340 patients who underwent conventional open instrumentation. He concluded that percutaneous pedicle screw fixation was a safe and effective means to treat thoracolumbar fractures. It was associated with reduced blood loss, operating time, and hospital stay. Similarly, Wang et al.⁶⁹ performed percutaneous pedicle screw fixation in 19 patients using the Sextant system and compared them with a conventional open group. After 2 years of follow-up, there were no significant differences in the postoperative sagittal Cobb angle, vertebral body angle, and the improvement of the vertebral body height and the kyphotic deformity correction between the 2 groups. He concluded that percutaneous pedicle screw placement is a good alternative to open procedures with shorter operating time and less blood loss. Another retrospective analysis by the same author compared MIS short-segment fixation with MIS long-segment fixation with screws in fractured vertebrae. Both of these procedures were then compared to the conventional open technique.⁶⁹ This is one of the unique articles that compared these 3 different techniques and found no statistical difference between any of them. However, percutaneous screws with an additional screw at fracture level were superior, with better height restoration and kyphosis correction (Fig. 8A, B).

(3) Cement augmentation

Chen and Lee⁷⁰ were the first individuals to use isolated cement injection to treat thoracolumbar burst fractures. They performed the technique on 6 patients. Although cement leak was seen radiographically in 4 patients, all of them remained asymptomatic. All the patients showed significant pain improvement postoperatively. Similarly, Huwart et al.⁷¹ described cement usage in 62 neurologically intact patients using CT-guided injection. Despite the high accuracy of the CT scan, cement leakage was still observed in 11%. All the patients showed significant improvement in Oswestry Disability Index (ODI) and VAS scores postoperatively. However, no long-term follow-up was available. In contrast to vertebroplasty, kyphoplasty involves an injection of contrast under low pressure within a confined



Fig. 8. (A) L1 unstable burst fracture. (B) Minimally Invasive screw placement rod fixation.

created space, theoretically reducing the chances of cement leakage. Hartmann et al.⁷² performed stand-alone kyphoplasty in burst fractures and reported significant post procedure improvement in pain. After 1-year follow-up, an average 6° loss of kyphosis correction was noticed radiologically though these patients remained asymptomatic. Currently, the literature available for stand-alone kyphoplasty and vertebroplasty in thoracolumbar trauma is very limited. Theoretically and based on small studies, kyphoplasty appears to be safer than vertebroplasty. However, despite such claims, isolated use of cement remains controversial in the trauma setting.

The objective of all forms of cement augmentation is to restore vertebral body height and support the anterior column. Cadaveric studies have shown that transpedicular vertebral body augmentation reduces pedicle screw bending moments by 59% in flexion and by 38% in extension, thereby decreasing the stresses on posterior instrumentation.⁷³ While depressed vertebral cortices can be reduced indirectly through ligamentotaxis via traction on the annular fibers, the central portion of the vertebral body remains depressed. Kyphoplasty offers a potential solution to this problem by directly reducing and buttressing the depressed endplate while providing stability to allow bony healing.⁷⁴ Multiple studies have shown benefits of cement augmentation with short-segment pedicle screw fixation.

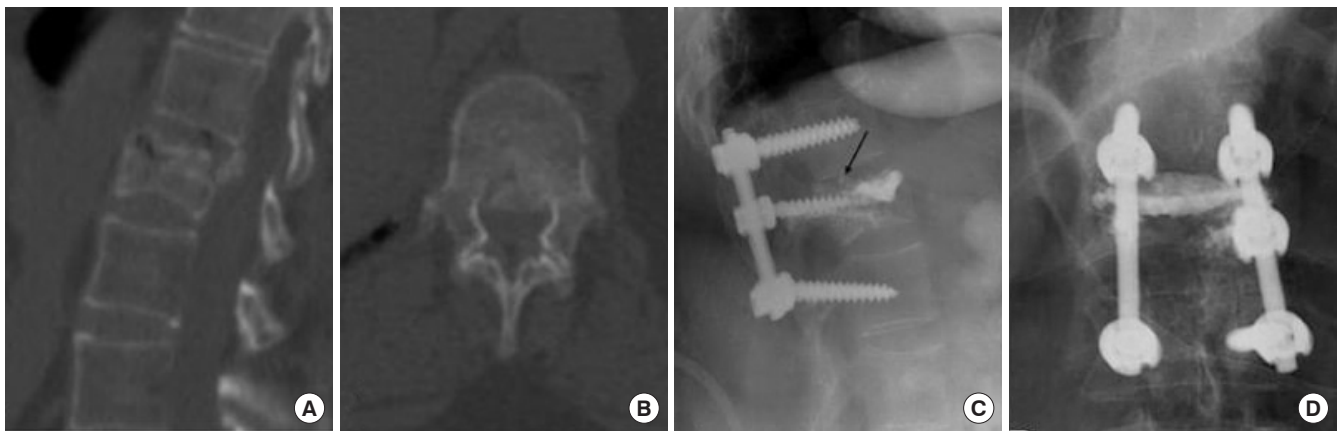


Fig. 9. Cement augmentation and screw placement of the fractured level. (A) D12 burst fracture computed tomography (CT) sagittal film. (B) D12 burst fracture axial CT scan. (C) Screw placement with incorporation of fracture segment and cement augmentation lateral view. (D) Screw placement and cement augmentation anteroposterior view.

Afzal et al.⁷⁵ reported a series of 16 patients with cement injection and short-segment fixation for burst fractures. Cement leakage into the canal was seen in 3 patients, which required immediate removal of cement. All their patients recovered successfully with no additional neurological deficits. Similarly, Verlaan et al.⁷⁶ and Fuentes et al.⁷⁷ showed similar results of cement augmentation and short-segment fixation in a limited number of patients with good kyphosis correction and stability. Cho⁷⁸ was one of the first ones to compare cement augmentation and short-segment fixation with short-segment fixation alone. The author concluded that at a 2-year follow-up, patients with cement augmentation have better kyphosis correction and pain improvement than other groups with no identifiable complications.⁷⁹ Lastly, a prospective randomized trial in patients older than 65 years with burst fractures was randomized into kyphoplasty (controls) and kyphoplasty with short-segment pedicle screw instrumentation. Patients treated with kyphoplasty and spinal instrumentation showed statistically improved VAS and ODI scores at the 2-year follow-up. In addition, the instrumented group exhibited better kyphosis reduction and maintenance of the corrected alignment (Fig. 9A–D).

CONCLUSION

Aforementioned data describe the various techniques that could be used to address thoracolumbar fractures with open posterior decompression and pedicle screw fixation being the most common surgical procedure employed across the world. Other forms of instrumentation are found to be equally effective, but lack of appropriate data and large randomized controlled

trials to back their claims.

The surgical treatment of unstable thoracolumbar fractures is still controversial. There is no difference in functional and radiological outcomes between fusion and nonfusion surgery. Less bleeding and less surgery time are the main advantages of non-fusion surgery.

WFNS SPINE COMMITTEE RECOMMENDATIONS

- For burst fractures, a short-segment posterolateral pedicle screw fixation is sufficient in most cases.
- For burst fractures of thoracolumbar junction, incorporating the fracture level screw is preferred to increase the strength of the construct. If fracture level screw cannot be incorporated, long-segment fixation should be applied.
- When using long-segment screws, there is no evidence that fusion is needed, as there is no difference in outcome with fusion or not.
- For thoracolumbar burst fractures, anterior or posterior approach does not make a difference in clinical outcomes.
- There is inadequate evidence that surgical treatment of burst fractures of the thoracic and lumbar spine may improve clinical outcome compared to nonoperative treatment.
- Minimally invasive techniques may be considered in the treatment of thoracolumbar burst fractures as the evidence suggests equivalent clinical outcomes, compared to open technique.
- Compared to fusion surgery, nonfusion surgery for thoracolumbar burst fractures has advantages of reduced bleed-

ing, surgical time, and donor site complications.

- There is no statistical data suggesting progression of regional kyphosis after nonfusion surgery.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Review Article

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Kyphosis After Thoracolumbar Spine Fractures: WFNS Spine Committee Recommendations

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Thoracolumbar fractures change the biomechanics of the spine. Load distribution causes kyphosis by the time. Treatment of posttraumatic kyphosis is still controversial. We reviewed the literature between 2010 and 2020 using a search with keywords “thoracolumbar fracture and kyphosis.” We removed osteoporotic fractures, ankylosing spondylitis fractures, non-English language papers, case reports, and low-quality case series. Up-to-date information on posttraumatic kyphosis management was reviewed to reach an agreement in a consensus meeting of the World Federation of Neurosurgical Societies (WFNS) Spine Committee. The first meeting was conducted in Peshawar in December 2019 with WFNS Spine Committee members’ presence and participation. The second meeting was a virtual meeting via the internet on June 12, 2020. We utilized the Delphi method to administer the questionnaire to preserve a high degree of validity. We summarized 42 papers on posttraumatic kyphosis. Surgical treatment of thoracolumbar kyphosis due to unstable burst fractures can be done via a posterior only approach. Less blood loss and reduced surgery time are the main advantages of posterior surgery. Kyphosis angle for surgical decision and fusion levels are controversial. However, global sagittal balance should be taken into consideration for the segment that has to be included. Adding an intermediate screw at the fractured level strengthens the construct.

Keywords: Thoracolumbar fracture, Kyphosis, Spine, Posttraumatic kyphosis

INTRODUCTION

Thoracolumbar fractures may significantly change the spinal biomechanics. The loss of height in the vertebral body and disruption of the posterior tension band may lead to kyphosis in the spine. As a result of the existing deformity, compensatory mechanisms try to achieve a sagittal balance. Especially, lumbar hyperlordosis is one of the effective methods for maintaining sagittal balance. However, in patients with insufficient compensatory mechanisms, a sagittal imbalance develops. The existing kyphosis progresses with the loads on the anterior column with a negative effect on sagittal balance.^{1,2} Secondary to kyphosis, the paraspinal muscles may stretch, which then causes inflammation and pain. With further progression of kyphosis, neuro-

logical damage occurs due to the stretching of the cauda equina fibers.²

MATERIALS AND METHODS

We reviewed the literature between 2010 and 2020 using a search with keywords “thoracolumbar fracture and kyphosis”; there were 907 results in PubMed and MEDLINE. We removed osteoporotic fractures, ankylosing spondylitis fractures, non-English language papers, case reports, and low-quality case series. Then, we analyzed 42 papers for this review. A flowchart of the literature search is shown in Fig. 1.

Up-to-date information on posttraumatic kyphosis management was reviewed to reach an agreement in a consensus meet-

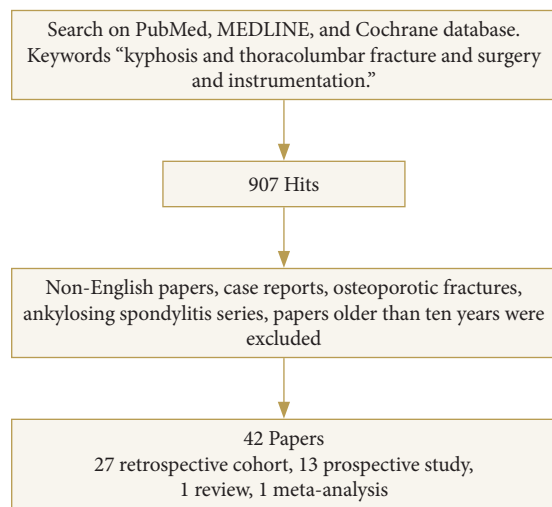


Fig. 1. Flowchart of literature search of thoracolumbar fracture and kyphosis.

ing of the World Federation of Neurosurgical Societies (WFNS) Spine Committee. The first meeting was conducted in Peshawar in December 2019 with WFNS Spine Committee members’ presence and participation. The second meeting was a virtual meeting via the internet on June 12, 2020.

Both meetings aimed to analyze a preformulated questionnaire through preliminary literature review statements based on the current evidence levels to generate recommendations through a comprehensive voting session. All voters (total 8) were spine experts and the member of the WFNS Spine Committee. Voting was done using google voting via cell phones anonymously.

We utilized the Delphi method to administer the questionnaire to preserve a high degree of validity. To generate a consensus, the levels of agreement or disagreement on each item were voted independently in a blind fashion through a Likert-type scale from 1 to 5 (1 = strongly disagree, 2 = disagree, 3 = somewhat agree, 4 = agree, 5 = strongly agree) (Table 1). Results were presented as a percentage of respondents who scored each item as 1 or 2 (disagreement) or as 3, 4, or 5 (Agreement). The consensus was achieved when the sum for disagreement or agreement was ≥ 66%. Each consensus point was clearly defined with evidence strength, recommendation grade, and consensus level provided.

RESULTS

We summarized the 42 papers on posttraumatic kyphosis in Table 2.

Table 1. Statements voted after “posttraumatic kyphosis after thoracolumbar fractures” presentation

Statement	Likert-type scale	No. of respondents (%)
1. The most common reason of posttraumatic kyphosis is untreated, unstable burst fractures	1. Strongly agree	2 (25.0)
	2. Agree	5 (62.5)
	3. Neutral	-
	4. Disagree	1 (12.5)
	5. Strongly disagree	-
2. For treatment of posttraumatic kyphosis, there is no definite certain kyphosis angle to decide for surgery. Instead, global sagittal balance has to be taken in consideration	1. Strongly agree	2 (25.0)
	2. Agree	6 (75.0)
	3. Neutral	-
	4. Disagree	-
	5. Strongly disagree	-
3. Posterior surgery can achieve satisfactory kyphosis correction with less blood loss and complications	1. Strongly agree	2 (25.0)
	2. Agree	6 (75.0)
	3. Neutral	-
	4. Disagree	-
	5. Strongly disagree	-

1. Definition and Measurement of Kyphosis Angle

The relationship between the degree of posttraumatic kyphosis and surgical indication is not clearly defined in the literature. Some publications state that the kyphosis angle is between 20° and 40°. ^{1,3-6} There is no universal agreement to measure this angle.

1) Cobb angle

The angle between the line drawn to the upper endplate of the above-fractured vertebra and the line drawn on the below-fractured vertebra’s lower endplate.

2) Gardner angle

The angle between the lower endplate of the fractured vertebra and the above-fractured vertebra’s endplate.

3) Vertebral compression angle

It is the angle between the upper and lower endplates of the fractured vertebra.

4) Anterior vertebral body compression percentage

The height from the anterior-upper corner to the anterior-lower corner of the vertebra is defined as anterior vertebral height (AVH), and the height from the posterior-upper corner of the vertebra to the posterior-lower corner is posterior vertebral height.

Table 2. Summary of the reviewed papers

No.	Study	Study design	Evi- dence level	No of pa- tients	Main target of the study	Conclusion
1	Zhang et al., ² 2011	Prospective	3	36	Posterior closing osteotomy	Posterior closing osteotomy has less blood and less complications
2	Curfs et al., ³ 2016	Retrospective	4	104	Radiographic analysis of posttraumatic kyphosis	AO type A3 fractures have risk of progression of kyphosis
3	Jiang et al., ⁴ 2012	Retrospective	4	35	Reliability of the measurement of kyphosis	Cobb angle is the most consistent in terms of reliabilities in the assessment of thoracolumbar burst fracture kyphosis
4	Kim et al., ⁵ 2014	Retrospective	4	42	Predictive factors for kyphosis after short-segment fixation	The short-segment pedicle screw fixation technique is an effective surgical method for the restoration and preservation of vertebral column stability in thoracolumbar burst fractures
5	Kim et al., ⁶ 2018	Retrospective	4	90	Comparison of lateral radiography and supine computed tomography (CT) in thoracolumbar fractures	A greater degree of kyphosis is observed in plain radiography than CT
6	Mejia-Munne et al., ⁸ 2021	Retrospective	4	9	Super-pedicle osteotomy for correction of focal thoracolumbar kyphosis	Super-pedicle osteotomy technique was clinically useful for thoracolumbar kyphosis
7	Jindal et al., ¹⁰ 2012	Prospective	3	50	Short-segment fixation, fusion	Adjunctive fusion is unnecessary for burst fractures of the thoracolumbar spine with short-segment pedicle screw fixation
8	Mayer et al., ¹¹ 2017	Retrospective	4	36	Posterior-only and combined postero-anterior surgery	Clinical consequences of T12 and L1 burst fracture patients depend on restoration of sagittal alignment
9	Aono et al., ¹² 2019	Prospective	3	76	Clinical and radiographic data examined to reveal the risk factors for postoperative kyphosis recurrence	High compromised canal ratio before surgery and a large preoperative kyphotic angle is related with correction loss
10	Chen et al., ¹⁴ 2012	Prospective	3	36	Comparison of anterior and posterior approach in the surgery of thoracolumbar fractures	Posterior approach has less complication rate and better kyphosis correction
11	Zeng et al., ¹⁵ 2013	Retrospective	4	34	Posterior surgical correction of posttraumatic kyphosis	The surgical success of kyphosis depends on the size of the kyphosis angle
12	Matsumoto et al., ¹⁶ 2018	Retrospective	4	20	Long-segment fixation for posttraumatic kyphosis	The main compensatory mechanism in long-segment fixation is the reduction of lumbar lordosis
13	Seo et al., ¹⁷ 2019	Retrospective	4	98	Analysis of risk factors for unfavorable radiological outcomes after posttraumatic kyphosis	Insufficient correction of thoracolumbar kyphosis was considered to be a major factor of an unfavorable radiological outcome
14	Shi et al., ¹⁸ 2011	Retrospective	4	52	The influence of correction loss in thoracolumbar fractures treated by posterior instrumentation	Restoring anterior vertebra height with posterior instrumentation positively affects clinical recovery
15	Sadatsume et al., ¹⁹ 2015	Retrospective	4	27	The effect of residual kyphosis after surgery on quality of life	There is no correlation between the final clinical result and residual kyphosis in patients with thoracolumbar burst fractures who undergo surgical treatment
16	Chen et al., ²⁰ 2014	Prospective	3	28	Anterior column support with short-segment posterior instrumentation	Excellent reduction and maintenance of thoracolumbar burst fractures can be achieved with short-segment pedicle instrumentation supplemented with anterior column reconstruction and intermediate screws

(Continued)

Table 2. Summary of the reviewed papers (continued)

No.	Study	Study design	Evidence level	No patients	Main target of the study	Conclusion
17	Chen et al., ²¹ 2016	Retrospective	4	122	Risk factors of kyphosis recurrence after implant removal in thoracolumbar burst fractures following posterior short-segment fixation	Short-segment fixation is an effective method. The loss of correction at follow-up after implant removal associated with age and height of the anterior vertebra
18	Li et al., ²² 2017	Review	5	12	Wedge osteotomy posterior closing osteotomy	Late kyphosis after thoracolumbar fractures can be treated with wedge osteotomy and posterior closing osteotomy
19	Xi et al., ²³ 2013	Retrospective	4	19	Posttraumatic thoracolumbar kyphosis, pedicle subtraction osteotomy	A single-stage posterior pedicle subtraction osteotomy is a safe and effective procedure for correction of posttraumatic thoracolumbar kyphosis
20	Liu et al., ²⁵ 2017	Retrospective	4	77	Radiological analysis of thoracolumbar junctional kyphosis	Maintaining sagittal balance and pelvic tilt is important for thoracolumbar junctional kyphosis
21	Rahman et al., ²⁶ 2018	Prospective	3	40	Comparison of surgery and conservative management for posttraumatic kyphosis	Patient selection is important for the treatment of posttraumatic kyphosis
22	Wood et al., ²⁷ 2015	Retrospective	4	37	Stable posttraumatic kyphosis: surgery vs. conservative management	Those with stable burst fractures treated non-operatively at long-term follow-up reported less pain and better function
23	Jo et al., ²⁸ 2015	Retrospective	4	13	Modified posterior closing wedge osteotomy	Modified posterior closing wedge osteotomy provided good fusion with less blood loss and fewer complications
24	Ituarte et al., ³⁰ 2019	Meta-analysis study	5	23	Meta-analysis study	A fixation method consisting of 2 levels above and 1 below with intermediate screws for the thoracolumbar burst fractures is successful
25	Avanzi et al., ³¹ 2015	Retrospective	3	36	The correlation between posttraumatic kyphosis and symptoms in patients undergoing conservative treatment for thoracolumbar burst fractures	There is no evident correlation between residual kyphosis, functional outcome, and patients' symptoms
26	Formica et al., ³³ 2016	Prospective	3	43	Risk factors of segmental kyphosis after short-segment thoracolumbar fracture fixation with intermediate screws	Short-segment fixation with intermediate screws is a viable technique with positive clinical and radiological outcomes
27	Schulz et al., ³⁴ 2014	Retrospective	4	94	Effect of 360° instrumented fusion for kyphotic deformity and functional outcome	A significant inversely proportional correlation between the Hannover scores and the degrees of local kyphosis was found
28	El Behairy et al., ³⁵ 2020	Prospective	3	32	Short-segment fixation of thoracolumbar fractures with incorporated screws at the level of fracture	Short-segment fixation of thoracolumbar fractures with inclusion of the fracture level into the construct offers good correction of segmental kyphosis, vertebral wedging, and vertebral height loss
29	Radcliff et al., ³⁶ 2012	Retrospective	4	40	Correlation of posterior ligamentous complex injury and neurological injury to loss of vertebral body height, kyphosis, and canal compromise	Translation greater than 3.5 mm was associated with PLC injury
30	Rojas-Tomba et al., ³⁷ 2017	Retrospective	4	40	Radiologic and functional outcomes in unstable thoracolumbar fractures treated with short-segment pedicle fixation	Unstable thoracolumbar fractures provide radiological and functional recovery with short-segment pedicle instrumentation
31	Martiniani et al., ³⁸ 2013	Retrospective	4	219	The effect of posterior alone surgery to prevent late kyphotic deformity	In some cases posterior fixation alone is not sufficient for long-term spinal stabilization and often can be not effective to prevent the late kyphotic deformity

(Continued)

Table 2. Summary of the reviewed papers (continued)

No.	Study	Study design	Evidence level	No patients	Main target of the study	Conclusion
32	Zhang et al., ³⁹ 2019	Retrospective	4	1,465	Comparing intermediate screws and kyphoplasty with posterior short-segment fixation for the treatment of thoracolumbar burst fractures	Posterior short-segment fixation with kyphoplasty provides better back pain relief, greater anterior body height reduction, and less correction loss, while intermediate screws have the advantages of less operative time, fluoroscopic time, and blood loss
33	El-Sharkawi et al., ⁴¹ 2011	Prospective	3	43	Comparing pedicle subtraction osteotomy (PSO) and anterior corpectomy and plating (ACP) for the treatment of posttraumatic kyphosis	2-Year follow-up. PSO seems to be equally safe but more effective than ACP
34	Ye et al., ⁴⁴ 2017	Retrospective	4	44	Comparing the efficacy of short-segment pedicle screw instrumentation with and without intermediate screws for treating unstable thoracolumbar fractures	Short-segment instrumentation with intermediate screw fixation is conducive to the correction of kyphosis and the maintenance of the reduction effects
35	Chokshi et al., ⁴⁵ 2019	Prospective	3	50	Clinical results of short-segment fixation and screw to fracture technique	Inclusion of the fracture level in short-segment fixation for thoracolumbar fracture dislocation gives good kyphosis correction and correction maintenance
36	Dobran et al., ⁴⁶ 2016	Retrospective	4	60	Comparing short-segment pedicle fixation with inclusion of the fracture level and long-segment instrumentation	Inclusion of fracture level in a short-segment fixation for a thoracolumbar junction fractures results in a kyphosis correction and in a maintenance of the sagittal alignment similar to a long-segment instrumentation
37	Aono et al., ⁴⁹ 2016	Prospective	3	27	Surgical outcomes of temporary short-segment instrumentation without augmentation for thoracolumbar burst fractures	Temporary short-segment fixation without augmentation yielded satisfactory results in reduction and maintenance of fractured vertebrae, and maintenance was independent of load-sharing classification
38	Khare and Sharma ⁵¹ 2013	Prospective	3	25	Surgical outcome of posterior short-segment transpedicle screw fixation for thoracolumbar fractures	Short-segment transpedicle posterior fixation is helpful for not only stabilization of the fractures and restoration of anatomy, but also maintaining the same over a period with good functional outcome
39	Kanna et al., ⁵³ 2015	Retrospective	4	32	Posterior fixation including the fractured vertebra	Posterior fixation including the fractured vertebra has biomechanical advantages over conventional short-segment fixation
40	Aono et al., ⁵⁴ 2017	Prospective	3	62	Thoracolumbar burst fracture who underwent short-segment posterior instrumentation using ligamentotaxis with Schanz screws with or without vertebraloplasty	Short-segment posterior instrumentation and vertebraloplasty is an effective method
41	Vu et al., ⁵⁵ 2015	Retrospective	4	31	Radiological outcome of short-segment posterior instrumentation and fusion for thoracolumbar burst fractures	Kyphotic impairment is greater after short-segment posterior instrumentation
42	Ökten et al., ⁵² 2015	Retrospective	4	70	Results of treatment of unstable thoracolumbar burst fractures using pedicle instrumentation with and without fracture level screws	Short-segment stabilization in thoracolumbar burst fractures with additional screws at the level of the fracture results in an improved kyphosis correction, sagittal index, and compression ratio of the anterior vertebral height

ght (PVH). Anterior vertebral body compression has been defined as the ratio of AVH to PVH.^{7,8}

5) Sagittal index

Local kyphotic deformity minus baseline sagittal curve at the level of the fracture (Baseline sagittal curve is 5° in the thoracic spine segments, 0° at the thoracolumbar junction).^{4,9,10}

2. Biomechanical Factors

Kyphosis developing in any part of the spine causes compression of the vertebral body due to gravity force-the height loss of the vertebra increases due to gravity forces. Kyphosis may increase progressively as the line of gravity shifts forward. It is well known that the posterior tension band is also under the influence of higher forces with the effect of kyphosis. The length and tension of the paraspinal muscle cause fatigue and inflammation.

The segments above and below the fractured vertebra compensate to maintain sagittal balance by increasing lordosis. Compensatory mechanisms that aim to balance the regional deformity have a negative impact on clinical outcomes.^{11,12} Facet joints have no load at flexion. It bears only 1/3rd of loads at extension. With hyperlordosis, the load on the facet joints at that segment and also in adjacent segments increases. Compression in the spinal canal increases with facet hypertrophy.¹³⁻¹⁵

3. Risk Factors for Kyphosis Development

Disc injury during trauma increases disc degeneration. It is known that disc degeneration and loss of disc height increase the development of kyphosis.^{4,16,17} Shi et al.¹⁸ mentioned that patients with thoracolumbar fracture had a loss of height in the fractured vertebra's upper disc. They reported that the loss of upper disc height also caused loss of postoperative kyphosis correction angle.

Osteoporosis is one of the main factors that increase post-traumatic kyphosis. The low quality of bone is unable to resist the vertebra's loads and causes vertebral body height loss.¹⁹ Failure to correct kyphosis during surgery, inability to increase the fractured vertebra's height, and failure to maintain sagittal balance after surgery are other important risk factors that will reduce postoperative kyphosis correction angles.^{14,17,20-23} Compression fractures may cause local kyphosis. Kyphosis above 20° may cause a positive sagittal imbalance in the clinical follow-up.^{22,24} Fractures that affect 3 columns, such as burst fractures, are more likely to progress to kyphosis. Especially thoracolumbar junction fractures are at risk to developing kypho-

Table 3. Risk factors for kyphosis development after trauma

Risk factors
≥ 50 years old
Osteoporosis
Disc injury above the fractured vertebra
3 column fractures
Fractures at T12–L1 level
AO type A3 fractures
Posterior ligament complex injury
Short fixation levels
Posterior only surgery
Previous laminectomy

sis.^{25,26} It is known that untreated unstable burst fractures cause kyphotic deformity.²⁷ Short fixation levels, only posterior surgery, pseudoarthrosis, previous laminectomy are other reasons that increase the risk of developing kyphosis.^{14,28} Curfs et al.³ reported that the AO type A3 fractures, fractures at T12–L1 level, and elderly patients are the risk factors that cause kyphosis. Schalke et al. published an article stating that patients with AO type A3 are more likely to develop kyphosis than A1. Mainly, posterior ligament complex (PLC) injury is one of the risk factors for development of kyphosis (Table 3).^{3,7,29,30}

4. Symptoms

Pain is the most common symptom of posttraumatic kyphosis. The distribution of the loads on the spine changes after trauma. Pain increases due to the increased loading forces on the vertebral body and increased posterior tension forces. There is no relationship between the degree of kyphosis and the severity of pain.^{14,30-34} Secondary lumbar hyperlordosis is related to back pain.^{15,24} Adjacent segment disease occurs with the disc's degeneration in the upper and lower parts of the fractured vertebra. A progressive neurological deficit may occur due to the direct compression of the bone structures or the narrowing of the spinal canal due to the facet joint hypertrophy.^{4,16,21,28,35} Radcliff et al.³⁶ reported that translation greater than 3.5 mm is found related to injury of the PLC and neurological injury.

Syringomyelia that occurs after trauma is another factor that increases the neurological deficit. Syrinx may develop in approximately 25% of trauma cases. Neurological deficit usually progresses slowly due to syrinx.^{11,37}

5. Surgical Indications for Posttraumatic Kyphosis

Patients with a kyphotic angle below 20°, less pain, and no

neurological deficits and Thoracolumbar Injury Classification and Severity Score (TLISS) less than 3 can be treated conservatively.^{30,31} Wood et al.²⁷ have compared the stable burst fractures that were treated conservatively and surgically. They have found that stable burst fractures have less pain and better functional outcomes.

Surgical treatment should be considered in patients whose complaints do not regress with conservative treatment. Surgery should also be considered in patients with progressive neurological deficits, progressive kyphosis, and pain. In old thoracolumbar fractures that kyphosis cannot be corrected in the first surgery, kyphosis may increase in the following periods due to pseudoarthrosis.^{2,25,30,38}

Patients with TLISS ≥ 5 , vertebral body height loss of more than 40%, kyphosis angle more than 20%, and canal stenosis more than 50% are candidates for surgery (Table 4).^{32,34,39}

6. Surgical Techniques for Posttraumatic Kyphosis

Management of thoracolumbar kyphosis is still controversial. Anterior, posterior, or combined methods are the surgical options for thoracolumbar fractures. It is difficult to compare the studies in the literature.

The primary purpose of the surgery is neurological decompression. Correcting kyphosis after neurological decompression

reduces the risk of neurological damage. One of the surgery's main goals is to stabilize the spine to resist the loads anteriorly and resist tensile forces posteriorly. Providing proper sagittal alignment while correcting focal deformity will increase the fusion rate.^{19,22,38,40,41} Sagittal imbalance promotes increasing pain, worse clinical outcomes, and a loss of health-related quality of life.^{11,39}

Buchowski et al.⁴² defined focal kyphosis with global sagittal balance as type I. And kyphosis with global sagittal imbalance as type II. Kyphosis in the type I group can be corrected with single or multiple Smith-Peterson osteotomy (SPO) osteotomies, which shortens the posterior column. They also divided type II kyphosis into minor and major sagittal imbalances. They reported that patients in the type II group having a minor sagittal imbalance (sagittal vertical axis [SVA] less than 5 cm) could be corrected with SPO osteotomies. They also mentioned that patients with major sagittal imbalance (SVA greater than 5 cm) in type II could be corrected with pedicle subtraction osteotomy (PSO) osteotomies.^{2,8,28,40}

Biomechanical properties of the thoracolumbar spine should be kept in mind to correct thoracic and lumbar curvature. A harmonized correction has to be improved to prevent higher loads on the thoracic spine.^{15,16,27,37} A correction loss of 10° even after surgery has a poor functional outcome. Schulz et al. have been reported that 12° T-L junction Cobb angle could be related to poor functional outcome. In their study, 5° of correction loss developed even after combined surgery.^{15,34} Seo et al.¹⁷ have been recommended to correct thoracolumbar junction Cobb angle less than 10.5°. Mayer et al.¹¹ published a study that they have treated T12 and L1 fracture with posterior and anterior-posterior combined surgery. They mentioned that patients that had a sagittal balance following the surgery had better clinical outcomes. Zeng et al.¹⁵ reported that only posterior closing osteotomies correct approximately 45°, whereas the anterior open-

Table 4. Surgical indications for posttraumatic kyphosis

Surgical indications
Progressive neurological deficit
Progressive kyphosis
Thoracolumbar Injury Classification and Severity Score ≥ 5
Vertebral body height loss > 40%
Kyphosis angle > 20%
Canal stenosis > 50%

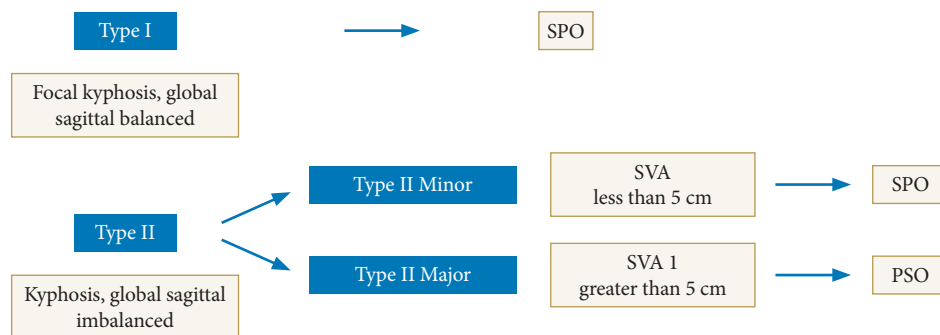


Fig. 2. Algorithm for the osteotomies according to posttraumatic kyphosis and sagittal balance. SPO, Smith-Peterson osteotomy; SVA, sagittal vertical axis; PSO, pedicle subtraction osteotomy.

ing and posterior closing corrects 80° of kyphosis. Algorithm for the osteotomies according to posttraumatic kyphosis and sagittal balance are shown in Fig. 2.

1) Posterior surgery

Posttraumatic kyphosis can be corrected with posterior osteotomies. With posterior osteotomies involving the anterior vertebral body, SPO and PSO can correct kyphosis without stretching the spinal cord. There are publications reporting that achieved up to 30° correction of kyphosis with PSO.^{28,38,41} The sagittal alignment can also be achieved in patients who have undergone anterior decompression with costotransversectomy.⁸ It is possible to correct kyphosis with multiple posterior closure osteotomies. Shorter surgical time, less bleeding, and fewer neurological deficits are the main advantages of this technique.^{2,28,39} However, osteotomy covering the posterior column is not appropriate for rigid curvatures in the thoracolumbar transition region, especially in the thoracolumbar transition region.^{2,21,40}

2) Anterior surgery

In thoracolumbar fractures, compression is usually anteriorly. Spinal compression can be decompressed directly via the anterior approach. Visualization and easier placement of the cage via anterior are the main advantages of this approach.² Studies report that decompression via the anterior approach provides better neurological recovery in the future, and there are also papers reporting that there is no difference.^{8,28} Kostuik has reported that they had corrected kyphosis cases with the only anterior approach.⁴³ It has been reported that, especially in patients with kyphosis, it is impossible to correct it with a posterior-only approach and without anterior support.^{44,45} Böhm et al. reported that the use of combined surgery in patients with posttraumatic kyphosis could lead to fusion development and alignment more easily.^{41,46,47}

Major vascular injuries, neurological injuries, graft donor site morbidity, pseudoarthrosis are the main complications of the anterior approach. Prolonged recovery and delayed rehabilitation are the disadvantages of the anterior approach.⁴¹ Osteoporosis is another disadvantage for anterior correction during the distraction forces. Loss of correction in time is another disadvantage of anterior surgery.

3) Combined surgery

Some authors have suggested combined surgery—the anterior approach for reconstructing the weight-bearing for anterior column and posterior short-segment instrumentation for ky-

phosis correction. Combined anteroposterior surgery has a higher perioperative complication rate (32%).⁴¹ Schulz et al.³⁴ has reported that they have been operated on thoracolumbar junction fractures with circumferential instrumented fusion to improve Oswestry and Hannover Scores. A comparative study of El-Sharkawi et al.⁴¹ mentioned that posterior surgery with PSO is more effective for kyphosis correction than anterior corpectomy and plating. And they believe that PSO provides better clinical outcomes.

4) Fusion levels (short or long instrumentation)

It is crucial to evaluate the global sagittal alignment in patients with focal deformity. While focal deformity can be corrected with shorter segment instrumentation, longer segment instrumentation should be used to correct the kyphosis with global sagittal imbalance.³⁸ It has been reported that kyphosis is more common in patients who underwent only posterior short-segment instrumentation.^{35,38}

Fusion levels are controversial in the literature. Some authors recommend short fixation (one level above and one level below the fractured level).^{9,44,46,48} While some authors report the advantage of better correction and less kyphosis correction loss of long-segment instrumentation.^{21,33,45}

(1) Short-segment instrumentation

Short fixation level can be reliable for type B fractures.^{9,45} Short-segment fixation has the benefit of decreased involvement of motion segments compared with long-segment instrumentation. However, short-segment instrumentation has implant failure rates ranging from 9% to 54% and progression of symptomatic kyphosis.^{9,49,50}

Especially in short-segment instrumentation, including the fractured vertebra leads to less correction loss. Biomechanical studies have shown better tension forces when fracture level is included.^{9,22,48,51} The screw in the fractured level acts as a push point and provides lordotic forces.⁹ Rojas-Tomba et al.³⁷ have recommended short-segment instrumentation including fractured level (one level above and one level below the fractured level) for unstable thoracolumbar fractures. Biomechanical study by Norton et al.⁵⁰ showed that using an intermediate screw with short-segment instrumentation strengthens the system. El Behairy et al.³⁵ offered short-segment fixation of thoracolumbar fractures including the fracture to get a good correction of segmental kyphosis, vertebral wedging, and vertebral height loss. Segmental fixation with the fracture level increased the construct stiffness and protected the fractured vertebral body from ante-

rior loads. Intermediate (screw at the fractured vertebra) provides anatomical continuity and increases construct stiffness.^{35,52}

With a pedicle fracture, including the fractured vertebra in the construct is relatively contraindicated. In this situation, Kanna et al. recommended inserting one screw on the fractured vertebra's nonfractured pedicle will be enough.^{9,10,53} According to Jindal et al., screw at the fractured vertebra increases short-segment instrumentation strength without anterior reconstruction.^{9,10,33,45}

Additional vertebroplasty provides supplemental load-sharing through anterior reconstruction.²⁰ Chen et al.²⁰ also recommended a bilateral intermediate screw (screw at the fractured level) to strengthen the fixation. Zhang et al.^{2,39} have compared kyphoplasty and intermediate screws in posterior short-segment instrumentation for thoracolumbar fractures. According to their study, they have found that the kyphoplasty group has more significant anterior body height reduction and less loss of correction. Posterior short-segment instrumentation group with the intermediate screw group has the advantage of less blood loss and less surgery time.

Many studies have shown that the removal of implants may be a significant risk factor for the development of kyphosis.^{12,51,54} High load-sharing classification score, a large postoperative vertebral body angle (VBA), and the difference between the VBA and superiorinferior endplate angle are the risk factors for kyphosis recurrence.^{5,55,56}

(2) Long-segment instrumentation

Posterior alone surgeries without vertebral body reconstruction have higher instrument failure and recurrence of kyphosis.¹⁷ To solve this problem, long-segment instrumentation is recommended. However, long-segment instrumentation has less preservation of spinal motion. Long-segment instrumentation for thoracolumbar fracture means stabilizing at least 2 vertebrae above and 2 vertebrae below the fracture.⁴⁶

Long-segment fixation can be reliable for type C fractures.^{9,44} Long-segment instrumentation result in better radiological outcome of local kyphosis, sagittal index, and anterior vertebral height loss.^{32,52,57} Dobran compared long and short-segment instrumentation and found no difference between the 2 groups.⁴⁶

Studies have shown that 50% of patients have pseudoarthrosis with short-segment instrumentation in posttraumatic kyphosis.²¹ The reported pseudoarthrosis rate varies from 9%–54%.^{1,11,31} To reduce the high rate of pseudoarthrosis, screw placement in the broken segment is one of the recommended methods. Biomechanical studies have shown that screw placement

in the broken segment strengthens the system.⁴⁴

CONCLUSION

Surgical treatment of thoracolumbar kyphosis due to unstable burst fractures can be done via a posterior-only approach. Less blood loss and reduced surgery time are the main advantages of posterior surgery. Kyphosis angle for surgical decision and fusion levels are controversial. However, global sagittal balance should be taken into consideration for the segment that has to be included. Adding an intermediate screw at the fractured level strengthens the construct.

WFNS SPINE COMMITTEE RECOMMENDATIONS

- The most common reason for posttraumatic kyphosis is untreated, unstable burst fractures.
- For treatment of posttraumatic kyphosis, there is no definite kyphosis angle to decide for surgery. Instead, the global sagittal balance has to be taken into consideration.
- Posterior surgery can achieve satisfactory kyphosis correction with less blood loss and complications.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Review Article

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INTRODUCTION

Thoracolumbar region represents one of the most common fracture sites in spinal injuries. Management is still a big challenge in spine surgery. Despite tremendous improvements in spinal imaging and management techniques over the last 2 decades, there is still a lack of consensus in several areas and no

Clinical and Radiological Factors Affecting Thoracolumbar Fractures Outcome: WFNS Spine Committee Recommendations

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To obtain a list of recommendations about clinical and radiological factors affecting outcome in thoraco-lumbar fractures with the aim of helping spine surgeons in daily practice. A systematic literature search in PubMed and Google Scholar database was done from 2010 to 2020 on the topic "thoracolumbar fracture AND radiology AND surgical outcomes" and "thoracolumbar fracture AND radiology AND surgical outcomes." A total of 58 papers were analyzed and WFNS (World Federation of Neurosurgical Societies) Spine Committee organized 2 consensus meetings to formulate the specific recommendations the first in Peshawar in December 2019 and in a subsequent virtual meeting in June 2020 to reach an agreement. Both meetings utilized the Delphi method to analyze preliminary literature review statements based on the current evidence levels to generate recommendations through a comprehensive voting session. Eight statements were presented and reached the consensus about this topic. A variety of clinical factors is known to influence outcome of patients with thoracolumbar fractures. Some of these are well-known established factors such as blood pressure augmentation and patient age, while some are not well studied. Overall, the quality of evidence is low and we need more randomized controlled studies to validate our results. Similarly, radiological factors that can predict outcome are well stated and there is a high accordance worldwide. In reverse, still under debate is the application to choose which surgical treatment is advisable based on them.

Keywords: Clinical factors, Radiological factors, Thoracolumbar fractures, Outcome, WFNS recommendations

standard guidelines for surgical approach, fusion levels, amount of kyphosis correction and timing of treatment and their influence on clinical outcome are present.¹

As these fractures are usually treated by surgical intervention, posterior pedicle screw placement serves as the most common technique to address these fractures worldwide.² The instrumentation serves as a tool to provide mechanical stability until the

bony union takes place. Based on these principles, postoperative recollapse of a well-reduced vertebral body or progressive kyphosis could be a lethal complication. These could increase neurological deficits, implant failure, and revision surgery.^{3,4} Unfortunately, it is quite difficult to predict recollapse or implant failure due to a magnitude of clinical and radiological factors coming into play.⁵ In 1994, McCormack et al.⁶ suggested a load-sharing classification to predict implant failure; however, the scoring system had a major limitation of not including patient-related clinical factors.

Moreover, the outcome can be influenced by many other different factors that can be divided into 2 main groups: clinical factors (such as American Spinal Injury Association [ASIA] grade at admission, preoperative neurological status, time and type of surgery, age, osteoporosis, body mass index [BMI], and major comorbidities) and radiological ones (such as fracture type - AOSpine classification, anatomic location of the injury, khyphotic deformity, etc.).⁷

To deal with these issues and try to reach some globally accepted recommendations, the World Federation of Neurosurgical Societies (WFNS) Spine Committee organized a Consensus Conference on thoracolumbar fracture management. In this paper, we present the recognized factors to influence outcome with the aim of assisting physicians in their daily practice, in line with previous recommendations published by WFNS regarding some different topics in spinal surgery.

MATERIALS AND METHODS

A systematic literature search in PubMed and Google Scholar database was done from 2010 to 2020. The quality assessment and clinical relevance criteria utilized were in accordance with the Agency for Healthcare Research and Quality criteria for diagnostic studies and observational studies. Level of evidence was defined as level I to IV based on the quality of evidence developed by the U.S. Preventive Services Task Force for therapeutic interventions. Strength of evidence rate was ranked as mild, moderate, or high.

The literature research was performed using the following keywords: (1) clinical factors thoracolumbar fracture outcome, (2) thoracolumbar fracture AND radiology AND surgical outcomes.

According to the review and the specific topic, we assessed the following questions to be answered: (1) How many factors can affect outcome?; (2) Which clinical factors influence outcome?; (3) Which radiological factors can affect outcome?

This data was reviewed in a consensus meeting in Peshawar in December 2019 and then in a virtual meeting (due to limitations correlated with the coronavirus disease 2019 emergency) in June 2020 to reach an agreement. Both meetings utilized the Delphi method to administer the questionnaire to preserve a high degree of validity. To generate a consensus, the levels of agreement or disagreement on each item were voted independently in a blind fashion through a Likert-type scale from 1 to 5. The consensus was achieved when the sum for disagreement or agreement was $\geq 66\%$. Each consensus point was clearly defined with evidence strength, recommendation grade, and consensus level provided. The important factors are discussed below.

Based on the most significant literature, 8 statements were defined, presented, and voted.

RESULTS

With the keywords “clinical factors thoracolumbar fracture outcome” the search yielded 175 studies in Google scholar and 152 in PubMed, respectively. Some of the results were duplicated between the 2 databases. The search was further refined by excluding the duplicate articles, those not in English, or when based on animal or cadaveric subjects. The results included case reports, case series, prospective and retrospective studies, randomized studies, systematic reviews, and meta-analysis, short-listing the count to 71. After reading the abstract, only 40 articles were selected for a full review in this consensus meeting (Fig. 1).

With the keywords “thoracolumbar fracture AND radiology AND surgical outcomes” there were 526 results in PubMed and MEDLINE. A manual search resulted in 2 further articles. We removed non-English language papers, case reports, and low-quality case series. Then, we analyzed 18 papers for this review. A flowchart of the literature search is shown in Fig. 2.

Analyzing the literature, we subdivided the factors affecting outcome into 2 main groups: clinical and radiological factors.

The clinical factors recognized to predict surgical outcome are: pre-existing neurological status, timing of surgery, blood pressure, age, bone strength, BMI, smoking, and comorbidities.

While the most relevant radiological factors usually used to choose the surgical treatment and predict outcome are: vertebral body height (VBH), interspinous distance; anatomical integrity of structures such as posterior ligamentous complex (PLC), facet joints/pedicles and disc, spinal canal stenosis, displacement/dislocation of the vertebral bodies, spinal lordosis/kyphosis, and consequent deformity correction and proper re-

duction by stabilization.

Based on the most significant literature, 8 statements were defined and are summarized in Table 1. All the selected statements on this topic reached a positive consensus in both Consensus Meetings of the WFNS Spine Committee, as detailed in the following part.

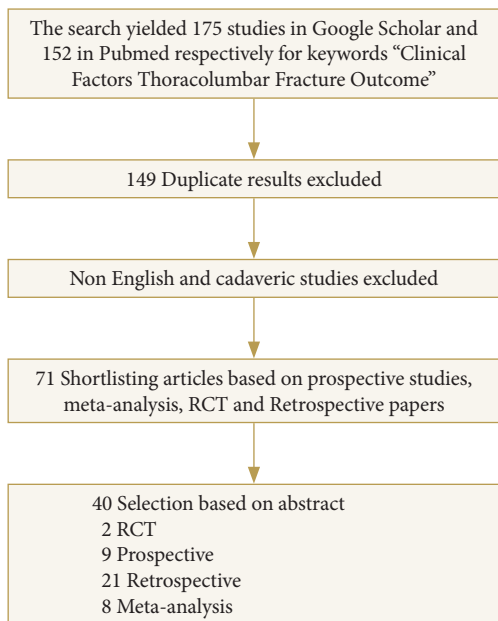


Fig. 1. Flow chart of a literature search of thoracolumbar fracture outcome and clinical factors. RCT, randomized controlled trials.

DISCUSSION

Management of thoracolumbar is still a topic under debate. Not only do clinical and surgical managements present some open queries, but the definition of outcome can also be challenging. In fact, as reported by Rojas-Tomba et al.⁸ there is often a discrepancy between radiological findings/outcome and clinical outcome.

Table 1. World Federation of Neurosurgical Societies recommendations for thoracolumbar traumatic fractures

Factors affecting surgical outcomes	
-	Obesity can worsen segmental kyphosis following surgery for a thoracolumbar burst fracture.
-	Increasing age is a predictor of poor outcome.
-	Comorbidities, smoking, and long-term high-dose steroid usage predict poor outcome.
-	Polytrauma and high injury severity score should not be considered as a contraindication for early surgery.
-	Anterior vertebral body height loss more than 50% may lead to progression of kyphotic deformity.
-	Detection of injury of posterior ligamentous complex is important, as it significantly influences the outcome.
-	Burst fractures with sagittal-transverse canal diameter ratio <0.40 are highly associated with neurological injury and outcome.
-	Cobb angle > 10.5° after surgery may predict poor outcome.

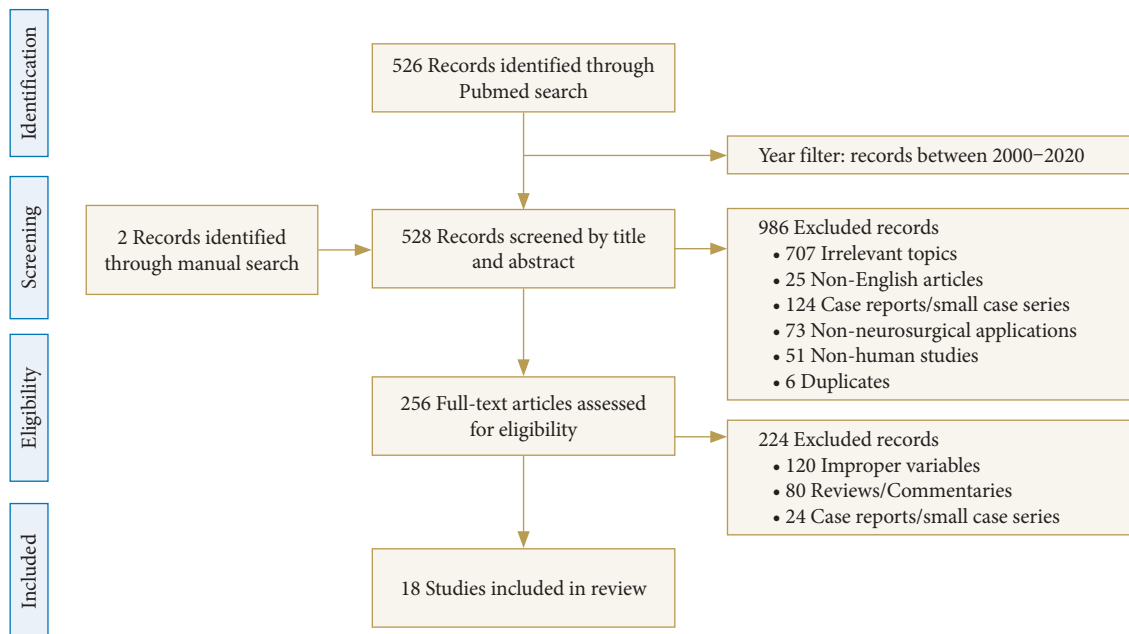


Fig. 2. Flowchart of the literature search we used.

1. Clinical Factors Affecting Outcome

1) *Pre-existing neurology*

ASIA scoring methodology was first published in 1982 and is widely used in evaluating, treatment, and outcomes of spinal cord injuries.⁹ Most of the current studies indicate the ASIA grade at presentation is the most important factor determining the outcome. Dimar et al.¹⁰ in a landmark study, showed that the severity of the neurologic injury was one of the most important factors influencing the outcome, including postoperative complications and longer hospital stay. Kaminski et al.¹¹ assessed the degree of functional improvement 1 year after spinal injury in 76 patients. Among factors such as age, sex, level, type of injury, comorbidities, and ASIA grade, ASIA grade was the dominant factor influencing the outcome. Over the course of years, multiple grades to assess neurology have been introduced. Irrespective of the scoring system used, the basic concept remains the same. However, ASIA grading continues to be the most commonly employed score due to easy reproducibility.

2) *Timing of surgical intervention*

The ideal time for a patient with a thoracolumbar fracture to undergo surgery has been a topic of long-standing debate. However, most of the current literature now suggests early surgery that is less than 72 hours may reduce hospital stay and morbidity and mortality. Bellabarba et al.¹² performed a systematic review of literature from 1990 to 2008 and indicated that early surgery led to better outcomes with less morbidity and mortality. Similarly, Bourassa-Moreau et al.¹³ also recommended early surgery within 24 hours for spinal injuries. In a setting of associated systemic injuries, up to 72 hours of delay may be acceptable. Another important paper by Kato et al.¹⁴ involving many spinal surgeons like Vaccaro and Fehlings suggests early surgery in patients with thoracolumbar fractures. Although the evidence is weak, their recommendation is largely based on the results extrapolated from patients with cervical spinal injuries. Early surgical intervention has been proven to be beneficial.

3) *Blood pressure*

Spinal cord ischemia is believed to play a central role in the secondary injury processes that cause delayed and progressive injury to the spinal cord.¹⁵ The secondary injury can be aggravated by hypotension, which develops due to loss of sympathetic outflow in the thoracic region. The first guidelines regarding the management of blood pressure came in 2002. Those guidelines recommended that a mean arterial blood pressure (MAP) of 85–90 mmHg should be targeted in the first 7 days after spi-

nal cord injury.¹⁶ Those guidelines are supported by a few weak level 3 studies performed in patients with cervical spine injuries.¹⁷ Similarly, Walters et al.¹⁸ also suggested that mean arterial pressure below 70 was associated with poor neurological recovery. Cohen et al.¹⁹ further complemented these findings. They reported a retrospective study of the relationship between episodes of hypotension noted in the medical record and outcomes using step-wise regression. They concluded that there might be a threshold of around 70 mmHg below which worse outcomes are seen. One of the major limitations to all these studies is that blood pressure augmentation was supplemented by other aggressive strategies to improve neurological recovery. These included different forms of physiotherapy and rehabilitation. Because no baseline control exists for all these patients, it is difficult to pinpoint the isolated role of blood pressure in improving overall outcomes. Such limitations were overcome by a detailed retrospective analysis conducted by Hawryluk et al.²⁰ Their results showed that the beneficial effect of high blood pressure was applicable only during the first 3 days of spinal cord injury.

The majority of the patients require some vasopressor therapy to increase blood pressure, particularly when a patient is in spinal shock. The Consortium guidelines published in 2008 declared different inotropes according to the level of injury.²¹ Their recommendation was to use dopamine or norepinephrine for injuries above T6 level. However, one study demonstrated that many patients received phenylephrine at or above T6 and dopamine below T6 in conflict with the guidelines, most likely due to the pre-guideline patients and physician comfort with dopamine.²² The study also showed that dopamine was significantly associated with complications even when used according to MAP goal guidelines. De Backer et al.²³ performed a meta-analysis of 2,768 patients in septic shock. His results showed that dopamine use was associated with high mortality. As a result, the current trend is to recommend norepinephrine as the first-line vasopressor for blood pressure augmentation.

4) *Age and bone strength*

Over the past decade, multiple clinical factors have been studied to identify their correlation with thoracolumbar fractures outcome. Age is the most extensively evaluated, with increasing age correlating with the poor overall outcome. A retrospective analysis of 208 patients was performed by Jang et al.²⁴ in 2019. He compared various clinical variables such as BMI, smoking, age, height, and comorbid conditions. He concluded that age >43 years was the most important clinical factor predicting implant failure or postoperative recollapse of the vertebra. Sim-

ilarly, a nationwide survey was conducted by Purvis et al.²⁵ The results showed that in patients aged >75 years, hospital stay and complications rates were much higher in operative patients compared to the nonoperative group. Although the survey had many limitations, it was still able to highlight the importance of age while planning surgical intervention. Another study by Cankaya et al.²⁶ highlighted the importance of age when managing elderly patients with thoracolumbar fractures. Although none of his 21 patients underwent surgery, he concluded that age >71 years was a strong predictor of complications. Patrick conducted a retrospective review of 73 patients who underwent anterolateral fixation for thoracolumbar fractures.²⁷ His results showed that supplemental posterior fixation was needed in patients aged more than 59 years.

Although the association of increasing age with postoperative complications has been well established, we can still not demarcate the exact limit at which complications are more likely to occur. Based on the available literature, patients aged over 45 years are at a higher risk of implant failure or revision surgery.

5) *Body mass index*

Increased BMI or body weight has been associated with increased risk of postsurgical infections and an overall increase in morbidity and mortality. Soroceanu et al.²⁸ performed a retrospective review of 241 patients, of whom 66 were obese undergoing spinal deformity correction. His patients were followed up to 2 years postoperatively with periodic radiological assessment. His results showed that obese patients (BMI > 30 kg/m²) were at considerably high risk of complications and wound infections than nonobese patients. Although all patients improved after surgery, the degree of improvement was also less in the obese group than the nonobese group. These results are consistent with the results of others, including a meta-analysis by Jiang et al.²⁹ Their study demonstrated that obesity is an independent risk factor for surgical-site infections. In patients undergoing lumbar fusion surgery, Mehta et al.³⁰ found that the thickness of subcutaneous fat and the skin-to-lamina distance are risk factors for surgical-site infections. This is probably because thicker subcutaneous fat may require further retraction, leading to increased dead space postoperatively, which in turn increases the risk of infection. Similarly, Formica et al.³¹ performed short-segment posterior fixation with an intermediate screw in 43 patients with thoracolumbar fractures. His patients were followed for 1 year with periodic x-rays to assess loss of kyphosis. His results showed that loss of kyphosis correction was mostly seen in obese patients while other factors like sex

and smoking did not influence the outcome.

6) *Comorbid conditions/high-dose steroids*

As stated previously, higher-aged patients are at greater risk of complications irrespective of the treatment modality chosen, surgical or nonsurgical. One of the major contributing factors is the presence of underlying comorbidities such as diabetes, hypertension, and ischemic heart disease, which complicates the management of a trauma patient. A prospective multicentric study was conducted by Dimar et al.¹⁰ in 2010 involving 230 patients. Factors such as neurological status at presentation, age, smoking, steroid use, and comorbidities through Charlson Comorbidity Index (CCI) were evaluated while following the patients for 6 months. An important parameter to note was that about 35% of patients were smokers. Multivariate logistic regression analysis showed that high CCI and steroid use were the most important clinically significant factors leading to untoward complications amongst all the stated factors. The CCI was first described in 1987 and is commonly used to estimate the risk of death from comorbid conditions.³² Each specific comorbidity is scored according to a weighted index to predict the cumulative effect of medical illnesses on mortality. In addition to CCI, multiple other scores have been developed to assess comorbidities, including the modified friability index and American Society of Anesthesiologists (ASA) physical status scoring system. Irrespective of the system used, all the scoring systems work similarly. A comparative analysis of all these comorbid scoring systems was done by Ondeck et al.³³ He performed a retrospective survey of 16,495 patients who underwent elective lumbar fusion. Although none of the selected patients were of trauma, his results showed that ASA physical status scoring was the most sensitive predictor of poor outcome with higher ASA physical status grades correlating with higher complications.

After a spinal cord injury, the use of steroids has been a controversial issue since the completion of the NASCIS (National Acute Spinal Cord Injury Study) studies, which demonstrated a small but significant improvement in neurologic outcomes when high doses were given intravenously immediately after spinal cord injury.³⁴ However, historical data on the use of methylprednisolone in spinal injuries have been challenged, with more recent studies stating no benefit of steroids.³⁵ Similarly, Chiu et al.³⁶ used steroids in 6 of his 8 patients presenting with L1 burst fracture with conus medullaris syndrome. His results showed that steroids played no role in patient recovery, and their use was largely dictated by faith rather than objective evidence. A

survey published in 2006 revealed that most respondents continue to administer methylprednisolone, but they are motivated predominantly by fear of litigation.³⁷

7) Smoking

The injurious effects of smoking on health are well known. A recent review summarized the results from multiple studies documenting the negative impact of smoking on the overall hospital care of surgical patients, including increased risk of perioperative complications, morbidity, mortality, and admission to the intensive care unit in patients undergoing general surgery.³⁸ The complications associated with smoking include wound infections, delayed wound healing, pneumonia, and myocardial infarction.³⁹ Smoking has similar adverse effects in patients with spinal injuries and is known to impair the fusion process significantly in patients undergoing spinal fixations. A cross-sectional analysis of 136,511 patients with spinal diseases was performed by Bisson et al.⁴⁰ over 5 years. Ten percent of his

patients were smokers. His results showed that smoking patients admitted for spinal disease in the sample had worse outcomes, increased complications, and higher costs than their nonsmoking counterparts. Similarly, Berman et al.⁴¹ showed that smoking significantly increases the risk of pseudoarthrosis for patients undergoing both lumbar and cervical fusions. In addition to nonunion, smoking also increases the risk of other perioperative complications such as infection and adjacent-segment pathology.

However, Dimar et al.¹⁰ in their prospective study, were unable to document any deleterious effects of smoking in the management of patients with thoracolumbar fractures. Similarly, Kuo et al.⁴² performed spinal surgery including fixations in 306 patients. Thirty-four patients were smokers, and all patients were clinically and radiologically followed for 2 years. His results did not show any significant increase in complications or pseudoarthrosis among smokers compared to nonsmokers. On the contrary, Antoni et al.⁴³ performed anterior cage placement

Table 2. Relevant papers for clinical factors affecting thoracolumbar fracture outcome

Study	Factors	Patient sample	Results
Dimar et al., ¹⁰ (2010)	Pre-existing neurology	230	The severity of neurologic injury independently increases the risk of having a major complication following surgical stabilization of thoracolumbar spine fractures
Kaminski et al., ¹¹ (2017)	Pre-existing neurology	76	The severity of neurological injury correlates with the outcome
Cohen et al., ¹⁹ (2010)	Blood pressure	74	Average MAP may only relate to neurological outcome in the first 2–3 days after injury
Casha et al., ¹⁷ (2011)	Blood pressure	Meta-analysis of 25 articles	There is weak evidence supporting the maintenance of MAP > 85 mmHg for a period extending up to 1 week following SCI.
Kato et al., ¹⁴ (2017)	Timing of surgery	Literature review	Early surgery is likely to reduce complications
Bourassa-Moreau et al., ¹³ (2013)	Timing of surgery	53	Surgical decompression within 24 hours in SCI may optimize neurological recovery
Bisson et al., ⁴⁰ (2015)	Smoking	136,511	Smoking patients admitted for spinal disease in the sample had worse outcomes, increased complications, and higher costs
Antoni et al., ⁴³ (2015)	Smoking	106	Smoking increases the risk of pseudoarthrosis
Dimar et al., ¹⁰ (2010)	Comorbids/steroids	230	Comorbidities and use of the high-dose steroids independently increase the risk of having a major complication following surgical stabilization of thoracolumbar spine fractures
Schroeder et al., ³⁵ (2014)	Comorbids/steroids	43	No obvious benefit of steroids shown with increased complications
Soroceanu et al., ²⁸ (2015)	BMI	241	Obesity and previous neurological symptoms may significantly increase the risk of morbidity
Jiang et al., ²⁹ (2014)	BMI	97,326	Obesity seemed to be associated with a higher risk of surgical-site infection
Jang et al., ²⁴ (2018)	Age	208	Age > 43 years is an independent risk factor for recollapse after posterior instrumentation
Hitchon et al., ²⁷ (2014)	Age	73	Age was the only significant risk factor predicting supplemental posterior instrumentation.

MAP, mean arterial blood pressure; BMI, body mass index; SCI, spinal cord injury.

in 106 patients with thoracolumbar fractures. His results showed a higher rate of pseudoarthrosis among smokers compared to nonsmokers. The effects of smoking in delaying fusion and pseudoarthrosis are well known. However, such pseudoarthrosis does not always translate into clinical symptomatology. Since the current literature shows no benefit of fusion versus nonfusion surgery in thoracolumbar fractures,^{44,45} it might explain the paucity of data correlating smoking with adverse outcomes in patients with thoracolumbar fractures (Table 2).

2. Radiological Factors Affecting Outcome

1) Vertebral body height

This parameter can be studied by x-ray and detailed with a computed tomography (CT) scan. It is an important parameter because a VBH loss > 50% with kyphotic deformity influence both type of surgical treatment and outcome in terms of post-operative disability and pain⁴⁶ (Fig. 3).

2) PLC/interspinous distance variation

The failure of PLC significantly influences the severity of the fracture and is related to neurological damage in patients with acute thoracic and lumbar burst fractures, furthermore it correlates with treatment that can shift from conservative to surgical.²

It can be suspected on plain x-ray but should be characterized by CT scan. Significant interspinous distance increase can relate with pure osseous failure of the posterior tension band.⁴⁷

Radiological signs such as vertebral translation > 3.5 mm or interspinous distance variations > 20% of widening (up to 7 mm can be considered normal) are both suggestive of an unstable

fracture that requires surgical treatment⁴⁸ (Fig. 4A, B).

3) Facet joints/pedicles

The first-line x-ray can detect facet joint luxation but to better characterize facet joints and pedicles situation CT and magnetic resonance imaging (MRI) scans are necessary. The pres-



Fig. 3. Computed tomography scan that shows fracture of L2 vertebrae with loss of height.

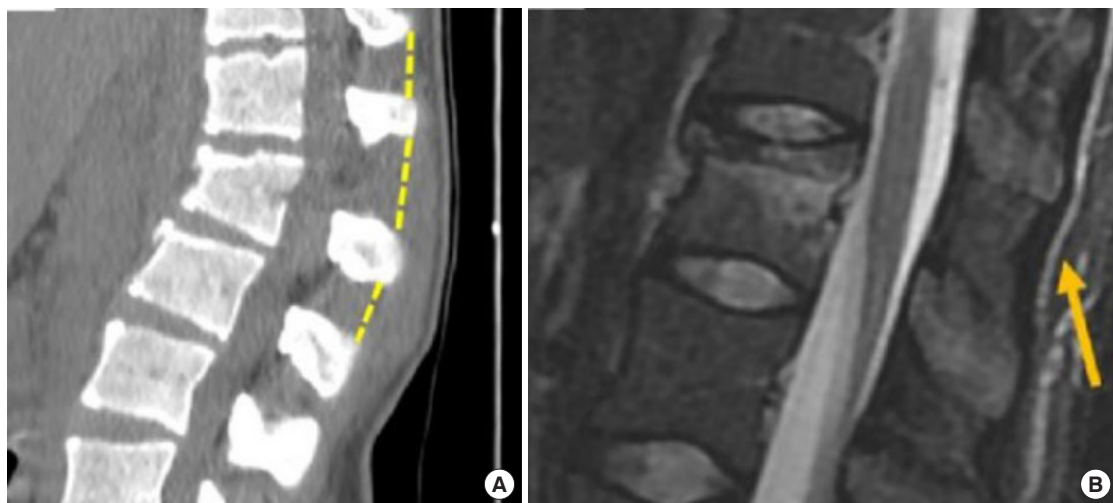


Fig. 4. (A) The figure shows the increment in interspinous distance suggestive for posterior ligamentous complex (PLC) injury. (B) Arrow showing PLC injury at magnetic resonance imaging scan.

ence of facet joint-pedicle complex subluxation-dislocation-fracture uni- or bilateral is an important factor that can predict outcome, in terms of risk of fracture progression without adequate correction, and to shift for a surgical treatment and which type of surgical treatment.⁴⁹

4) Intervertebral disc space

This parameter can be detected on x-ray in terms of narrowing of the discal space and coronal and sagittal displacement, but an MRI scan is necessary to characterize it. It is important because a discal injury is advisable of instable fractures and requires surgical treatment^{47,50,51} (Fig. 5).

5) Displacement - dislocation

The presence of spinal displacement or dislocation in coronal, sagittal, and axial planes is advisable of highly unstable thoracolumbar fracture because it implies the affection of all the spinal columns. Its presence requires surgical treatment and is highly suggestive for severe neurological deficits. Its presence negatively affects clinical and radiological outcome.⁵²

6) Spinal canal diameter

Another important factor that can influence outcome is the

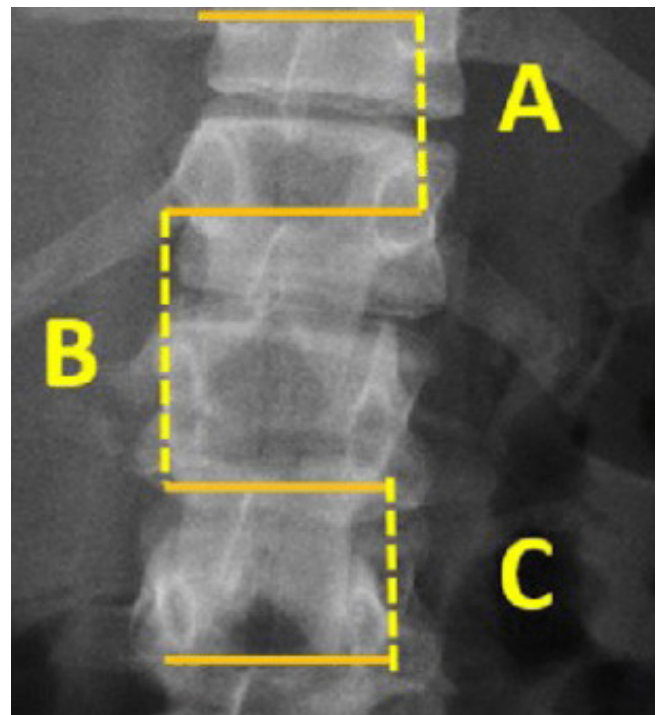


Fig. 5. Sagittal view of thoracolumbar segment with interspinous distances. Panels A and C indicate normal interspinous distance and panel B indicates augmented interspinous distance suggestive for fracture.

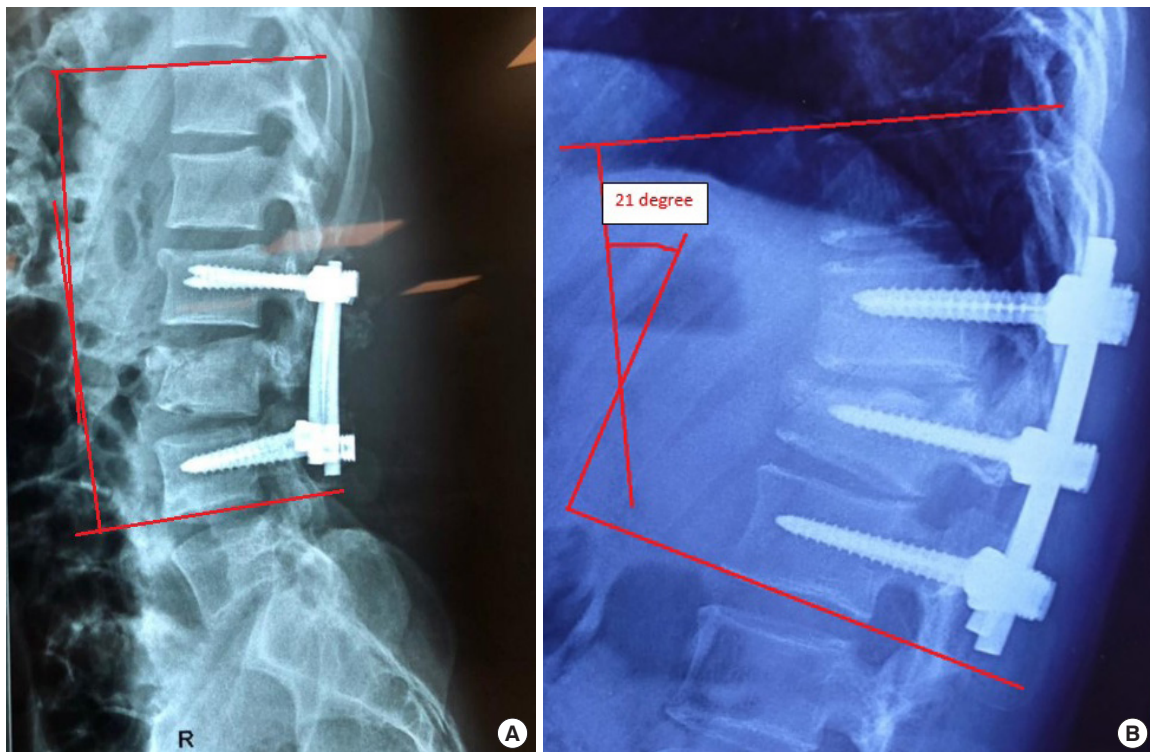


Fig. 6. (A) Favorable correction, (B) Cobb angle $> 10.5^\circ$ unfavorable correction.

neurological damage varies between vertebral levels. Nevertheless, a sagittal-transverse diameter ratio < 0.40 is highly associated to neurological injury and requires surgical intervention to decompress neurological structures.⁵³

7) Spinal lordosis

Lastly, spinal lordosis should be evaluated. Insufficient correction leads to late progression of kyphosis, the return to the normal range of thoracolumbar curvature is necessary to avoid additional excessive loading to the spine, which might be another secondary complication with chronic pain and disability.⁵⁴

The usual target of correction is Cobb angle $< 7^\circ$ for the reasonable functional outcome.⁵⁵

Correction loss at the follow-up (Cobb $\geq 20^\circ$) has a strong correlation with severe back pain and postoperative disability.⁵⁶

Seo et al.⁵⁶ correlates insufficient correction to late progression of kyphosis (Cobb angle $> 10.5^\circ$) immediately after surgery with unfavorable radiological outcome, which is related to a poor clinical outcome (Fig. 6A, B).

CONCLUSIONS

A variety of clinical factors is known to influence outcome of patients with thoracolumbar fractures. Some of these are well-known established factors such as blood pressure augmentation and patient age, while some are not well studied. Overall, the quality of evidence is low and we need more randomized controlled studies to validate our results.

On the other hand, radiological factors that can predict outcome are well stated and there is a high accordance worldwide. In reverse, still under debate is the application to choose which surgical treatment is advisable based on them.

WFNS SPINE COMMITTEE RECOMMENDATIONS

Based on the presented literature and personal experience, the Steering Committee voted the following statements with a positive consensus and they were converted to recommendations.

- Obesity can worsen segmental kyphosis following surgery for a thoracolumbar burst fracture.
- Increasing age is a predictor of poor outcome.
- Comorbidities, smoking, and long-term high-dose steroid usage predict poor outcome.
- Polytrauma and high injury severity score should not be

considered as a contraindication for early surgery.

- Anterior VBH loss more than 50% may lead to progression of kyphotic deformity.
- Detection of injury of posterior ligamentous complex is important, as it significantly influences the outcome.
- Burst fractures with sagittal-transverse canal diameter ratio < 0.40 are highly associated with neurological injury and worse outcome.
- Cobb angle $> 10.5^\circ$ after surgery may predict poor outcome.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Review Article

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Incidence and Epidemiology of Thoracolumbar Spine Fractures: WFNS Spine Committee Recommendations

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This review aims to search the epidemiology and incidence rates of thoracolumbar spine fractures. A systematic review of the literature of the last 10 years gave 586 results with “incidence,” and 387 results with “epidemiology,” of which 39 papers were analyzed. The review results were discussed and voted in 2 consensus meetings of the WFNS (World Federation of Neurosurgical Societies) Spine Committee. Out of 39 studies, 15 studies have focused on thoracolumbar trauma, remaining 24 studies have looked at all spine trauma. Most were retrospective in nature; few were prospective and multicenter. Some studies have focused on specific injuries. The annual incidence of TL fractures is about 30/100,000 inhabitants including osteoporotic fractures. There is a trend to increase the fractures in elderly population especially in developed countries, while an increase of motor vehicle accidents in developing countries. The mortality rate among male elderly patients is relatively high. The incidence of thoracolumbar spine fractures is increasing because of low-velocity falls in the elderly population. The main reasons are falls and traffic accidents. Learning the regional differences and some special forms of trauma such as extreme sports, war, and gunshot injuries will help the prevention of the thoracolumbar spine fractures.



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Keywords: Thoracolumbar spine fracture, Epidemiology, Osteoporotic fracture, Spinal fusion, Nonfusion surgery

INTRODUCTION

Thoracolumbar spine trauma can have significant affect to the quality of life with neurologic deficits, pain, and deformity. The incidence and epidemiology of thoracolumbar spine trauma would help to develop preventive strategies. This review has focused on this issue by searching the last 10-year literature, reporting evidence on this issue, and giving the recommendations of the World Federation of Neurosurgical Societies (WFNS) Spine Committee after 2 consensus meetings.

MATERIALS AND METHODS

The literature between 2010 and 2020 was reviewed using a search with keywords “thoracolumbar fracture and incidence”; there were 586 results in PubMed and MEDLINE. A similar search, “thoracolumbar trauma and epidemiology,” had 387 results. We removed non-English language papers, case reports, and low-quality case series. Then, we analyzed 39 papers for this review.

Up-to-date information on thoracolumbar trauma incidence or epidemiology was reviewed to reach an agreement in a consensus meeting of the WFNS Spine Committee. The first meet-

ing was conducted in Peshawar in December 2019 with WFNS Spine Committee members' presence and participation. The second meeting was a virtual meeting via the internet on June 12, 2020.

Both meetings aimed to analyze a preformulated questionnaire through preliminary literature review statements based on the current evidence levels to generate recommendations through a comprehensive voting session.

We utilized the Delphi method to administer the questionnaire to preserve a high degree of validity. To generate a consensus, the levels of agreement or disagreement on each item were voted independently in a blind fashion through a Likert-type scale from 1 to 5 (1 = strongly disagree, 2 = disagree, 3 = somewhat agree, 4 = agree, 5 = strongly agree). Results were presented as a percentage of respondents who scored each item as 1 or 2 (disagreement) or as 3, 4, or 5 (agreement). The consensus was achieved when the sum for disagreement or agreement was $\geq 66\%$. Each consensus point was clearly defined with evidence strength, recommendation grade, and consensus level provided.

RESULTS

There were 39 studies. Fifteen studies have focused on thoracolumbar trauma, remaining 24 studies have looked at all spine. Some studies focused on specific injuries such as war-combat injury, penetrating injury, extreme sports, fall from a tree, water sports, child abuse, etc.

Most were retrospective in nature; few were prospective and multicenter; there were also systematic reviews and meta-analyses (Table 1).

DISCUSSION

1. General Epidemiological Features

One prospective multicenter study (Germany and Austria) of the Spine Study Group of the German Association of Trauma Surgery contained 733 patients.¹ The paper was focused on surgical approaches collected for 2 years interval. Conservatively treated patients were excluded. The etiology included falls from a height (225), motor vehicle accidents (173), and simple falls (116).¹

Doud et al.² used United States (US) databases in different time intervals; NTDB (National Trauma Databank), NASS (National Automotive Sampling System), and NIS (National Inpatient Sample) collected. The retrospective review had approximately 40,000 patients. The study aimed to determine if the in-

cidence of thoracolumbar spine injuries increased in the US from 1998 to 2011.²

They reported that while motor vehicle crash-related injuries are declining in general, the incidence of thoracolumbar injury is not reducing.² This may be due to the immediate use of whole-body computed tomography (CT) scans after trauma and sensitive screening and may also be related to the increasing use of seatbelts.

An extensive retrospective series comes from Sweden, including 13,496 patients.³ The authors gathered Swedish Hospital Discharge Registry from 1997 to 2010. They included all fractures, including osteoporotic fractures. Men were in the majority (62%), and the annual incidence of thoracolumbar (TL) fractures was 30 per 100,000 inhabitants. The most frequent etiology was traffic accidents (38.7%) and fell from heights (23.8%).³

That Swedish registry did not document if the patient had osteoporosis. Patients 60 years or older were two-thirds of the study population (66%), and two-thirds were women (68%). More than half of the patients were 80 years or older, and the majority had lumbar vertebral fractures. However, they conclude that the incidence did not change considerably during the study period. The annual incidence was 13 per 100,000 in the age of <60 years. Operated patients were 15% of all patients, most frequent in 20–39 years of age. Among elderly patients (>60 years), operation proportion was 2%.³

A systematic review from the US between 2005–2011 included 12 studies to update practice management guidelines of “The Eastern Association for the Surgery of Trauma”⁴ From 2007 to 2011, the screening of blunt trauma patients changed the multi-detector CT scans as a screening modality of choice. Patients without altered mentation or effective mechanism may be excluded by clinical examination without imaging. Patients with gross neurologic deficits or clinical examination findings with negative imaging are considered for magnetic resonance imaging.⁴

In another study by Shah et al.⁵ from the US using a national database including more than 39,000 lumbar fractures between 2007–2016, showed that lumbar spine fractures have doubled. The majority of the fractures were between ages 80–89 and were more often in females. Falls were the most common cause of lumbar spine injuries.⁵

The conservative treatment of traumatic thoracolumbar vertebral fractures is often not clearly defined. A systematic review of 35 papers has concluded that the choice of a conservative or operative treatment strategy is based on the primary stability of the fracture, the degree of deformity, the presence or absence of

Table 1. Summary of the 39 papers searched in this review

No.	Study	Category	Location of study	Design of study	Period of study	Patients
1	Reinhold et al., ¹ (2010)	Thoracolumbar	Germany, Austria	Prospective, multicenter	2002–2003	733
2	Doud et al., ² (2015)	Thoracolumbar	USA databases: NTDB, NASS, NIS	Retrospective	NTDB 2002–2006, NASS 2000–2011, NIS 1998–2007	Approximately 40,000
3	Jansson et al., ³ (2010)	Thoracolumbar	Sweden	Retrospective	1997–2001	13,496
4	Sixta et al., ⁴ (2012)	Thoracolumbar	USA	Systematic review	2005–2011	12 Studies
5	Spiegl et al., ⁶ (2018)	Thoracolumbar	All world	Systematic review	Till 2018	35 Studies
6	Bouyer et al., ⁷ (2015)	All spine	Multicenter, France	Prospective	2011	580
7	Glennie et al., ⁸ (2015)	Thoracolumbar	Canada, USA	Retrospective	2009–2013	390
8	Marek et al., ⁹ (2018)	Thoracolumbar	Minnesota, USA	Retrospective	2008–2013	138
9	Oliver et al., ¹⁰ (2012)	All spine	California, USA	Retrospective	1996–2008	2,562
10	Katsuura et al., ¹¹ (2016)	Thoracolumbar	All world	Meta-analysis	1980–2014	21 Studies
11	Li et al., ¹² (2019)	Thoracolumbar	Tianjin, China	Retrospective	2006–2015	132
12	Liu et al., ¹³ (2018)	All spine	China National Database	Retrospective	2014	168
13	Wang et al., ¹⁴ (2012)	All spine	China	Retrospective	2001–2010	3,142
14	Aldosari et al., ¹⁵ (2019)	All spine	Saudi Arabia	Prospective	2016–2017	120
15	Brito et al., ¹⁶ (2011)	All spine	Sao Luis, Brazil	Retrospective	2008–2009	87
16	Yousefzadeh et al., ¹⁷ (2010)	All spine	Iran	Retrospective	2005–2006	245
17	Mathur et al., ¹⁸ (2015)	All spine	Jaipur, India	Retrospective	2000–2008	2,716
18	Khurjekar et al., ¹⁹ (2015)	Thoracolumbar	India	Prospective	2009–2012	92
19	Chua et al., ²⁰ (2018)	All spine	Cambodia	Retrospective	2013–2016	277
20	Saul and Dresing ²¹ (2018)	All spine	Germany	Retrospective	1998–2014	546 Pediatric cases
21	Dauleac et al., ²² (2019)	All spine	Lyon, France	Retrospective	2005–2016	73 Children
22	Falavigna et al., ²³ (2018)	All spine	Brazil	Retrospective	Not mentioned	215 Children
23	Babu et al., ²⁴ (2017)	All spine	Bengaluru, India	Retrospective	2002–2014	196 Children
24	Ernat et al., ²⁵ (2016)	All spine	Dallas, USA	Retrospective	2003–2011	97 Children < 10 years
25	Jauregui et al., ²⁶ (2019)	All spine	USA National Database	Retrospective	2000–2012	116 Child abuse
26	Satyarthee et al., ²⁷ (2017)	Thoracolumbar	India	Retrospective	2008–2012	312 Children
27	Mukherjee et al., ²⁸ (2016)	Thoracolumbar	USA	Retrospective	1996–2011	299
28	Pintar et al., ³¹ (2012)	Thoracolumbar	USA	Retrospective	1993–2010	204 Traffic accidents with front crash
29	Beck et al., ³² (2016)	All spine	Victoria, Australia	Retrospective	2000–2010	29 Rear-seat occupants
30	Javadi and Naderi, ³³ (2013)	All spine	Iran	Retrospective	2011	50 Fall from walnut tree
31	Hasler et al., ³⁴ (2012)	All spine	Switzerland	Retrospective	2000–2009	89 Extreme sports
32	Bigdon et al., ³⁵ (2019)	All spine	All world	Systematic review	1994–2012	Winter sports skiing and snowboarding
33	Gosteli et al., ³⁶ (2016)	Thoracolumbar	Switzerland	Retrospective	1998–2008	616 Extreme sports
34	Kane et al., ³⁷ (2015)	All spine	USA	Retrospective	2008–2010	60 Water sports
35	Jakoi et al., ³⁸ (2015)	All spine	Systematic review	Meta-analysis	Not restricted	Gunshot injuries
36	Formby et al., ³⁹ (2015)	All spine	USA	Retrospective	2003–2013	24 War Injuries
37	Eardley et al., ⁴⁰ (2012)	All spine	UK, Iraq, Afghanistan	Retrospective	2005–2009	57 War injuries
38	Freedman et al., ⁴¹ (2014)	Thoraco-lumbar	USA, Germany, Iraq, Afghanistan	Retrospective	2007–2010	65 War injuries
39	de Melo-Neto et al., ⁴² (2017)	All spine	Sao Paulo, Brazil	Retrospective	2008–2012	62 Elderly > 60 years

NTDB, National Trauma Databank; NASS, National Automotive Sampling System; NIS, National Inpatient Sample.

disc injury, and the patient's clinical state.⁶

2. Regional Differences

In a prospective multicenter epidemiological study from France involving 518 patients in 2011,⁷ 67% of the fractures involved the thoracic or lumbar segment. Thirty percent of patients had multiple fractures and 28% had neurological impairment. The authors conclude that spinal trauma is still a source of significant morbidity despite progress in management (minimally invasive surgery techniques and achieving a good sagittal balance). Conserved sagittal balance appeared to be associated with better functional outcomes.

A retrospective review of data in a registry from different centers in Canada and the US collected 390 patients with thoracic and lumbar fractures.⁸ Etiology was falls from height (39.5%), sports (28.0%), and traffic accidents (27.2%). The neurologic deficit was presented in 140 patients (36%). Operative treatment was applied in 276 patients (70.8%). Adverse events in surgical cases were observed in more than half of the patients, and neurologic injury was an important predictor of adverse events.

Marek et al.⁹ have searched the long-term outcomes of traumatic thoracolumbar spine fractures, specifically addressing quality of life, chronic pain, and employment. They collected 138 patients between 2008 and 2013. In general, patients without neurologic deficits were generally able to return to work and had a good quality of life.

A retrospective review from Los Angeles, US, for 13 years (1996 minimally invasive surgery 2008) was done to see if there is any change in epidemiology.¹⁰ They found that the mortality rate due to spinal injury, the incidence rate of spinal cord injury (SCI), and motor vehicle accidents decreased significantly over the study period. However, they reported spinal injuries are increasing with increasing age. There was a reduction in mortality attributable to spinal injury. Decline in SCI due to motor vehicle accidents is related to improvements in motor vehicle safety and traffic regulations.¹⁰

A meta-analysis from 2016 containing 21 studies reported the rate of thoracolumbar fractures in blunt trauma patients as 6.9%.¹¹ It included whole spine injuries. The most common vertebra injured was L1 at a rate of 34.40%. Etiology for TL fractures were motor vehicle collision (36.7%) and high-energy falls (31.7%).

The statements of this review are: mortality rate after a spinal injury is decreasing in developed countries. This is more with motor vehicle accidents due to improvements in motor vehicle

safety and traffic regulations. However, the incidence of low-velocity falls is increasing, especially in the elderly population. The mortality rate among male elderly patients is relatively high. The most common cause of thoracolumbar fractures are falls and traffic accidents. The actual incidences and epidemiology in developing countries are not well known. The annual incidence of TL fractures is about 30 per 100,000 inhabitants, if osteoporotic fractures are also included. Vertebral fractures in children are usually multiple.¹¹

Li et al.¹² have examined the epidemiology profile of thoracolumbar junction (T11–L2) fractures in the Tianjin region of China between 2006–2015. Totally 132 cases were identified and the incidence rate was 2.4 patients per million population. The incidence ratio is increased annually. The average age became older by the time, and the rate of osteoporotic fractures increased by the time.

In a database search from China (China National Fracture Study) involving 512,187 individuals, the incidence rate for traumatic spinal fractures was 32.80 per 100,000 people.¹³ Fractures of the thoracolumbar vertebra (T11–L2) were the most common, followed by fractures of the lumbar vertebra (L3–5). Four independent risk factors were: aging, alcohol drinking, sleeping < 7 hours per day, and having a previous fracture history.

Another epidemiological retrospective study from the Chongqing area of China has collected 3,142 patients in 10 years.¹⁴ Accidental falls and traffic accidents were the most common causes of spinal fractures (58.9% and 20.9%, respectively). The commonest area of fracture was the thoracolumbar spine (54.9%). Lumbar spinal fractures were more common in accidental fall patients. American Spinal Injury Association A injuries were more common in patients who suffered thoracic spinal fractures (15.09%) than in those with fractures in other areas of the spine.

The numbers of fall-induced and sports-related injuries increased steadily with age. These results indicate that there should be an increased concern for the consequences of fall- and sports-related injuries among the elderly.¹⁴

In a retrospective study from Saudi Arabia involving 120 patients, 85 patients had thoracolumbar spinal fractures.¹⁵ Sixty-six point six percent (n = 80) of all patients were managed conservatively, whereas the remaining 33.3% (n = 40) were managed surgically.

A retrospective study from Brazil, including 87 patients with spinal cord injury, has shown the proportion of falls from height was more significant than the number of traffic accidents.¹⁶ The most compromised segment of the spine was the thoracic (33

cases, 37.9%), and the main etiology was traffic accidents.

An epidemiological study from Iran involving 245 cases reported the most common causes as motorcycle vehicle accidents 127 (52%) and fell 106 (43%).¹⁷ The most common fracture in the spine was thoracolumbar (115 patients). Forty-four patients had neurological deficits.

A prospective observational study from India focused on traumatic spinal cord injury for 8 years period collected 2,716 cases, of which 1,400 were cervical and 1,316 thoracolumbar.¹⁸ Around 79% of patients were from rural backgrounds (farmers and laborers). Causes of injury fell from height (53%) and road traffic accidents (28%). Complete paralysis was found in 20.5% cervical and 23.3% in thoracic injuries.¹⁸

Authors have concluded that epidemiological factors of SCI in India are different from Western countries, with the primary cause being fall. The low socioeconomic status and younger age group had a significant financial, social and psychological impact as most of the patients were the immediate earning members of the family.¹⁸

Another prospective study from India¹⁹ contained 92 patients for a 3-year interval. All were surgically treated. The main reason for the trauma was a fall from height (46 patients, 50%).

A retrospective review from Cambodia involving 277 patients, cervical trauma was 71 (25.6%), and thoracolumbar trauma was 206 patients (74.4%).²⁰ Etiology was motor vehicle accidents (31.3%) and fell (51.4%). Motor vehicle accidents were mainly by motorcyclists (66.7%). Falls causing thoracolumbar trauma were predominantly work-related, including falls at construction sites (32.9%) and from palm and mango trees (34.3%).²⁰

The authors have reported that they could have similar surgical costs between \$100 to \$280 per surgery in a significantly resource-limited community.²⁰

3. Pediatric Injuries

In a retrospective pediatric series from Germany, including 546 patients (average age 12.8 ± 6.2 years), the leading cause of trauma was fall from height (58%).²¹ Of all series, 27% were found at T7/T8 and 17% at T12/L1. Multiple fractures are standard 53.2%. The authors have concluded that vertebral fractures in children are usually multiple and should lead to broad diagnostic coverage. Prevention should especially conceal falls and traffic accidents. Lesions for operative fixation are rare due to the excellent elasticity of the pediatric spine.²¹

A retrospective review of pediatric patients in France between 2005 and 2016, including 73 children, with a mean age of 14.1 years, has shown that spinal injuries were more common in the

teenage group (14–18 years).²² The etiology was motor vehicle collision (36%). Teenagers presented more with lumbar traumas, while young children had more cervical traumas. Teenagers had more fractures, while younger ages had more luxations. The authors conclude that disco-ligamentous maturation is an essential concept in spine traumas in children.²²

A retrospective multicenter study from Brazil of 215 spinal trauma cases in individuals < 18 years of age, showed a mean age of 14.7 years.²³ Falls were responsible for 52% of the spinal trauma. Most were located at the thoracic level (58.7%). Neurological impairment was mostly observed due to shallow water diving and fractures between the lower cervical spine and the thoracic spine.²³

A retrospective review of pediatric spinal injuries over 12 years from India contained 90 children with TL spine injuries.²⁴ The mean age was 159 years and the leading cause of injury was fall from height (69 cases, 71.1%), then motor vehicle accidents (18 patients, 20%). The lumbar spine was the most common injury level (53.3%). The authors concluded that TL injuries are most common in children older than 10 years old, and many involve the lumbar region.²⁴

The use of vehicular restraints has reduced the morbidity and mortality of children involved in motor vehicle collisions. The effect of restraint type was examined in a retrospective review below 10 years of age for 8-year period.²⁵ Two- or 3-point seat-belt use is associated with lower rates of cervical spine trauma but higher thoracic and lumbar trauma rates, particularly flexion-distraction injuries, compared with a car or booster seat. Children in car seat/booster seat and those who are unrestrained sustain high rates of cervical spine injury.

A retrospective review of the Kids' Inpatient Database in the US was conducted in pediatric patients below 18 years with child abuse for a 12-year interval.²⁶ Among 22,192 pediatric patients diagnosed with spinal cord or vertebral column injury, 116 (0.5%) had a documented abuse diagnosis. Abused patients were more likely to be below 2 years of age, female. Abused patients had more thoracic and lumbar vertebral column fractures, and the mean length of stay was longer. Physicians should maintain a higher level of suspicion of abuse in patients with spine injuries, especially patients under 2 years of age.²⁶

Satyarthee et al.²⁷ have reported 25 pediatric cases of TL fractures from India. The most common reason was fall (76%). Eleven patients (44%) had a neurologic injury.

4. Motor Vehicle Accidents

In a multicenter database called Crash Injury Research and

Engineering Network,²⁸ the authors searched the incidence of neurological deficits in motor vehicle collisions. Neurological deficits were more common in pediatric ages (0–10 years, 26.7%) and geriatric ages (70–80 years, 18.4%). The highest risk of neurological injury existed in crashes in which airbags deployed and a seatbelt did not restrain the occupant. Collisions with a greater than 50 km/hr had a significantly higher risk of spinal cord injury. Current vehicle safety technologies are geared toward a normative body morphology. They need to be reevaluated for various body morphologies and torso compliances to lower the risk of neurological injury resulting from thoracolumbar fractures.²⁸

Epidemiological studies on motor vehicle accidents in Finland have stressed that seat belts and airbags have created a different environment for automotive trauma.²⁹ The high-energy deaths tended to occur pretty quickly. However, the mortality rate of spine injuries is decreasing.^{29,30}

Pintar et al.³¹ have searched US databases to find a relation between front crushes and injury patterns. There was a significantly increasing trend in thoracic and lumbar vertebral body fractures as a function of vehicle model year. Major burst type fractures occurred predominantly at T12, L1, or L5.

A retrospective review of 29 rear-seat occupants after frontal crashes in motor vehicle accidents (aged 9–80 years) from Australia and 10 years interval has reported that the seat belt was the most common source of injury to rear-seat occupants.³² There is a need to provide an appropriate belt fit and better control seat belt loads for rear-seat passengers.

5. Fall From Height

Falls from trees are often in some countries. A report from Iran has collected 50 cases of falls from walnut trees in one harvest season in 2011.³³ Fractures were detected in 7 patients, including 5 cervical fracture-dislocations and 2 thoracolumbar fractures. Complete spinal cord injury was found in 8 cases. The falls from the walnut trees mainly result in cervical fractures with quadriplegia with a poor prognosis in a young group of workers.

6. Sports Injuries

Airborne sports are associated with a high frequency of severe injuries, especially to the spine. A retrospective analysis from the Swiss Alps for a 9-year period of 181 patients (11 BASE-jumpers, 144 paragliders, 19 parachuters, 1-speed flyer, 4 delta gliders, 2 skysurfers) was included.³⁴ Eighty-nine patients (49.2%) sustained spinal fractures. Type A fractures were predominant

(91.5%), and the most common level was L1 (35.1%). The lumbopelvic junction is especially vulnerable as high impact forces from vertical and horizontal deceleration need to be absorbed.

A systematic review of alpine winter sports and spine trauma yielded 64 studies.³⁵ Skiing, snowboarding, and tobogganing are the reasons for falls. The thoracolumbar spine is the most common region for spinal injury. Spinal cord injury is relatively rare, usually with cervical spine trauma. Disc injuries seem to occur more commonly in alpine winter sports athletes than in the general population.³⁵

A study from Switzerland examined the trauma cases due to extreme sports in Swiss Alpines.³⁶ A total of 616 patients rescued with helicopters for a ten-year interval (1998–2008) were examined. Two hundred nineteen (36%) were high-risk extreme sports accidents. Mortality at 48 hours was 11%, thoracolumbar vertebral fractures were the most common injuries, with at least one of 32% of all cases.

The epidemiology of water sports injuries at a coastal area in the US has collected 105 patients.³⁷ Among water-based activities or recreational sport are counted swimming, surfing, boating, personal watercraft use. Personal watercrafts accounted for the majority of injuries (n = 39). Cervical (33.3%) and thoracolumbar (21.9%) injuries accounted for most injury types. Spinal cord injuries were more common than other types of trauma.

7. War and Combat Injuries

A systematic review of spinal gunshot injuries showed that the gunshot injuries are the third commonest cause of spinal injury.³⁸ Surgical treatment is typically indicated for progressive neurologic changes, spinal instability, persistent cerebrospinal fluid leak, and infection. Surgical exploration and removal of missile fragments in the spinal canal are typically indicated for incomplete or worsening neurologic injury. Surgical treatment for gunshot injuries affecting T12 and caudal often has a better outcome than for those cranial to T12.

A retrospective review of combat-related burst fractures engaged in the wars in Iraq and Afghanistan has collected 24 patients of low lumbar (L3–5) burst fractures.³⁹ Eleven patients had a neurological injury, 4 of which were complete.

One hundred twenty-eight spinal fractures during military deployments of the United Kingdom army between 2005–2009 were collected.⁴⁰ Ballistic (79%) and nonballistic mechanisms contribute to vertebral fracture, a high incidence of lumbar spine fractures, which are more likely to be due to explosion than gunshot wounding. The authors concluded that due to the predominance of explosive injury in current conflicts, and the research

must be directed to this injury mechanism.⁴⁰

War injuries have also been an interest of some studies. The US army collected 65 cases of explosive device assaults on up-armored vehicles during the Afghanistan and Iraq wars.⁴¹ All had thoracolumbar burst fractures, and neurological deficits were present in 43%.

8. TL Injuries in the Elderly

The incidence of low-energy falls increases, and older men have a disproportionate increase in death from spine injuries.²⁹ The authors have commented on this gender difference, with men being less likely to accept age changes, do not use a cane or walker, and continuing activities may result in falls. Fall prevention and bone metabolism optimization must be focused not only on women but also on men in older ages.²⁹

A retrospective study of elderly patients (>60 years of age) with spinal cord injury included 62 elderly patients⁴² showed that elderly individuals with SCI have distinct characteristics and clinical factors. Women had fractures at the thoracolumbar junction, while men had cervical fractures.

CONCLUSIONS

The incidence of thoracolumbar spine fractures is increasing since the low-velocity falls in the elderly population are increasing. The epidemiology in developing countries is not well studied, but the main reasons are falls and traffic accidents. Learning the regional differences and some special forms of trauma such as extreme sports, war, and gunshot injuries will help the prevention of the thoracolumbar spine fractures.

WFNS SPINE COMMITTEE RECOMMENDATIONS

- The most common cause of thoracolumbar fractures are falls and traffic accidents.
- The annual incidence of TL fractures is about 30 per 100,000 inhabitants if osteoporotic fractures are counted together.
- The real incidences and epidemiology in developing countries are not well known.
- The incidence of low-velocity falls is increasing, especially in the elderly population.
- Mortality rate after the spinal injury is decreasing in developed countries. This is more with motor vehicle accidents due to improvements in motor vehicle safety and traffic regulations.

- The thoracolumbar trauma mortality rate among male elderly patients is relatively high.
- Vertebral fractures in children are usually multiple.

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Review Article

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Indications for Nonsurgical Treatment of Thoracolumbar Spine Fractures: WFNS Spine Committee Recommendations

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Thoracolumbar spine is the most injured spinal region in blunt trauma. Literature on the indications for nonoperative treatment of thoracolumbar fractures is conflicting. The purpose of this systematic review is to clarify the indications for nonsurgical treatment of thoracolumbar fractures. We conducted a systematic literature search between 2010 to 2020 on PubMed/MEDLINE, and Cochrane Central. Up-to-date literature on the indications for nonoperative treatment of thoracolumbar fractures was reviewed to reach an agreement in a consensus meeting of WFNS (World Federation of Neurosurgical Societies) Spine Committee. The statements were voted and reached a positive or negative consensus using the Delphi method. For all of the questions discussed, the literature search yielded 1,264 studies, from which 54 articles were selected for full-text review. Nine studies (4 trials, and 5 retrospective) evaluating 759 participants with thoracolumbar fractures who underwent nonoperative/surgery were included. Although, compression type and stable burst fractures can be managed conservatively, if there is major vertebral body damage, kyphotic angulation, neurological deficit, spinal canal compromise, surgery may be indicated. AO type B, C fractures are preferably treated surgically. Future research is necessary to tackle the relative paucity of evidence pertaining to patients with thoracolumbar fractures.

Keywords: Thoracolumbar fractures, Conservative treatment, Indications for nonoperative treatment, Compression fractures, Burst fractures, Neurological deficit



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INTRODUCTION

Thoracolumbar spine fractures occur in every 7/10 blunt trauma cases and make up to 9/10 of the spinal fractures recorded.¹⁻⁵ Every 1 in 4 thoracolumbar spine fracture patients have concomitant spinal cord injury.^{1,4} Long-term care in cases with persistent disability post thoracolumbar fractures indicates a significant burden on healthcare funding.^{1,2,4-6} Furthermore, such cases often have numerous visceral and bony injuries, and therapeutic decision-making can be quite demanding.^{4,6}

For the aims of these recommendations, “thoracolumbar” in-

cludes the rigid thoracic (T1–10), transitional thoracolumbar junction (T10–L2), and flexible lumbar spine (L3–5).⁷ This transition from the rigid thoracic spine with its link to ribs and sternum to the more mobile lumbar spine subjects the thoracolumbar region to significant biomechanical stress.^{5,8}

Neurological injuries quite often will further complicate the thoracolumbar junction fractures.^{9,10} The probability of deficit in neurological function depends on the type of fracture. In a multicentric study, the occurrence of deficit of neurological function varied from 22% to 51% depending on the fracture type (22% in type A, 28% in type B, and 51% in type C fracture, ac-

ording to the AO classification).¹¹

Traditional classification protocols are described based on the morphology of the fracture, trauma mechanism, deficit of the neurological function, and damage to posterior ligamentous complex (PLC).¹² There remains an absence of agreement on a few key areas such as indications for surgery and nonsurgical treatment of thoracolumbar fractures, as well as surgical stabilization's superiority over conservative therapy for thoracolumbar burst fractures.^{13,14} The World Federation of Neurosurgical Societies (WFNS), Spine Committee initiated this effort to formulate recommendations regarding the indications for surgery and nonsurgical treatment of thoracolumbar spine fractures through the published evidence and using elaborated methodology. Finally, these recommendations were formulated to improve patient care by defining the relevant literature and decision-making processes involved in the indications for surgical and nonsurgical treatment of thoracolumbar fractures. The surgical management of these patients often involves a multidisciplinary team. These recommendations were formulated as a guidance tool for surgeons through a series of indications for surgery and nonsurgical treatment of thoracolumbar spine fractures.

MATERIALS AND METHODS

The systematic review and meta-analysis was conducted following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The review followed the methods recommended by the Cochrane Handbook for Systematic Reviews of Interventions.

An international committee of spinal surgeons (members of the WFNS Spine Committee) organised a consensus meeting on the indications of surgical and nonsurgical management of thoracolumbar fractures. The meeting was conducted in Peshawar in December 2019 with WFNS Spine Committee members' presence and participation. The meeting aimed to analyze a preformulated questionnaire through preliminary literature review statements based on the current evidence levels to generate recommendations through a comprehensive voting session.

We utilized the Delphi method to administer the questionnaire to preserve a high degree of validity. To generate a consensus, the levels of agreement or disagreement on each item were voted independently in a blind fashion through a Likert-type scale from 1 to 5 (1 = strongly disagree, 2 = disagree, 3 = somewhat agree, 4 = agree, 5 = strongly agree). Results were presented

as a percentage of respondents who scored each item as 1 or 2 (disagreement) or as 3, 4, or 5 (agreement). The consensus was achieved when the sum for disagreement or agreement was $\geq 66\%$. Each consensus point was clearly defined with evidence strength, recommendation grade, and consensus level provided. The search strategy in the published protocol included studies on the indications for surgery and nonsurgical treatment of thoracolumbar spine fractures.

1. Eligibility Criteria

Articles were considered for review if they met the following inclusion criteria:

- Types of studies: randomized controlled trials, retrospective/prospective studies.
- Types of participants: patients who underwent conservative treatment for thoracolumbar spine fractures.
- Types of diagnosis: traumatic thoracolumbar spine fractures. Any osteoporotic thoracolumbar fractures were excluded.
- Types of treatments: nonoperative treatments.
- Outcomes: pain evaluation via visual analogue score (average VAS score), radiological features (mean kyphotic angle), loss in vertebral height (%), quality of life (36-item Short Form Health Survey [SF-36]), evaluated via physical compartment score, mental score, return to working life (days), length of hospital stay (days).

2. Search Strategy

The electronic databases of PubMed, MEDLINE, and the CENTRAL (Cochrane Central Register of Controlled Trials), were searched from 2010 till 2020. A highly sensitive search strategy based on the Cochrane Handbook recommendations for Systematic Reviews of Interventions, combined with medical subject headings and keywords to identify potential articles, was employed. The search strategy was compiled in consultation with members of WFNS Spine Committee. In addition to the electronic database search, coauthors manually checked the list of references eligible trials and previous reviews. The complete search strategy is available.

3. Study Selection

The coauthors initially screened titles and abstracts of all records after duplicates were removed. The full-text article for each potentially eligible article was screened.

4. Data Extraction

The coauthors independently used a standardized data ex-

traction form to collate study characteristics (publication year, country, diagnosis [fracture type + neurological deficit], number of patients), type of intervention (nonoperative). Studies published induplicate were only included once.

RESULTS

The panel was asked to vote on the indications for nonsurgical treatment of thoracolumbar fractures. A total of 6 statements were drafted and voted in Peshawar in December 2019.

Publication date from 2010 to 2020; English language; main word search in all-fields: “thoracolumbar” “fractures” and “treatment” We obtained 1,264 articles across all databases, and after removing duplicates, we were left with 504 articles. Four hundred fifty papers (nonrelated) after abstract review by an independent double-check up were excluded. Following a full-text review of the remaining 54 studies, the authors selected 9 studies that met the inclusion criteria to draw conclusions (Fig. 1). Out of 17 studies, 4 were randomized controlled trials, and rest were retrospective.

Excluded studies included studies published in any language other than English, any case reports, animal studies, experimental studies, studies on osteoporotic thoracolumbar spine fractures, studies solely investigating surgical treatments.

Below is the review summary from those studies comparing nonoperative and operative treatment in AO type A fractures.

1. Pain (VAS Score)

Five studies reported pain outcomes through average VAS scores.¹⁴⁻¹⁸ Although average VAS score for nonoperative cohort (2.25) was 0.37 lower than surgery cohort (2.62), there was no significant difference in the average VAS scores between the 2

cohorts ($p=0.33$).

2. Kyphotic Angle (Degrees)

Three studies reported posttreatment kyphotic angle.^{15,16,19} No statistically significant results were found between nonoperative (19.45°) and surgery (17.30°) ($p=0.8$).

3. Loss of Vertebral Body Height

Four studies have reported average posttreatment loss of vertebral height.^{15,16,19,20} No statistically significant differences ($p=0.17$) were observed between the average loss of vertebral body height for nonoperative cohort (37.72%) and the surgery cohort (20.19%).

4. Quality of Life (Physical Compartment, Mental Compartment Scores)

Five studies analyzed quality of life using the SF-36 test.^{14,16,20-22} No statistically significant differences were observed between nonoperative and surgery cohorts for physical compartment (56.29 vs. 63.37, $p=0.48$) and mental compartment scores (59.30 vs. 63.74, $p=0.65$).

5. Length of Hospital Stay

No statistically significant differences were observed between nonoperative (6.25 days) and surgery cohorts (6.09 days) for length of hospital stay ($p=0.97$).^{15,16}

6. Return to Work

Two studies reported the time needed to return to work after treatment.^{15,17} No statistically significant differences ($p=0.84$) were observed between nonoperative (76.6) and surgery (63.90) cohorts (Tables 1, 2).

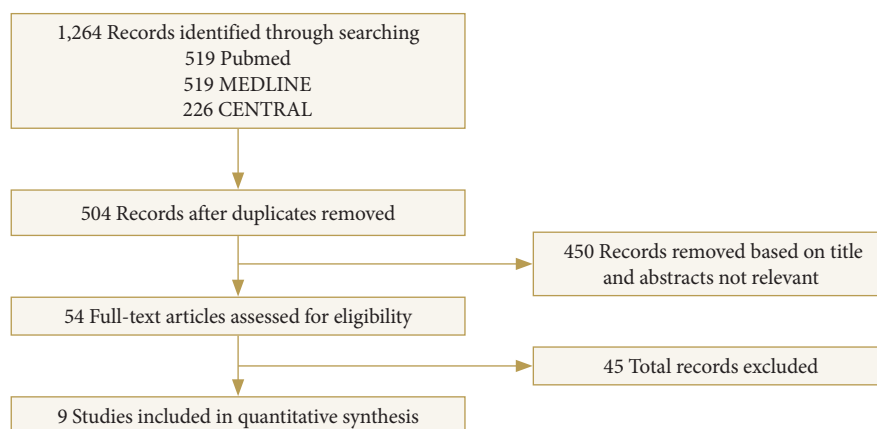


Fig. 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of the review process.

Table 1. Clinical outcomes following nonoperative and operative treatments for AO type A thoracolumbar fractures

Study	Study design	Country	No.	Fracture type + neurological deficit	Type of treatment	Mean pain score (VAS)	Mean kyphotic angle (°)	Mean vertebral height loss (%)	Mean physical compartment score (SF-36)	Mean mental compartment score (SF-36)	Mean hospital stay (day)	Mean return to work (day)
Karaali et al. ¹⁵ (2020)	Retrospective	Turkey	74	Compression + burst fractures No neurological deficit	Nonoperative vs. surgery	Nonoperative, 2.64; surgery, 1.91	Nonoperative, 35.5; surgery, 25.12	Nonoperative, 62.9; surgery, 21.2	N/A	N/A	Nonoperative, 1.50; surgery, 3.18	Nonoperative, 142.2; surgery, 104.79
Pehlivanoglu et al. ¹⁶ (2020)	Retrospective	Turkey	45	A3, A4 burst fractures No neurological deficit	Nonoperative vs. surgery	Nonoperative, 2.3; surgery, 1.9	Nonoperative, 11.65; surgery, 4.09	Nonoperative, 12.78; surgery, 7.87	Nonoperative, 56.67; surgery, 56.74	Nonoperative, 55.5; surgery, 55.47	Nonoperative, 11.0; surgery, 9.0	N/A
Nataraj et al. ¹⁷ (2018)	Retrospective	Canada	230	Burst fractures + no neurological deficit	Nonoperative vs. surgery	Nonoperative, 2.9; surgery, 3.3	N/A	N/A	N/A	N/A	N/A	Nonoperative, 11.0; surgery, 23.0
Urquhart et al. ²¹ (2017)	Randomized controlled trial	Canada	96	A3 fractures (burst) + no neurological deficit	TLSO (Brace) vs. no bracing	N/A	N/A	N/A	TLSO, 46.5%; no bracing, 45.5%	TLSO, 55.8%; no bracing, 55.2%	N/A	N/A
Hitchon et al. ¹⁸ (2016)	Retrospective	USA	68	Burst No deficit	Nonoperative vs. surgery	Nonoperative, 1.9; surgery, 3.0	N/A	N/A	N/A	N/A	N/A	N/A
Shen et al. ¹⁹ (2015)	Retrospective	China	129	Burst + no (new) neurological deficit	Nonoperative vs. surgery	N/A	Nonoperative, 11.3; surgery, 22.7	Nonoperative, 29.4; surgery, 31.5	N/A	N/A	N/A	N/A
Wood et al. ¹⁴ (2015)	Prospective randomized	USA	47	Stable burst fracture No neurological deficit	Nonoperative vs. surgery	Nonoperative, 1.5; surgery, 3.0	N/A	N/A	Nonoperative, 89.5; surgery, 70.0	Nonoperative, 89.0; surgery, 72.0	N/A	N/A
Shamji et al. ²⁰ (2014)	Randomized controlled trial	Canada	23	Burst No neurological deficit	Bracing (TLSO) vs. no bracing	N/A	N/A	TLSO, 47.6%; no bracing, 44%	TLSO, 51.6%; no bracing, 51.2%	TLSO, 43.3%; no bracing, 46.6%	N/A	N/A
Bailey et al. ²² (2014)	Randomized equivalence trial	Canada	47	Burst No neurological deficit	Orthoses vs. no orthoses	N/A	N/A	N/A	TLSO, 39.1%; no bracing, 36.6%	TLSO, 52.2%; no bracing, 50.8%	N/A	N/A

VAS, visual analogue scale; SF-36, 36-item Short Form Health Survey; NA, not available.

Table 2. A comparative analysis between nonoperative versus operative treatments for AO type A thoracolumbar fractures

Characteristic	Nonoperative	Surgery	p-value
Mean pain VAS score	2.25	2.62	0.33
Mean kyphotic angle (°)	19.45	17.30	0.81
Mean vertebral height loss (%)	37.72	20.19	0.17
Mean physical compartment score (SF-36)	56.29	63.37	0.48
Mean mental compartment score (SF-36)	59.30	63.74	0.65
Mean hospital stay (day)	6.25	6.09	0.97
Mean return to work (day)	76.60	63.90	0.84

VAS, visual analogue scale; SF-36, 36-item Short Form Health Survey.

DISCUSSION

This review discusses guidelines and highlights the lack of high-level evidence studies regarding the indications for non-surgical versus surgical treatment of traumatic thoracolumbar spine fractures. Several spinal fracture studies contain a high level of heterogeneity in the studied populations, including the spinal levels (mixed cervical and thoracolumbar and lumbar), mechanism of trauma, anatomical classification of trauma, surgical approaches performed as well as follow-up periods.

1. Stability of the Thoracolumbar Spine Fracture

Fracture stability (comprised of mechanical and neurological stability) is a significant variable in formulating the therapeutic plan.

Denis²³ in 1983 first classified instability into 3 subgroups, mechanical instability, neurological instability, and the combined instability. The mechanical stability of the thoracolumbar spine is analyzed based on the integrity of the bony structures and the integrity of the posterior ligament complex.²⁴⁻²⁶ On plain radiographs, reduction in the vertebral body height (50%), increased interspinous distance, and greater than 30°–35° of kyphotic deformity are indicators of injury to the posterior ligament complex.²⁷⁻²⁹ Computed tomography (CT) could be used for evaluating diathesis of facet joints.^{30,31} Magnetic resonance imaging is regarded as the most crucial examination in formulating the therapeutic plan for a patient with suspected PLC injury as it can analyze the PLC directly.³²⁻³⁴

Neurological symptoms caused by a traumatic spinal injury can be classified with the Frankel scale or American Spinal Injury Association scale. Involvement of individual nerve root is categorized as Frankel grade E.³⁵ Apart from grade E, the other grades of thoracolumbar spine fracture with a complete or incomplete deficit of neurological function due to the role of spi-

nal canal compromise are considered unstable fractures, irrespective of the instability from fracture itself or injury to the posterior element. Despite the above, fractures accompanied with the neurological deficit are not necessarily an absolute indication for surgery.³⁶⁻³⁹ The surgical treatment is commonly conducted for cases with an incomplete neurological function deficit. It prevents further progression of neurological injury, aids in neurological recovery, and makes early mobilization possible by attaining fracture stability. However, if cases have Frankel A paralysis with complete neurological injury, the neurological exam should be conducted again after the period of spinal shock. If the neurological status is not changed on the second examination, there is a slim chance of neurological recovery expected due to decompression surgery.⁴⁰ Hence, the treatment aims to restore spinal alignments and fracture stabilization, resulting in faster mobilization and improved rehabilitation options and results.^{35,41}

2. Classification of Thoracolumbar Spine Fractures

Since the first sophisticated classifications introduced by Holdsworth in 1962 and by Denis in 1983, several classification systems have been formulated to aid in better communication among physicians, determine therapeutic strategies, and analyze the prognosis. Among such classification systems, McAfee classification, AO classification, and the thoracolumbar injury classification and severity score (TLICS) classification are most frequently utilized (Table 3).^{12,23,24,27,42-54}

The mainstay of the thoracolumbar spine trauma management is based on modern comprehensive and easily reproducible classification that is based on:

- Objective clinical and imaging assessment.
- Provide standardized grading of the trauma.
- Identify any type of injury.
- Facilitates the decision if the fracture is stable/unstable.

Table 3. The major characteristics and pros/cons of each classification system being used in evaluating thoracolumbar spine fractures

Classification system	Characteristics	Pros/cons
Denis	<ol style="list-style-type: none"> 1. A 3-column theory based on 2-column theory of Holdsworth²⁴ 2. Suggests that fractures of the middle column were very unstable. 3. According to morphology of the fracture and mechanism of injury, thoracolumbar fractures were classified as compression, burst, flexion-distraction, and fracture dislocation. 	<p>Pros: It is simple and introduces the idea of damage to the neurological system⁴³</p> <p>Cons: it is quite challenging to identify thoracolumbar stable and unstable burst fractures⁴⁴, and interobserver reliability is low. Furthermore, it does not allow physicians to assess their therapeutic options for special fracture patterns on numerical evaluation of post-fracture stability⁴⁵</p>
McAfee	<ol style="list-style-type: none"> 1. PLC is a significant structure for the stability of the fracture, owing to the CT results. 2. Subcategorised the middle column trauma and suggested that the middle column fails by a trio of several forces such as axial compression, distraction, and translation. 3. Taking the mechanism of trauma into account, the authors separated such fractures into various categories, wedge compression fractures, stable, unstable burst fractures, chance fractures, flexion-distraction injuries, and translational injury²⁷ 	<p>Pros: Clear picture on surgical intervention required for type of fractures – stable burst or unstable burst⁴⁵</p> <p>Cons: lack of studies evaluating its reliability and validity⁴⁴</p>
McCormack	<ol style="list-style-type: none"> 1. Forecasts the risk of failure of implant post posterior short-segment fixation for thoracolumbar spine fractures. 2. Primarily introduction was in the aim of avoiding repeat kyphosis and failure of posterior short-segment fixation with pedicle screws through allowing the most suitable approach regarding approach (surgery). 	<p>Pros: Load sharing score links well with the degree of spinal instability⁴⁶</p> <p>Excellent inter- and intraobserver reliability was noted for junior surgeons⁴⁷</p> <p>Cons: This classification intends only to identify fractures that would require additional anterior fixation following a posterior surgery⁴⁸</p>
AOSpine	<ol style="list-style-type: none"> 1. Categorises trauma into 3 groups, A (compression), B (distraction), and C (translation) injuries⁴⁹ taking into account mechanism of trauma, morphology of the fracture, and mechanical stability. 2. Each category was further subcategorised from A1 to C3 (the higher the subgroup, the higher the severity of trauma and more unstable fractures) 	<p>Cons: AO Classification attempted to advise the comprehensive classification including all varied type of fractures, it showcased solely moderate intraobserver and interobserver reliability owing to its complexity^{45,50,51}</p> <p>Further drawbacks include its inability to formulate a definition of stability of the fracture as well as no mention of a injury to the neurological function⁴³</p>
TLICS	<ol style="list-style-type: none"> 1. The classification appears more comprehensive in comparison to the previous AO classification and includes information on neurological status and posterior ligamentous integrity¹² 2. In terms of neurological functional status, grades vary from N0 (Neurologically intact), N1 (Transient deficit of neurological function), N2 (radicular symptoms), N3 (incomplete SCI or cauda equina injury), N4 (complete SCI), NX (unknown neurologic status owing to sedation or trauma to the head)⁴⁹ 3. Morphological analyzes hold a great deal of significance as it aids in therapeutic choices²³ and categories vary from MM1 (abnormal alignment of vertebral column), MM2 (comminution of the vertebral body), MM3 (stenosis of the spinal canal), MM4 (intervertebral disc lesion).⁴² The complete score was counted by tallying up the scores from each of the 3 categories, and used to decide which treatment is most appropriate. 4. Conservative treatment is indicated for the total score of 3 points, 4 points to the grey area, where the decision on the therapy is taken by the physician, a score of 5 points indicates surgical treatment 	<p>Pros: The classification appears more comprehensive in comparison to the previous AO classification and includes significant information on neurological status and posterior ligamentous integrity¹²</p> <p>Evaluation of TLISS showcased fair to substantial intraobserver and interobserver reliability in various studies^{52,54}</p>

PLC, posterior ligamentous complex; CT, computed tomography; SCI, spinal cord injury; TLICS, thoracolumbar injury classification and severity score; TLISS, thoracolumbar injury severity score.

- It gives the treatment direction – to fix or not to fix.
- Easily reproducible and easy to use in everyday practice.

Unfortunately, we are still searching for the ideal classification that will comply in 100% of the cases with the above criteria.

Oner et al.⁵⁵ and Wood et al.⁵⁰ indicated that the Denis classification system showed higher interobserver reliability than the AO classification system. Lenarz et al.⁵⁶ reported the comparison of Denis, AO, TLICS systems in 97 thoracolumbar fractures and observed that changes in reliability were present in all 3 scenarios, with the highest reliability happening in the senior resident cohort and attending spine surgeon cohort.⁵⁶ The lowest reliability was in the nonspine attending orthopedic and junior residents. In each cohort, the neurological function had the highest interobserver and intraobserver reliability. The researchers concluded that the TLICS is considered a widely deemed reliable tool compared to Denis and AO classification systems.⁵⁷⁻⁵⁹

3. Indications for Treatment of Thoracolumbar Spine Fractures

The goal of the management of thoracolumbar fractures involves reinstating the structural integrity and stability of the damaged spine, thus providing a biomechanically optimum environment for helping recovery. Historically, thoracolumbar fractures were managed primarily nonoperatively. However, recent technological improvements have shifted the transition from nonoperative to surgical treatment. However, the neurological deficit is seldom observed in cases managed nonoperatively. There is a lack of high-quality comparative research papers, with literature not confirming surgical treatment's superiority over nonoperative treatment regarding pain management and restoration of neurological function.⁶⁰⁻⁶³

Surgical treatment is seldom suggested for compression fractures. However, a vast proportion of flexion-distraction/fracture dislocations require surgery (stabilization). As surgical treatment is frequently recommended for thoracolumbar fractures with neurological deficits, the current review's main focus is the surgical management of fractures with neurological systems intact. To date, there is no high-quality, randomized research study supporting the superiority of surgical treatment over conservative treatment when there is no deficit of neurological function. Siebenga et al.⁶⁴ revealed that AO type A fractures (with an intact neurological system) treated by surgical treatment compared to nonoperative treatment revealed superior radiological results; however, clinical outcomes were similar.⁶⁴

Literature suggests that conservative treatment is indicated even in burst fractures with canal encroachment in the absence

of a neurologic function's major deficit. The spinal canal's spontaneous remodelling is one of the variables favouring nonoperative management.⁶⁵

Many spinal surgeons do not necessarily prioritize minimal neurological deficits (monoradicular symptoms) unless it is severe with spinal canal compromise in surgical decision-making. Meanwhile, all of the spinal trauma classification systems consider evaluation of spinal cord damage.^{23,45,66,67}

4. Nonoperative Management of Thoracolumbar Spine Fractures

In a spinal cord injury case, trauma to the neural structures happens both at the time of the trauma (primary – nonmodifiable) and in the subsequent period due to vascular dysfunction, edema, ischemia, electrolyte shifts, production of free radical, inflammation, and delayed apoptotic cell death (secondary – potentially modifiable) or iatrogenic reasons.⁶⁸ During prehospital treatment and in the emergency department management, also follow-up care, all the necessary measures should be taken to immobilize spinal trauma patients safely, to avoid a focal neurological deficit.¹²

The statistics suggest that the majority of thoracolumbar fractures are stable, amenable to nonoperative management. The aim of nonoperative treatment is an appropriate regime of immobilization and, as early as possible, ambulation of the patient.⁶⁹ At the start, a short duration of bed rest may be indicated. Successful nonoperative treatment is based on patient collaboration, physiotherapists, nurses, and senior physicians. A change in treatment plan may be considered in the event of significant deterioration of clinical or radiological presentation.⁴²

Half of the thoracolumbar fractures are classified as compression type due to axial compression alone or flexion forces and present with wedge deformities of the vertebral body on radiological evaluation. Patients with compression-type fractures are seldom treated operatively as they are rarely associated with a current or potential deficit of neurological function.⁴³

Various pharmacological therapies are thought to alleviate secondary trauma have been studied in depth. These include steroids (anti-inflammatory), gangliosides, naloxone (opiate receptor blocker), calcium channel blockers, free radical scavengers, and neurotropic agents. Steroids were used quite heavily in the clinical management of spinal cord injury since mid of the 1960s. In animal spinal cord injury models, neurological recovery improved following steroid use.⁷⁰ After encouraging outcomes via an elevated dose of steroids in NASCIS (National Acute Spinal Cord Injury Study) 1 and 2 trials. However, in a third

study, methylprednisolone failed to demonstrate an effect in comparison to placebo. Additionally, due to increased risk of infections, its use is no longer recommended.⁷¹ American Association of Neurological Surgeons/Congress of Neurological Surgeons guidelines state that administration of methylprednisolone is no longer recommended as there is no class 1 or 2 study that has shown benefits. Hurlbert reported that the utility of high-dose methylprednisolone in the therapy of acute spinal cord injury is not proven as a standard of patient care.⁷² A survey (2006) indicated that most of the respondents continue to give methylprednisolone, but by fear of litigation. However, in the current times, a high dose of steroid treatment is not considered to be a mainstream treatment.⁷³

Bracing is no longer considered necessary for the treatment of fractures of the vertebral column. Independent randomized control trials revealed no advantages from wearing braces.^{21,22} In a systematic review, Giele et al.⁷⁴ reported that there is no evidence for the efficacy of bracing in cases with traumatic thoracolumbar fractures.

1) Pain improvement (VAS score)

Literature regarding pain improvement from nonoperative and operative management of AO type A fractures is conflicted. A randomized prospective study evaluating stable burst fracture management revealed a statistically significant pain improvement from nonoperative treatment compared to surgical intervention.¹⁴ Similar results were revealed by a large-scale retrospective study (n = 230). However, the difference was not statistically significant.¹⁷ On the other hand, Karaali et al.¹⁵ evaluating compression, burst fractures (without neurological deficit) revealed that surgical management might yield a superior pain improvement in comparison to nonoperative management.

2) Kyphotic angle and loss of vertebral body height

During conservative care, it is common to oversee a certain degree of increasing fracture kyphosis in most patients, frequently closer to the pretreatment sagittal alignment. However, kyphosis has not been showcased to link with increased pain levels in various studies, even up to 30°.^{13,75,76}

Nonoperative management is less efficacious in decreasing kyphotic angle in comparison to surgical management. Karaali et al.¹⁵ revealed that the nonoperative cohort's kyphotic angle (at the final follow-up, 24 months) of 17.61° to be higher than the surgical cohort (p < 0.001). Similar results were observed from a range of retrospective studies (Pehlivanoglu et al.¹⁶ and Shen et al.¹⁹).

Furthermore, nonoperative management seemed less successful in halting the loss of vertebral height than surgical management. Karaali et al.¹⁵ revealed that at all follow-ups (3 months, 6 months, and 24 months), the nonoperative cohort had a significantly higher (p < 0.001) loss of vertebral height versus the surgical cohort. Similar results were reported by the other retrospective designed studies; however, the 2 cohorts' differences were not statistically significant.

Shamji et al.²⁰ evaluated bracing and nonbracing cohorts, and results revealed bracing to not be significantly superior to nonbracing cohorts in limiting vertebral height loss.

3) Quality of life (SF-36)

Literature on which management leads to a higher quality of life is conflicted. Pehlivanoglu et al.¹⁶ revealed that the surgical cohort had a higher mental and physical compartment score than nonoperative cohorts. In contrast, Wood et al.¹⁴ demonstrated that nonoperative cohorts had a significantly higher mental and physical score versus the surgical cohort.

Studies evaluating bracing and nonbracing cohorts did not reveal any statistically significant results regarding improving quality of life.²¹

4) Length of hospitalisation and return to work

Literature on length of hospital stay for compression/burst fractures (without neurological deficit) managed nonoperatively and surgically is conflicted and lacking. While Karaali et al.¹⁵ revealed a shorter hospital stay for patients managed nonoperatively, Pehlivanoglu et al.¹⁶ showed otherwise.

All studies revealed that surgical management leads to a faster return to work versus nonoperative management regarding returning to work.

5. Future Research

Each section within these recommendations suggests areas of need for future high-quality studies. However, as an overall requirement, future research should try to analyze patients with thoracolumbar trauma separate from patients with cervical trauma to better clarify the most effective diagnostic and treatment ways for these patients in particular.

CONCLUSION

Ensuring the best indications for nonsurgical or surgical treatment for the patients sustaining thoracolumbar fractures remains crucial. However, the available literature is still not unanimous,

and further research is necessary. Compression-type fractures and stable burst fractures are mostly managed conservatively. If there is significant vertebral body structural damage, kyphotic angulation, neurological deficit, spinal canal compromise, surgical treatment may be considered. AO types B, C fractures are to be treated primarily surgically. The majority of the AO type A fractures may be treated conservatively.

WFNS RECOMMENDATION ON INDICATIONS FOR SURGICAL TREATMENT OF THORACOLUMBAR FRACTURES

- AO types B and C fractures preferably should not be treated conservatively (strongly agree 16.7%, agree 66.7%, disagree 16.7%).
- AO types A2, A3, and A4 can be treated conservatively if there is no significant vertebral body collapse, significant kyphotic angulation, or canal compromise with neurological impairment (agree 100%).
- There is no clinical evidence that bracing for conservative treatment of thoracolumbar fractures will improve the outcome (agree 100%).
- Fracture dislocations and cases with significant instability (score ≥ 5 of TLISS classification) should preferably be operated (strongly agree 16.7%, agree 83.3%).
- For burst fractures with neurological deficits, surgical decompression and stabilization may be considered, although there is not enough scientific evidence to support that (strongly agree 16.7%, agree 66.7%, disagree 16.7%).
- Burst fractures without neurological deficits can be treated either with conservative or surgical techniques (strongly agree 16.7%, agree 83.3%).

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Review Article

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Demographic Predictors of Treatment and Complications for Spinal Disorders: Part 2, Lumbar Spine Trauma

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Objective: To study the impact of demographic factors on management of traumatic injury to the lumbar spine and postoperative complication rates.

Methods: Data was obtained from the National Inpatient Sample (NIS) between 2010–2014. International Classification of Diseases, 9th revision, Clinical Modification codes identified patients diagnosed with lumbar fractures or dislocations due to trauma. A series of multivariate regression models determined whether demographic variables predicted rates of complication and revision surgery.

Results: A total of 38,249 patients were identified. Female patients were less likely to receive surgery and to receive a fusion when undergoing surgery, had higher complication rates, and more likely to undergo revision surgery. Medicare and Medicaid patients were less likely to receive surgical management for lumbar spine trauma and less likely to receive a fusion when operated on. Additionally, we found significant differences in surgical management and postoperative complication rates based on race, insurance type, hospital teaching status, and geography.

Conclusion: Substantial differences in the surgical management of traumatic injury to the lumbar spine, including postoperative complications, among individuals of demographic factors such as age, sex, race, primary insurance, hospital teaching status, and geographic region suggest the need for further studies to understand how patient demographics influence management and complications for traumatic injury to the lumbar spine.

Keywords: Lumbar spine trauma, Fusion, Decompression, Trauma, National Inpatient Sample



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INTRODUCTION

Traumatic injury to the lumbar spine is typically treated with nonoperative therapy with bracing.¹ However, surgical intervention for traumatic fractures of the lumbar spine is indicated when the biomechanical stability of the spine is compromised

or to mitigate the risks of further neurological deficits.² Lumbar spinal fusion, including simple and complex fusion, allows vertebrae to be joined and can be used for vertebral fractures and dislocations.³ Surgical decompression is useful for improving neurological functions following lumbar spine trauma by preventing secondary injury to the spinal cord.⁴

Demographic predictors of outcomes after surgery for lumbar spine trauma are not well studied, including predictors such as race, insurance type, hospital teaching status, and geographic region. In this study, the publicly available National Inpatient Sample (NIS) database, which reports data from hospitals across the United States, was queried to identify patients with a primary diagnosis of traumatic injury to the lumbar spine. These patients were analyzed for surgical management and outcomes, including complications and complication rates, type of surgery performed, and revisions. These data were then subject to a set of multivariate analyses. The goal of this study was to identify demographic risk factors for a poor outcome, which may help guide clinical decision-making for surgeons treating traumatic lumbar spine disorders and improve the care for more vulnerable patient populations.

MATERIALS AND METHODS

This paper is part of a series which examines demographic predictors of surgical outcomes in patients undergoing lumbar spine surgery. Data were obtained from the NIS, a Healthcare Cost and Utilization Project (HCUP) database which includes a 20% sample of discharges from HCUP-participating hospitals. Overall, the NIS includes data on over 7 million discharges per year; this study includes data from 2010–2014. International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) codes were used to identify all patients with a primary diagnosis of a traumatic injury of the lumbar spine including open and closed lumbar fractures without mention of spinal cord injury (805.4, 805.5), open and closed lumbar fractures with mention of spinal cord injury (806.4, 806.5), and multiple or ill-defined dislocations of lumbar vertebra (839.20, 839.30).

A total of 38,249 patients were identified and were examined for 1 of 3 surgical outcomes: (1) decompression alone (3, 3.09, 80.5, 80.51), (2) simple fusion involving 3 or less vertebral levels (81, 81.04, 81.05, 81.06, 81.07, 81.08, 81.62), and (3) complex fusion involving greater than 3 vertebral levels or a 360° spinal fusion (81.61, 81.63, 81.64). The patients were stratified by different demographic variables including age, sex, race, primary insurance, hospital teaching status, and geographic region. Surgical patients were assessed for various complications including implant-related complications, wound-related complications, incidental durotomy, laceration or puncture, hemorrhage, bacteremia, postoperative infection, postoperative shock, myocardial infarction, iatrogenic stroke, neurologic complications, venous thromboembolism, urinary complications, and death. ICD-

9-CM codes used to define sets of diagnoses and complications are provided in the supplemental materials.

A series of multivariate Poisson regression analyses was used to determine if any individual demographic variable predicted a surgical outcome such as the odds of receiving any surgery (decompression or fusion) or the odds of receiving a fusion in particular. Furthermore, a series of regressions was used to determine if any individual demographic variable as well as any particular type of operation (decompression, simple fusion, or complex fusion) predicted surgical complications, including the need for a revision operation. Additionally, the presence of a comorbid spinal deformity, such as kyphosis (737.1, 737.19, 737.41), lordosis (737.2, 737.42), scoliosis (737.3, 737.32, 737.34, 737.43, 737.49), or other idiopathic curvatures of the spine (737.4, 754.2, 756.19), was assessed as a predictor of surgical complication. All multivariate regression models were controlled for age, sex, primary insurance type, median household income, geographic region, hospital teaching status, comorbidity status, and additional variables displayed in the Results section tables. Multivariate analyses were presented as odds ratios, with corresponding 95% confidence intervals (CI) and p-values; (odds ratio [OR]; 95% CI; $p < x$). Given the cohort sample size and the series of multivariate analyses, a p-value < 0.05 was used to determine significance. Data extraction, analyses, and statistical tests were done with Stata 11.2 (StataCorp LLC, College Station, TX, USA) and RStudio (R ver. 3.5.1, R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

1. Demographics

A total of 38,249 patients were identified for analysis over a 5-year period. In this cohort, 5,776 (15.1%) patients received surgery, including 1.9% decompressions, 8.8% simple fusions, and 4.4% complex fusions. The average age was 65.8 ± 21.4 . In terms of sex, 56.1% of patients were female. For racial background, 81.1% were White, 8.3% were Hispanic, 5.1% were Black, 2.6% were Asian/Pacific Islander, and 2.5% were from other groups. Within this cohort, 58.2% had Medicare, 23.5% of patients had private insurance, and 6.1% had Medicaid.

In terms of hospital teaching status, 51.8% admitted to urban teaching hospitals, 38.2% admitted to urban nonteaching hospitals, and 9.9% of patients were admitted to rural hospitals. In terms of geographic region, 43.5% of hospitals were in the South, 19.0% of hospitals were in the Midwest, 19.0% of hospitals were in the West, and 18.6% hospitals were in the Northeast. The av-

Table 1. Characteristics of patients* with traumatic lumbar spine injury from 2010 to 2014 in the National Inpatient Sample

Characteristic	2010	2011	2012	2013	2014
Total patients	7,975	7,628	7,547	7,489	7,610
Total operations	1,148 (14.4)	1,147 (15.0)	1,130 (15.0)	1,175 (15.7)	1,176 (15.5)
Decompression (%)	1.6	2.0	1.9	2.1	2.0
Simple fusion (%)	8.8	8.6	8.8	9.1	8.5
Complex fusion (%)	4.0	4.4	4.2	4.4	5.0
Age (yr)	64.8 ± 22.3	67.0 ± 21.2	65.7 ± 21.3	65.8 ± 21.1	65.9 ± 21.3
Female sex (%)	54.7	57.2	56.6	56.1	56.2
Race					
White (%)	81.5	82.5	81.4	80.2	79.8
Black (%)	5.0	4.9	4.5	5.4	5.9
Hispanic (%)	8.1	7.9	8.3	8.8	8.3
Asian/Pacific Islander (%)	2.6	2.0	2.8	2.8	2.8
Other (%)	2.4	2.3	2.5	2.4	2.7
Primary insurance					
Private (%)	25.9	23.2	23.5	22.7	22.2
Medicare (%)	54.8	60.1	58.4	59.4	58.5
Medicaid (%)	6.0	5.7	5.3	5.5	8.1
Hospital teaching status					
Rural (%)	11.9	10.1	10	9.7	7.8
Urban, nonteaching (%)	41.5	44.4	39.8	39.0	26.3
Urban, teaching (%)	46.5	45.5	50.2	51.3	65.9
Geographic region					
Northeast (%)	19.2	19.7	17.9	18.1	17.9
South (%)	43.9	43.6	43.9	42.6	43.6
Midwest (%)	16.9	18.5	19.5	20.6	19.4
West (%)	20.0	18.2	18.8	18.8	19.0
Death (%)	0.76	0.71	0.85	0.53	0.72
Charlson Comorbidity Index score	0.90 ± 1.39	0.97 ± 1.44	0.99 ± 1.47	1.03 ± 1.49	1.03 ± 1.54

Values are presented as number (%) or mean ± standard deviation.

*Unweighted data, national estimates not provided.

average Charlson Comorbidity Index (CCI) score was 0.99 ± 1.5 (Table 1).

2. Surgical Versus Conservative Management

After adjusting for age, median household income, and Charlson comorbidity status, it was found that female patients had lower odds of receiving surgery than male patients (OR, 0.79; 95% CI, 0.74–0.84; $p < 0.001$). Moreover, Black patients (OR, 0.76; 95% CI, 0.66–0.86; $p < 0.001$) and Hispanic (OR, 0.89; 95% CI, 0.80–0.99; $p = 0.028$) patients had lower odds of receiving surgery compared to White patients. When considering insurance type of patients, Medicare (OR, 0.55; 95% CI, 0.50–0.60;

$p < 0.001$) and Medicaid (OR, 0.79; 95% CI, 0.71–0.89; $p < 0.001$) patients had a significantly lower rate of receiving surgery compared to private insurance patients. Patients at rural hospitals had lower odds of receiving surgery compared to patients at urban, nonteaching hospitals (OR, 1.92; 95% CI, 1.66–2.23; $p < 0.001$) and urban teaching hospitals (OR, 2.62; 95% CI, 2.27–3.03; $p < 0.001$). When analyzing the geographic region of hospitals where patients were treated, we found that patients treated in the South (OR, 1.2; 95% CI, 1.1–1.32; $p < 0.001$) and West (OR, 1.15; 95% CI, 1.04–1.27; $p = 0.007$) had higher odds of receiving surgery when compared to patients treated in the Northeast. Patients with spinal deformity (scoliosis, kyphosis, or lordosis)

Table 2. Odds ratio for receiving surgery in patients with a primary traumatic condition of the lumbar spine - multivariable Poisson regression, National Inpatient Sample data, 2010–2014

Variable	Incidence rate ratio	95% CI	p-value
Sex			
Male	Reference		
Female	0.79	0.74–0.84	< 0.001
Race			
White	Reference		
Black	0.76	0.66–0.86	< 0.001
Hispanic	0.89	0.80–0.99	0.028
Asian/Pacific Islander	0.94	0.77–1.14	NS
Other	1.02	0.85–1.22	NS
Primary insurance			
Private	Reference		
Medicare	0.55	0.50–0.60	< 0.001
Medicaid	0.79	0.71–0.89	< 0.001
Hospital teaching status			
Rural	Reference		
Urban, nonteaching	1.92	1.66–2.23	< 0.001
Urban, teaching	2.62	2.27–3.03	< 0.001
Geographic region			
Northeast	Reference		
Midwest	0.98	0.89–1.09	NS
South	1.20	1.1–1.32	< 0.001
West	1.15	1.04–1.27	0.007
Year			
2010	Reference		
2011	1.19	1.08–1.31	< 0.001
2012	1.11	1.01–1.22	0.039
2013	1.19	1.08–1.31	< 0.001
2014	1.10	0.99–1.21	NS
Spinal deformity			
None	Reference		
Scoliosis, kyphosis, lordosis	4.81	4.23–5.45	< 0.001

Also adjusted for age, Charlson comorbidity status, and median household income.

CI, confidence interval; NS, not significant.

were found to have significantly higher odds of receiving surgery when compared to patients without spinal deformity (OR, 4.81; 95% CI, 4.23–5.45; $p < 0.001$) (Table 2).

3. Spinal Fusion

For patients that received surgery due to traumatic injury to the lumbar spine, we analyzed the odds of these patients receiving a fusion based on sex, race, primary insurance type, and co-existing spinal deformity. Models which also adjusted for age, median household income, and CCI score, found that female patients (OR, 0.76; 95% CI, 0.64–0.89; $p = 0.001$) had lower odds of receiving a fusion compared to male patients. Similarly, Black patients (OR, 0.63; 95% CI, 0.47–0.85; $p = 0.002$) undergoing surgery had lower odds of receiving a fusion compared to White patients. When considering insurance status in patients receiving surgery for traumatic lumbar spine injury, we found that Medicare (OR, 0.69; 95% CI, 0.54–0.89; $p = 0.004$) and Medicaid (OR, 0.73; 95% CI, 0.55–0.99; $p = 0.042$) patients that were operated on had lower odds of receiving fusion compared to private insurance patients. Lastly, patients with a spinal deformity (OR, 17.42; 95% CI, 8.01–48.93; $p = 0.001$) had significantly higher odds of receiving fusion compared to patients without a spinal deformity.

4. Surgical Complications

We analyzed complication rates for surgical patients with a primary traumatic condition of the lumbar spine. The total complication rate for the cohort was 30.1%. Hemorrhage/hematoma/seroma was seen in 18.1% of patients, urinary complications in 8.0% of patients, incidental durotomy in 3.2% of patients, implant-related complications in 2.1% of patients, venous thromboembolism in 1.7% of patients, wound-related complications in 1.3% of patients, bacteremia/septicemia in 1.2% of patients, postoperative infection in 1.1% of patients, and neurologic complications in 0.9% of patients. The death rate for 1,148 surgical patients in 2010 was 1.2% (Table 3).

We utilized a multivariate Poisson regression model to determine if demographic factors influenced the odds of developing surgical complications. Patients undergoing complex fusion, defined as 4+ levels fused (OR, 1.98; 95% CI, 1.62–2.45; $p < 0.001$), and simple fusion, defined as 2–3 levels fused (OR, 1.98; 95% CI, 1.62–2.45; $p < 0.001$), had higher odds of developing complications compared to patients undergoing decompression alone. When considering sex, female patients (OR, 1.3; 95% CI, 1.15–1.46; $p < 0.001$) were found to have higher odds of developing complications compared to male patients. Moreover, Hispanic (OR, 0.77; 95% CI, 0.63–0.95; $p < 0.014$) and Asian/Pacific Islander (OR, 0.66; 95% CI, 0.43–0.97; $p = 0.041$) patients had lower odds of developing complications compared to White patients. In terms of insurance status, Medicare patients (OR,

Table 3. Complication rates in surgical patients with a primary traumatic condition of the lumbar spine from 2010 to 2014 in the National Inpatient Sample (NIS)

Variable	2010	2011	2012	2013	2014
Total patients	1,148	1,147	1,130	1,175	1,176
Complication rates					
Total complication rate* (%)	27.8	28.7	30.8	31.7	31.4
Implant-related complication	1.39	2.53	1.77	2.04	2.64
Wound-related complication	1.66	1.39	1.24	1.02	-
Incidental durotomy	2.87	3.75	3.10	3.40	3.06
Hemorrhage/hematoma/seroma	15.85	16.56	18.31	19.74	20.15
Bacteremia/septicemia	1.05	-	1.77	0.94	1.02
Postoperative infection	1.22	0.96	0.97	-	-
Neurologic complication	0.96	-	-	-	0.85
Venous thromboembolism*	1.48	1.13	1.77	2.3	1.96
Urinary complication*	8.01	8.37	8.58	7.91	7.06
Death (%)	1.22	-	-	-	-

NIS prohibits publication of patient groups < 10.

*Total complication rate excluding death. Venous thromboembolism includes diagnostic codes for pulmonary embolism and thromboembolism in deep vessels of the lower extremities. Urinary complication includes diagnostic codes for urinary tract infection and unspecified urinary complication.

1.36; 95% CI, 1.14–1.62; $p < 0.001$) had higher odds of surgical complications compared to private insurance patients, whereas there was no difference observed with Medicaid patients. Unlike patients at urban nonteaching hospitals, patients at urban teaching hospitals (OR, 1.59; 95% CI, 1.18–2.19; $p < 0.003$) were more likely to experience complications compared to patients at rural hospitals (Table 4).

In addition to complications, we looked at the odds of patients receiving revision surgery for traumatic injury to the lumbar spine. Patients undergoing simple fusion (OR, 6.47; 95% CI, 2.36–26.69; $p = 0.002$) and complex fusion (OR, 10.1; 95% CI, 3.66–41.85; $p < 0.001$) had higher odds of receiving a revision operation compared to patient receiving decompression alone. Furthermore, we found that female patients (OR, 1.44; 95% CI, 1.00–2.09; $p < 0.001$) had higher odds of receiving revision surgery compared to male patients. Unlike Medicaid patients, Medicare patients (OR, 2.66; 95% CI, 1.60–4.51; $p < 0.001$) had higher odds of receiving revision surgery compared to private insurance patients. Lastly, patients with a coexisting spinal deformity were at increased odds of receiving a revision operation (OR, 1.71; 95% CI 1.04–2.69; $p = 0.027$) (Table 5).

DISCUSSION

In this study, we performed a retrospective analysis of nation-

al administrative hospital data from a 5-year period. The objective of this study was to identify demographic predictors of patient management decisions and postoperative complications in a large sample of patients diagnosed with a primary traumatic condition of the lumbar spine. We utilized multivariate predictive modeling to control for patient-specific confounding variables. We found that demographic variables such as sex, race, insurance type, geographic region, and hospital teaching status may have significant influences on whether patients will receive conservative or surgical therapy for trauma to the lumbar spine. Moreover, additional multivariate models were created to determine if certain patient variables could predict complication rates. Our results suggest that surgery type, sex, race, insurance type, and hospital teaching status may predict inpatient complications within our large cohort.

There are very few studies that have studied the role of demographic variables on patient outcome after spine trauma. Schoenfeld et al.⁵ found that patient demographics such as race and insurance status could influence outcomes after traumatic injury to the spine. Namely, they found that minority patients, including Black patients, were at increased risk of mortality.⁵ In our analysis, we found that Black patients were less likely to receive a fusion for lumbar spine trauma compared to White patients. Moreover, our findings show that Black and Hispanic patients were overall less likely to be surgically managed for

Table 4. Odds ratio for surgical complication* in patients with a primary traumatic lumbar condition - multivariable Poisson regression, National Inpatient Sample data, 2010–2014

Variable	Incidence rate ratio	95% CI	p-value
Surgery type			
Decompression	Reference		
Simple fusion (2–3 levels)	1.98	1.62–2.45	< 0.001
Complex fusion (4+ levels)	2.84	2.29–3.55	< 0.001
Sex			
Male	Reference		
Female	1.30	1.15–1.46	< 0.001
Race			
White	Reference		
Black	0.84	0.64–1.08	NS
Hispanic	0.77	0.63–0.95	0.014
Asian/Pacific Islander	0.66	0.43–0.97	0.041
Other	0.88	0.62–1.23	NS
Primary insurance			
Private	Reference		
Medicare	1.36	1.14–1.62	< 0.001
Medicaid	1.22	0.99–1.50	NS
Hospital teaching status			
Rural	Reference		
Urban, nonteaching	1.22	0.89–1.70	NS
Urban, teaching	1.59	1.18–2.19	0.003
Spinal deformity			
None	Reference		
Scoliosis, kyphosis, lordosis	0.86	0.70–1.06	NS

Also adjusted for age, Charlson comorbidity status, year, and median household income.

CI, confidence interval; NS, not significant.

*One or more surgical complications listed in Table 4, excluding death.

lumbar spine trauma compared to White patients, which is a finding supported in another study comparing rates of surgical intervention among different racial groups for lumbar spine surgery among many other types of surgery.⁶ Interestingly, we found that Hispanic and Asian/Pacific Islander patients were less likely to suffer complications following surgery for lumbar spine trauma compared to White patients. Our data also show that there is no difference in the likelihood of developing complications between Black and White patients. To our knowledge, the effect of race on postoperative complication rates for lumbar spine trauma has not been studied and further studies would be useful to shed light on the clinical relevance of these differ-

Table 5. Odds ratio for receiving a revision operation in surgical patients with a primary traumatic condition of the lumbar spine - multivariable Poisson regression, National Inpatient Sample data, 2010–2014

Variable	Incidence rate ratio	95% CI	p-value
Surgery type			
Decompression	Reference		
Simple fusion (2–3 levels)	6.47	2.36–26.69	0.002
Complex fusion (4+ levels)	10.1	3.66–41.85	< 0.001
Sex			
Male	Reference		
Female	1.44	1.00–2.09	0.049
Primary insurance			
Private	Reference		
Medicare	2.66	1.60–4.51	< 0.001
Medicaid	1.71	0.82–3.35	NS
Spinal deformity			
None	Reference		
Scoliosis, kyphosis, lordosis	1.71	1.04–2.69	0.027

Adjusted for age, year, Charlson comorbidity status, and median household income.

CI, confidence interval; NS, not significant.

ences as the United States becomes increasingly diverse ethnically and racially.⁷

Prior studies have shown that insurance status can affect the likelihood of patients receiving surgery.^{8–10} We found that Medicare and Medicaid patients were less likely to receive surgery for traumatic injury to the lumbar spine when compared to private insurance patients. Furthermore, insurance status has also been shown to influence mortality as well as length of stay for patients after traumatic injury to the spine.⁵ In terms of complications, we found that Medicare but not Medicaid patients were more likely to experience surgical complications. Similarly, Medicare, but not Medicaid patients, were more likely to receive a revision operation. Although higher complication rates have been reported after spine surgery among the elderly,^{11–13} our analyses of demographic predictors adjusted for age among other factors. Medicaid patients have been found previously in some studies to have higher complication rates after spine surgery.^{14–17} However, to the best of our knowledge, no studies have analyzed the role of patient demographics on complication rates after surgery to treat traumatic injury to the lumbar spine. Our study, which has the advantage of including a large sample size and thus increasing power, does not show that Medicaid pa-

tients having surgery for lumbar trauma are more likely to suffer from postoperative complications. Although it appears that insurance status, including having Medicare or Medicaid, may impact the likelihood of patients receiving surgery for lumbar spine trauma, we found that only Medicare patients appear to be at increased risk for complications postoperatively.

The role of sex on patient management and outcome after surgery for lumbar spine trauma is still unclear and prior studies on this topic are limited. In a relatively small study of acute traumatic spinal cord injury, it was found that therapeutic approaches, mortality, comorbidities, and length of stay were similar between male and female patients.¹⁸ Some studies have shown that surgical complications are higher for female patients that undergo spine surgery¹⁹ and that female patients receive surgery at a later stage of their disease due to reluctance to undergo surgery.^{20,21} Our results show that female patients, when compared to male patients, were less likely to receive surgery, less likely to receive a fusion when undergoing surgery, had higher complication rates, and were more likely to undergo revision surgery. To our knowledge, our study is the first to illuminate disparities in the management and postoperative complication rates between male and female patients treated for traumatic injury to the lumbar spine.

Aside from insurance status, race, and sex, we show that hospital teaching status can also influence patient management and postoperative complications after lumbar spine trauma. We found that postoperative complications were more likely to occur in urban teaching hospitals but not urban nonteaching hospitals when compared to rural hospitals. These results align with previous findings that complications are more frequent in teaching hospitals compared to nonteaching hospitals.²²

This study has some limitations. As a retrospective analysis, there are biases inherent to the study design. In addition, a challenge for large administrative database studies is determining how clinically important or relevant a difference is since small differences can be found to be statistically significant.²³ Also, the data from this study was obtained from a relatively short time period (2010–2014) due to the mandatory change from ICD-9 to ICD-10 coding in 2015. The decision to limit the data to this five-year period eliminates the potential confounds associated with 2 different ICD coding systems. Additionally, individual variation in the use of ICD-9-CM codes among surgeons could be a source of limitation. Despite these limitations, a strength of this study is its sample size (38,249 patients) which better reflects the population of patients with traumatic injury to the lumbar spine, which would not be practical for study de-

signs producing higher levels of evidence with fewer sources of bias.

CONCLUSION

Lumbar spine trauma is common, and surgery is at times necessary to prevent further damage and to improve quality of life. Demographic variables such as age, sex, race, primary insurance, hospital teaching status, and geographic region may have significant influences on management (conservative versus surgical treatment) of traumatic injury to the lumbar spine, as well as postoperative complications. Further studies are needed to fully understand the influence of patient demographics for patients undergoing surgery for traumatic injury to the lumbar spine.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Review Article

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INTRODUCTION

Regional anesthesia (RA), which includes epidural anesthesia (EA) via catheter infusion and spinal anesthesia (SA) via single-shot injection, is commonly used for procedures of known duration that involve the lower extremities, perineum, pelvic girdle, or lower abdomen.¹⁻⁸ The literature notes numerous advantages of RA over general anesthesia (GA), including favorable perioperative hemodynamic stability, reduced mortality, intraoperative blood loss, arterial and venous thrombosis, pulmonary embolism, myocardial infarction, renal failure, and decreased incidence of cognitive dysfunction.⁹⁻¹⁵

Regional Anesthesia for Lumbar Spine Surgery: Can It Be a Standard in the Future?

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This paper is an overview of various features of regional anesthesia (RA) and aims to introduce spine surgeons unfamiliar with RA. RA is commonly used for procedures that involve the lower extremities, perineum, pelvic girdle, or lower abdomen. However, general anesthesia (GA) is preferred and most commonly used for lumbar spine surgery. Spinal anesthesia (SA) and epidural anesthesia (EA) are the most commonly used RA methods, and a combined method of SA and EA (CSE). Compared to GA, RA offers numerous benefits including reduced intraoperative blood loss, arterial and venous thrombosis, pulmonary embolism, perioperative cardiac ischemic incidents, renal failure, hypoxic episodes in the postanesthetic care unit, postoperative morbidity and mortality, and decreased incidence of cognitive dysfunction. In spine surgery, RA is associated with lower pain scores, postoperative nausea and vomiting, positioning injuries, shorter anesthesia time, and higher patient satisfaction. Currently, RA is mostly used in short lumbar spine surgeries. However, recent findings illustrate the possibility of applying RA in spinal tumors and spinal fusion. Various researches reveal that SA is an effective alternative to GA with lower minor complications incidence. Comprehensive insight on RA will promote spine surgery under RA, thereby broadening the horizon of spine surgery under RA.

Keywords: Regional anesthesia, Spinal anesthesia, Epidural anesthesia, Lumbar spine

Even though RA is widely accepted in other fields, the use of RA during elective lumbar surgery failed to gain wide acceptance.^{1-5,16} GA is the preferred and most commonly used anesthesia technique for lumbar spine surgery such as microdiscectomy or lumbar decompression.^{1,7,17-20} This may be due to greater acceptance by patients, the ability to easily extend the duration of an operation using GA, and/or anesthesiologist preference for GA because of a more secure airway establishment during the prone position.^{5,21} Also to consider RA, it is important to assess the nature and duration of surgery, patient comorbidities, the ease of spinal insertion (i.e., positioning and spinal pathology), and the relative benefits and risks to the individual.

Nonetheless, RA has been reported to be a safe and effective as GA for lumbar spine surgery of short duration.^{1-5,7,15,22-26} Considering the wide usage of RA in other surgical fields, RA can have many applications in lumbar spine surgery.

This paper is an overview of various features of RA. Our knowledge of RA for spine surgery is largely based on very limited data. The aim of the study was to introduce spine surgeons unfamiliar with RA and to promote lumbar spine surgery under RA. We will discuss RA from a spine surgeon's point of view, rather than giving specifics about the anesthesia itself.

WHAT IS REGIONAL ANESTHESIA?

RA, also called neuraxial anesthesia, can be used while you are awake or in combination with sedation or GA. SA (via single-shot injection) and EA (via epidural catheter) are the most commonly used RA methods. SA is also called a spinal block, subarachnoid block, intradural block, and intrathecal block. It is a form of neuraxial RA involving the injection of a local anesthetic and/or opioid into the subarachnoid space. The local anesthetic and/or opioid injected into the cerebrospinal fluid (CSF) provides anesthesia, analgesia, and motor and sensory blockade. Otherwise, EA injects analgesics and local anesthetics through a catheter placed into the epidural space. The injection can result in a loss of sensation including pain by blocking the transmission of signals through nerve fibers in or near the spinal cord. EA can be used both during and after surgery for pain management.

DIFFERENCES BETWEEN EPIDURAL ANESTHESIA AND SPINAL ANESTHESIA

The similarities between SA and EA often confuse people that they are the same anesthetic techniques. Important differences are summarized in Table 1. Generally, EA requires a larger drug dose than SA. The onset of analgesia is slower with EA (>20 minutes) than SA (<5 minutes), which also causes a more gradual decrease in blood pressure. EA can be performed anywhere along the vertebral column including cervical, thoracic, lumbar, and sacral vertebrae. For EA, the epidural catheters are punctured at least 2 intervertebral levels above the surgical level (e.g., for the L5–S1 at the L3–4 intervertebral space).²⁷ Adequate anesthesia was considered usually at the T6–10 for spinal surgery. EA can perform an epidural block postoperatively through an already inserted epidural catheter. SA is mostly performed below the second lumbar vertebral body to avoid piercing the

Table 1. Differences between epidural anesthesia and spinal anesthesia

Features	Epidural anesthesia (EA)	Spinal anesthesia (SA)
Drug dose	Larger dose than SA	Smaller dose than EA
Onset of anesthesia	Approximately 25–30 minutes	Approximately 5 minutes
Spine level that can be performed	Anywhere along the vertebral column	Lumbar only (mostly below the L2 vertebral body)
Quality of anesthesia	Not as good as SA	High
Intraoperative redosing	Possible, can be continued postoperatively via a catheter	Generally, a single-shot injection
Duration of block	Adjustable, prolonged	Brief, usually 2–4 hours

spinal cord and consequently damaging the spinal cord. SA wears off in a cephalad to caudad direction, thus sacral levels will last longer than thoracic. The anesthetic effect of SA after a single-shot injection usually lasts about 2–4 hours.

There is also a method of combined SA and EA (CSE).²⁸ It is a method that pursues the reliability of SA and the flexibility of EA simultaneously. The dose of local anesthetics for SA can be reduced so that the spinal level of sensory block is lowered, and adverse effects can be reduced. The advantage of CSE is the ability to use a low dose of intrathecal local anesthetic, with the preparation that the epidural catheter may be used to extend the block if necessary. This allows surgeons not to be chased during anesthesia, helping surgeons to focus on the operation itself.

CONTRAINDICATIONS TO REGIONAL ANESTHESIA

There are few contraindications to RA and are summarized in Table 2.^{2,4,17,23,24,29,30} The most important absolute contraindication is patient refusal. Surgeons, as well as anesthesiologists, should be concerned about the patient's anxiety. Others include localized infection and allergy to drugs planned to be administered for the anesthesia. A patient's inability to stay still during needle puncture, which may lead to traumatic injury to the neural structures,³¹ as well as increased intracranial pressure, which may cause brainstem herniation,³² should be accounted as absolute contraindications to RA.

Patients with coagulopathy including taking antiplatelets/anticoagulants are relatively contraindicated due to the risk of an epidural hematoma. The history of previous lumbar spine sur-

Table 2. Contraindications to regional anesthesia

Absolute contraindications	Relative contraindications
Patient refusal	Infection
Localized sepsis	Coagulopathy
Allergy to drugs planned for administration	Previous spine surgery
Patient's inability to maintain stillness during needle puncture	Neurologic disease
	Myelopathy or peripheral neuropathy
	Severe or multilevel spinal stenosis
	Multiple sclerosis
	Spina Bifida
	Arachnoiditis
	Increased intracranial pressure
	Cardiac
	Aortic stenosis or fixed cardiac output states (preload dependent states)
	Uncorrected hypovolemia

gery also increases the risk of nerve damage due to anatomical changes and epidural adhesions. The spread of local anesthetics may be restricted by scar tissue. Undetermined neurological disease is a relative contraindication. Demyelinating diseases such as multiple sclerosis (MS) should be careful when considering RA due to their increased susceptibility to local anesthetic toxicity. However, there is no clear evidence that RA exacerbates the neurological symptoms of MS.³³ It is safe not to undergo RA if it deviates from the normal anatomical vertebral structure. Traditionally, RA has been considered contraindicated in patients with preload (volume) dependent states such as aortic stenosis due to the risk of acute decompensation in response to decreased systemic vascular resistance. The patients with hypovolemia may exhibit an exaggerated hypotensive response to the vasodilatory effects of RA which results in a sympathectomy 2–6 dermatomes above the sensory block.

Additionally, there are contraindications specific to spine surgery patients. Severe or multilevel spinal stenosis, near complete-total myelographic block, or myelographic demonstration of arachnoiditis is contraindicated.²⁴

ADVANTAGES OF REGIONAL ANESTHESIA

The pros and cons of RA are summarized in Table 3. Compared to GA, RA is associated with reduced intraoperative blood loss,^{12,13,34,35} reduced mortality, arterial and venous thrombosis, pulmonary embolism, perioperative cardiac ischemic incidents, renal failure, and hypoxic episodes in the postanesthetic care unit (PACU).^{9,10,36} Though there are conflicting results, RA is associated with lower postoperative morbidity and mortality com-

Table 3. Advantages and disadvantages of regional anesthesia compared to general anesthesia

Advantages	Disadvantages
Reduced blood loss	Patient acceptance
Reduced mortality	Airway securance
Reduced risk of thrombosis	Risk of anesthetic failure
Reduced myocardial infarction	Interference with IONM
Reduced renal failure	Neurologic complications
Reduced hypoxic episodes in PACU	Cauda equina syndrome
Lower pain score and PONV in PACU	Radiculopathy
	Myelopathy
Shorter anesthesia time	Risk of sympathetic block
Higher patient satisfaction	Severe bradycardia
Ability to self-position during surgery	Intraoperative hypotension

IONM, intraoperative neuromonitoring; PACU, postanesthetic care unit; PONV, postoperative nausea and vomiting.

pared with GA,^{10,37} and decreased incidence of cognitive dysfunction.¹¹

In the case of spine surgery, RA is associated with lower pain scores during PACU stay, shorter anesthesia time, and higher levels of patient satisfaction than GA after spinal surgery.¹ Multiple studies show RA is associated with decreased incidence of postoperative nausea and vomiting,^{3,21,23,38,39} due to its reduced systemic side effects and less cerebral-targeted drug action.³ RA offers the patient self-position in prone cases. This is likely to reduce the chance of positioning injuries, such as brachial plexus injury, complications related to head malposition, such as pressure necrosis of the face, blindness, and pressure sores.^{5,21,23} Further, SA is more time-efficient than GA. The use of SA for lumbar spine surgery showed 19 minutes of shorter anesthesia time compared to GA.⁷ By using continuous EA, the patient can manage postoperative pain via epidural analgesia, which provides better pain control and lower stress response.³⁹

DISADVANTAGES OF REGIONAL ANESTHESIA

There are concerns in using neuraxial anesthesia in patients with spinal pathology. There are decreased patient acceptance and a problem with securing the airway.^{5,21} There is a need for multiple attempts and risk of failure due to anatomical changes, either induced by previous interventions or pre-existing. It was reported that patients with spine pathology are prone to experience paresthesia during SA conduction.⁴⁰ It is challenging for the patient to maintain a prone position for a long duration while awake, so GA is preferred in procedures lasting more than 2

hours or with excessive blood loss.⁵ If an awake patient should move during the procedure, the nerve could be injured. Though these problems have never been reported, it is hard to denounce the possibility.^{3,13,23,38} Intraoperative neuromonitoring is obsolete with RA since it interferes with voltage-gated sodium channels in neural synapses, reducing neuro-axis transmission.⁴

Serious neurologic complications are rare, but RA has a risk of cauda equina syndrome and invariably results in permanent neurologic deficit.⁴¹ RA occasionally causes neurologic sequelae such as radiculopathy or myelopathy and in patients with severe spinal stenosis not undergoing lumbar surgery, SA has been associated with an increased risk of new neurologic deficit.⁴²

RA can cause blockade of thoracic sympathetic fibers originating at T1–5, leading to the development of severe bradycardia or intraoperative hypotension.⁴³ The upper sensory level should be at T10 or higher to provide adequate anesthesia. However, high levels of motor block are poorly tolerated in the prone position due to lack of abdominal muscle strength and the inability to breathe deeply against increased abdominal pressure.⁵ Due to these reasons, surgery higher than T10 is not recommended under neuraxial anesthesia.

CURRENT UTILIZATION OF REGIONAL ANESTHESIA IN SPINAL SURGERY

A recent meta-analysis on this matter analyzed previous randomized studies.³ RA is mostly used in lumbar spine surgery, especially in microdiscectomy and lumbar decompression. As described above, neuraxial anesthesia in spine surgery is limited to T10, due to strenuous breathing and the possibility of thoracic sympathetic blockade, which can lead to severe bradycardia or intraoperative hypotension.^{5,43} Also, the use of RA illustrating lumbar fusion was very limited in literature. However, more recent evidence proposes the possibility of applying RA in other spinal surgeries. In their preliminary paper, Ogrenski et al.⁴⁴ focused on the possibility of using SA in spinal tumor surgery in elderly patients. Tumorectomy and fusion of the spinal columns were performed in the patient group. Cheng and Chen⁴⁵ illustrated the use of RA in thoracic spinal stenosis patients. Percutaneous endoscopic thoracic decompression was performed under local anesthesia in patients with lower thoracic lesions. However, they did not specify the anesthetic methods. Several studies, including a randomized controlled trial, used regional anesthesia to perform minimally invasive transforaminal interbody fusion and showed a positive outcome.^{46–48} More recent evidence shows RA can be used in revision surgery for lumbar

pseudoarthrosis in a patient with a high risk for GA.⁴⁹

DISCUSSION

The use of RA for lumbar spine surgery has been strongly debated. Yet RA is a safe and efficacious technique for lumbar spine surgery.^{13,21,50} The literature regarding spinal anesthesia used for lumbar decompression is largely supportive, suggesting spinal anesthetic is at least comparable with general anesthesia in terms of safety and efficacy and that it may be superior to general anesthesia in some ways.^{7,21} A retrospective review investigated the outcomes of elective lumbar spine surgery under SA to GA.³⁸ The study demonstrated SA is an effective alternative to GA and had lower minor complications incidence.

Compared to GA, RA showed favorable hemodynamic status, reduced blood loss, and postoperative analgesic requirements in randomized controlled trials (RCTs).^{13,24,27,35} Studies show reduced blood loss in patients undergoing spine surgery with RA.^{12,13,24,27,34,35} This is most likely due to a combination of sympathetic blockade, producing vasodilation and hypotension, coupled with lower intra-thoracic pressure generated by spontaneous breathing by patients.²¹ In the case of an intraoperative laceration of the dura (with consecutive loss of CSF), no alteration of the SA effect happens. The receptors are blocked just after the injection, so a loss of CSF does not reduce the SA effect.

Previous researcher³⁸ found deep venous thrombosis was significantly more common in patients who had undergone GA than RA. Reduced thrombo-embolic complications have also been reported in spine surgery patients receiving RA. This is probably related to either faster mobility and/or modulation of the hypercoagulable state that occurs and persists after major surgery, and the preventive effect of RA in postoperative inhibition of fibrinolysis.^{38,51}

In terms of mortality, Guay et al.³⁷ reported a systematic review comparing GA and RA, illustrating a lower mortality rate by approximately 2.5% in surgery with an intermediate-to-high cardiac risk, and the risk of perioperative pneumonia. In an overview of randomized trials, mortality was reduced by a third in patients under RA.⁹

There are conflicting results on lower postoperative pain score.^{13,17,24,27,30,50} However, recent RCT showed a strong association with lower pain scores during PACU stay, lower postoperative nausea and vomiting, and high levels of patient and surgeon satisfaction after RA.^{1,2,24}

On the other hand, RA is believed to increase the risk of sym-

pathetic block causing severe bradycardia or intraoperative hypotension, or risk of causing cauda equina syndrome or other neurologic complications such as radiculopathy and myelopathy.^{41,42} The lumbosacral roots are vulnerable to direct exposure to large doses of anesthetics and neurotoxic properties of local anesthetics may lead to irreversible neuron damage if less diluted within the CSF.⁵² There is a widespread acceptance of GA in spine patients and anesthesiologists prefer GA since a secure airway can be achieved in prone position.^{5,21}

1. Suitable Patients and Surgeries

Factors favoring the use of RA over GA are relatively limited in current literature. In general, RA is considered feasible in patients undergoing surgeries with a duration of less than 2 hours and with less predicted blood loss.⁵³ Currently, RA is most widely used and deemed acceptable in decompressive lumbar surgeries. RA is a better alternative for patients with risk for GA-related complications. Currently, patients with medical comorbidities with an American Society of Anesthesiologists (ASA) physical status classification grade of III or IV are not considered eligible for spinal surgery under GA. It has been shown that when major medical comorbidities are present, performing spinal surgery under RA is a safe and effective alternative to GA.⁵⁴

2. Future Application of Regional Anesthesia

Despite some drawbacks, the results point to the likelihood that RA can be widely used in elderly patients. The average life expectancy is increasing with the development of medical technology and the number of geriatric populations who require surgical treatment is increasing accordingly. Due to a lack of physiologic reserve, elderly patients are exposed to higher anesthetic risk. Nevertheless, as physical activity contributes to multiple aspects of the quality of life, more surgical treatment can be required for elderly patients to pursue active physical activity. Therefore, an anesthetic method with low anesthetic risk is enticing to the geriatric population.

A recent study evaluated the risks of GA in patients 66 or older undergoing spinal surgery. Deyo et al.⁵⁵ reported a 3.1% (984 out of 32,152 patients) of major medical complications, including cardiorespiratory arrest, acute myocardial infarction, respiratory failure, pulmonary embolism, pneumonia, and stroke. Similarly, another investigator⁴ reported major complications of 3.5% (2 out of 56 patients) in patients 70 or older undergoing spinal surgery with RA. Older patients are more susceptible to hypoxemic episodes during recovery. Patients who undergo RA are associated with a lower risk for hypoxemia than GA.³⁶

Many surgeons wonder about using RA in a procedure lasting more than 2 hours,⁵ but a recent study demonstrated surgical time exceeding 3 hours in 5 of their cases, illustrating the possibility of longer periods of surgery than previously thought.⁴ A more recent article suggested that it is feasible to use SA in lumbar spinal tumors in elderly patients with the ASA physical status classification grade III or IV scores who are at high risk of GA.⁴⁴ These studies substantiate the possibility of widening the spectrum of using RA in lumbar spine surgery.

A decline in cognition in elderly patients is associated with postoperative delirium.⁵⁶ In a randomized controlled study, reduced depth of anesthesia decreased the incidence of postoperative delirium.¹¹ It is possible to reduce cognitive decline in elderly patients by decreasing the incidence of postoperative delirium using RA instead of GA.

However, there are extra precautions regarding RA in elderly patients. Advanced age is associated with increased block height. In elderly patients, CSF volume decreases, and specific gravity increases. CSF volume is an important factor contributing to the spread of SA and is negatively correlated.¹⁸ Nerve roots are more sensitive to local anesthetics in the geriatric population.

There have been numerous attempts to apply RA in various fields of spinal surgery, especially in minimally invasive surgeries.^{46,47,49} Researchers showed a possibility of using RA including, but not limited to, a revision spinal fusion,⁴⁹ robotic minimally invasive fusion,⁴⁷ and spinal tumors.⁴⁴ Also, a randomized controlled study depicted the successful use of continuous EA in lumbar endoscopic surgery, which can be used without time limit, unlike other methods of RA, and as a postoperative epidural analgesia.⁴⁶ In terms of outcome, a recent large-scale study using a national registry showed the type of anesthesia does not affect the outcomes of lumbar decompressions or lumbar fusion.⁵⁷

In the institution of the senior authors, SA is used as a standard procedure in elective, noninstrumented lumbar spine surgery. Previous spine surgeries as well as antiplatelet therapy are not regarded as a contraindication. A retrospective evaluation of 473 cases showed that per case 19 minutes of anesthesia time could be saved using SA without increasing the risk of complications.⁷

CONCLUSION

In short, the neuraxis anesthesia technique for lumbar spine surgery is gaining acceptance and is a viable option, especially in the geriatric population. It offers advantages over GA but

some concerns must be taken into consideration. Nevertheless, concerns can be avoided with caution and mostly theoretical. When deciding which anesthetic method to use, the surgeon must consider the benefits and the risks. The surgeon should bear in mind that the general outcome of spinal surgery using RA has no significant difference with optimal selection of patient and surgery. Hence optimal planning between the surgeon and the patient is crucial. Although not all patients and procedures are adequate to use RA, there is no concrete evidence to be hesitant about using RA. Further work should concentrate on enhancing the quality of RA use by reducing anticipated complications and broadening the spectrum of its clinical use.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Original Article

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Clinical and Radiological Clues of Traumatic Craniocervical Junction Injuries Requiring Occipitocervical Fusion to Early Diagnosis

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Objective: The purpose of this study is to find the clinical and radiographic characteristics of traumatic craniocervical junction (CCJ) injuries requiring occipitocervical fusion (OC fusion) for early diagnosis and surgical intervention.

Methods: We retrospectively reviewed 12 patients with CCJ injuries presenting to St. Michael's Hospital in Toronto who underwent OC fusion and looked into the following variables; (1) initial trauma data on emergency room arrival, (2) associated injuries, (3) imaging characteristics of computed tomography (CT) scan and magnetic resonance imaging (MRI), (4) surgical procedures, surgical complications, and neurological outcome.

Results: All patients were treated as acute spinal injuries and underwent OC fusion on an emergency basis. Patients consisted of 10 males and 2 females with an average age of 47 years (range, 18–82 years). All patients sustained high-energy injuries. Three patients out of 6 patients with normal BAI (basion-axial interval) and BDI (basion-dens interval) values showed visible CCJ injuries on CT scans. However, the remaining 3 patients had no clear evidence of occipitoatlantal instability on CT scans. MRI clearly described several findings indicating occipitoatlantal instability. The 8 patients with normal values of ADI (atlanto-dens interval interval) demonstrated atlantoaxial instability on CT scan, however, all MRI more clearly and reliably demonstrated C1/2 facet injury and/or cruciate ligament injury.

Conclusion: We advocate measures to help recognize CCJ injury at an early stage in the present study. Occipitoatlantal instability needs to be carefully investigated on MRI in addition to CT scan with special attention to facet joint and ligament integrity.

Keywords: Craniocervical junction injuries, Occipitocervical fusion, Ligament injury, High-energy injuries, Magnetic resonance imaging



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INTRODUCTION

Although advances in universal spine precautions and spine stabilization techniques have increased the number of patients surviving acute traumatic instability at the craniocervical junction (CCJ), a delay in diagnosis and mismanagement in the

Emergency Department (ED) can have potentially devastating consequences.¹ Unfortunately, an accurate diagnosis is frequently not established at the time of initial evaluation because altered level of consciousness of patients due to the presence of head injury and multiple other life-threatening injuries could complicate the process of diagnosis.² Furthermore, difficulty

and inexperience in radiological analysis of CCJ anatomical relationships is another possible cause for misdiagnosis.² Therefore, clarification of specific characteristics of trauma and imaging clues suggestive of CCJ injuries is extremely important to raise awareness for this pathology. The advent of magnetic resonance imaging (MRI) revolutionized the assessment of traumatic CCJ injuries by providing unique and accurate information about the integrity of the CCJ ligaments, based on which surgical indication could be determined.³

The purpose of this study is to find the clinical and radiographic characteristics of traumatic CCJ injuries requiring occipitocervical fusion (OC fusion) for early diagnosis and surgical intervention.

MATERIALS AND METHODS

1. Data Collection

We conducted a retrospective study of traumatic CCJ injury cases who required OC fusion at St. Michael's Hospital in Toronto, from 2013 to 2018. All of these cases were preoperatively diagnosed with occipitotlantal instability on computed tomography (CT) scan and MRI with radiological findings as follows; fracture dislocation and/or disruption of ligaments in the occipitotlantal segment. Traumatic CCJ injuries requiring only C1–2 fusion were excluded. Following institutional review board approval, 12 consecutive cases were identified. All medical records and spinal imaging studies were retrospectively reviewed to identify the following variables: (1) initial trauma data on ED arrival, (2) associated injuries, (3) imaging characteristics of CT scan and MRI, (4) surgical procedures, surgical complications, and neurological outcome. Based on these data, key points leading to early identification of surgical candidates and surgical outcomes are investigated.

2. Initial Patient Management

On arrival at St. Michael's Hospital, patients were evaluated according to standard Advanced Trauma Life Support protocol.⁴ A cross-table lateral conventional radiograph of the spine was obtained as part of the initial trauma evaluation. Head and cervical CT scans (occiput-T3) were routinely obtained in all patients because of the high-energy mechanism of their injuries. Some patients had been seen at outside hospitals for triage and were re-evaluated as acute trauma patients in the aforementioned manner after transfer to St. Michael's Hospital. Once traumatic CCJ injury was identified or suspected, patients were kept on spinal precautions and provisional stabilization secured by a

rigid cervical collar or halo vest. Cervical spine MRI was then performed to evaluate the presence of hematoma, ligamentous disruption, facet injury, intervertebral disc injury, and spinal cord injury (SCI).

3. Operative Technique

All cases underwent rigid OC fusion using occipital plates, rods, and screws as soon as the physiological general conditions of patients permitted and prepared for surgery. Surgical procedure was conducted in the operating room in the following sequence. We achieved a fiberoptic awake intubation in the supine position and checked the patient's neurological status to confirm no neurological deterioration was caused by the intubation. The patient was then placed in the spine position on a spinal surgery operating table (Jackson Table; OSI, Union City, CA). At this point, we performed closed reduction and adjustment of cervical alignment under fluoroscopic guidance with great care before the patient was rotated 180°. Rigid titanium screws, rods, and plate devices (Stryker Spine, Allendale, NJ, USA) were used to fixate the affected segments with 3-dimensional navigation (Stryker Spine, Allendale, NJ, USA) or fluoroscopic guidance (Ziehm Vision FD vario 3D, Ziehm Imaging, Nuremberg, Germany). Arthrodesis was undertaken by putting local bone from spinous processes of the affected levels on the decorticated laminae and facet joints.

4. Postoperative Clinical and Radiographic Assessment

Postoperative external immobilization was achieved with a cervical brace. Postoperative cervical CT scans and radiographs were obtained to assess spinal alignment and the adequacy of screws and plates locations. After discharge, radiographic and clinical follow-up data were obtained at the outpatient clinic. Upright flexion-extension lateral radiograph was evaluated for assessment of spinal alignment in all patients on a periodic basis.

RESULTS

1. Initial Trauma Assessment

Table 1 provides a summary of initial trauma assessment data acquired in emergency room. All patients were treated as acute spinal injuries and underwent OC fusion on an emergency basis. Patients consisted of 10 males and 2 females with an average age of 47 years (range, 18–82 years). In all cases, the patients sustained high-energy injuries, such as motor vehicle collision (MVC) with ejection (4 patients) or without ejection (3 patients), fall from height (3 patients), or assault (2 patients). Eight patients

exhibited transient or protracted loss of consciousness at the scene and reduced Glasgow coma scale (GCS) was noted in 7 cases on ED arrival including 3 cases of severely impaired consciousness (GCS 3 and 6).

2. Associated Injuries

Associated injuries were summarized in Table 2. Six cases

with closed head injury (CHI) were noted on head CT scan. While only 1 case underwent emergency craniotomy, 5 other cases with CHI were treated conservatively. Seven cases sustained scalp injury or facial fracture, or facial laceration. Subaxial cervical spine injuries were detected in 5 cases, while thoracic or lumbar spine injury was seen in only 1 case. Carotid or vertebral artery injuries were found in 3 cases (1 case had coex-

Table 1. Summary of initial trauma data

Variable	Value
Sex, male:female	9:3
Age (yr), mean (range)	47 (18–82)
Injury mechanism	
MVC	7
Fall down	3
Assault	2
Ejection from vehicle	
Yes	4
No	3
NA	5
GCS score, mean \pm SD	11.6 \pm 1.3
LOC	
Yes	8
No	4

MVC, motor vehicle collision; NA, not applied; GCS, Glasgow coma scale; SD, standard deviation; LOC, loss of consciousness.

Table 2. Summary of associated injuries

Variable	No. (%)
Closed head injury	6 (50)
Scalp or facial injuries	
Scalp injury	3 (25)
Facial injury or fracture	4 (33)
Subaxial C-spine injuries	
C2/3 jumped facet	1 (8)
C4 vertebral body fracture	1 (8)
C6 facet fracture	1 (8)
C7 facet fracture	1 (8)
C7 lamina fracture	1 (8)
T- or L-spine injuries	
T3 compression fracture	1 (8)
Vascular injuries	
Carotid artery injury	2 (17)
Vertebral artery injury	2 (17)

Table 3. Imaging characteristics of CT scan and MRI

Case No.	CT findings	BAI (mm)	BDI (mm)	ADI (mm)	MRI findings
1	C1 fracture, O/C1 and C1/2 dislocation	<u>18</u>	<u>15</u>	7	NA
2	C1 fracture, O/C1 and C1/2 dislocation	7	3	1	ALL injury, O/C1 and C1/2 facet injury, cruciate ligament injury
3	C1 and C2 fracture, O/C1 and C1/2 dislocation	10	3	1	Spinal cord injury, O/C1 and C1/2 facet injury
4	C2 fracture, C1/2 dislocation	10	8	1	O/C1 facet injury, cruciate ligament injury
5	C1 fracture, C1/2 dislocation	<u>14</u>	<u>12</u>	2	O/C1 and C1/2 facet injury, cruciate ligament injury
6	C2 fracture, C1/2 and C2/3 dislocation	7	8	1	ALL injury, O/C1 and C1/2 facet injury, cruciate ligament injury
7	C2 fracture, C1/2 dislocation	<u>19</u>	8	1	ALL injury, O/C1 and C1/2 facet injury cruciate ligament injury
8	C1 fracture, O/C1 and C1/2 dislocation	<u>19</u>	2	<u>4</u>	ALL injury, O/C1 facet injury cruciate ligament injury
9	C1 fracture, O/C1 and C1/2 dislocation	2	2	1	ALL injury, O/C1 and C1/2 facet injury cruciate ligament injury
10	C1 and C2 fracture, O/C1 and C1/2 dislocation	11	12	7	O/C1 and C1/2 facet injury cruciate ligament injury
11	Condyle fracture, O/C1 and C1/2 dislocation	11	12	1	O/C1 and C1/2 facet injury
12	C1 fracture, C1/2 dislocation	5	4	5	O/C1 and C1/2 facet injury cruciate ligament injury

Abnormal values of BAI, BDI, ADI are highlighted and underlined.

CT, computed tomography; MRI, magnetic resonance imaging; BAI, basion-axial interval; BDI, basion-dens interval; ADI, atlanto-dens interval; NA, not applied; ALL, anterior longitudinal ligament.

isting carotid and vertebral artery injuries). Antiplatelet therapy was initiated following the surgical procedure and maintained throughout the acute critical management in all cases.

3. Imaging Characteristics of CT Scan and MRI

The abnormal imaging findings that suggested the presence of traumatic CCJ injury are summarized in Table 3. Head and cervical spine CT scans (Occipital bone to T3) was obtained in all patients because of the high-energy mechanism of their injuries after patients were optimized hemodynamically. All but 1 case (case 1) underwent both of cervical spine CT scan and MRI. Case 1 was in a state of deep coma with unilateral blown pupil due to CHI (GCS 3) on arrival and emergency decompressive craniectomy and OC fusion was performed without obtaining MRI. Bony displacement and malalignment were measured and reported in all patients on CT scans. Overall, 6 patients (cases 1, 5, 7, 8, 10, 11) had values of basion-axial interval (BAI; normal < 12 mm) and/or basion-dens interval (BDI; normal < 10 mm) outside of normal limits and 4 patients (cases 1, 8, 10, 12) showed abnormal values of atlanto-dens interval (ADI; normal < 3 mm), respectively. Three patients (cases 2, 3, 9) out of 6 patients (cases 2, 3, 4, 6, 9, 12) with normal BAI and BDI values showed visible occipitoatlantal facet joint dislocation or diastasis based on CT scans. However, the remaining 3 patients (cases 4, 6, 12) had no clear evidence of occipitoatlantal instability on CT scans. MRI clearly described several findings indicating occipitoatlantal instability, such as anterior longitudinal ligament injury, cruciate

ligament injury, or occipitoatlantal facet injury. The 8 patients (cases 2, 3, 4, 5, 6, 7, 9, 11) with normal values of ADI demonstrated atlantoaxial malalignment and facet diastasis on CT scan and a diagnosis of atlantoaxial instability was established on CT scans. However, all MRI more clearly and reliably demonstrated C1/2 facet injury and/or cruciate ligament injury. No patient had an isolated occipitoatlantal dislocation without atlantoaxial instability.

4. Surgery, Surgery-Related Complications, and Neurological Outcome

There were no cases of occipitocervical and occipitothoracic pseudoarthrosis or hardware failure. A postoperative surgical site infection occurred in 1 patient (case 5), who was successfully treated with irrigation and debridement, revision of hardware, and antibiotic agents. One patient (case 7) was complicated by postoperative deep venous thrombosis, which was also successfully treated with anticoagulation therapy. Another patient (case 11) who developed hydrocephalus following CHI received ventriculoperitoneal shunt successfully. The mean follow-up duration was 12 months (range, 6–24 months). No patients experienced worsening of neurological symptoms postoperatively. Seven patients (58%) exhibited normal neurological functions (American Spinal Injury Association impairment scale [AIS] grade E) and 5 (42%) suffered incomplete SCI preoperatively. The severity of SCI was AIS grade C (3 patients) and AIS grade D (2 patients). All SCI patients (AIS grade C–D) made improvement by at least one AIS grade postoperatively (Tables 4, 5).

Table 4. Surgical procedures and surgical complications

Variable	No. (%)
Surgical levels (most caudal level)	
C2	1 (8)
C3	5 (42)
C4	5 (42)
T4	1 (8)
Other surgeries	
Craniotomy	1 (8)
Internal fixation of the midfoot	1 (8)
Fixation of craniofacial fracture	1 (8)
Tracheostomy	2 (17)
Ventriculoperitoneal shunt	1 (8)
Postoperative complications	
Surgical site infection	1 (8)
Deep venous thrombosis	1 (8)
Hydrocephalus	1 (8)

5. Illustrative Case (Case 5)

The patient was an 18-year-old man who was involved in an MVC. He was initially taken to an outside hospital and subsequently transferred to St. Michael's Hospital. There was no loss of consciousness. Head CT and CT angiography showed no ev-

Table 5. Neurological outcome

Preoperative AIS grade	Postoperative AIS grade				
	A	B	C	D	E
A	0	0	0	0	0
B	0	0	0	0	0
C	0	0	0	2	1
D	0	0	0	0	2
E	0	0	0	0	7

AIS, American Spinal Injury Association impairment scale.

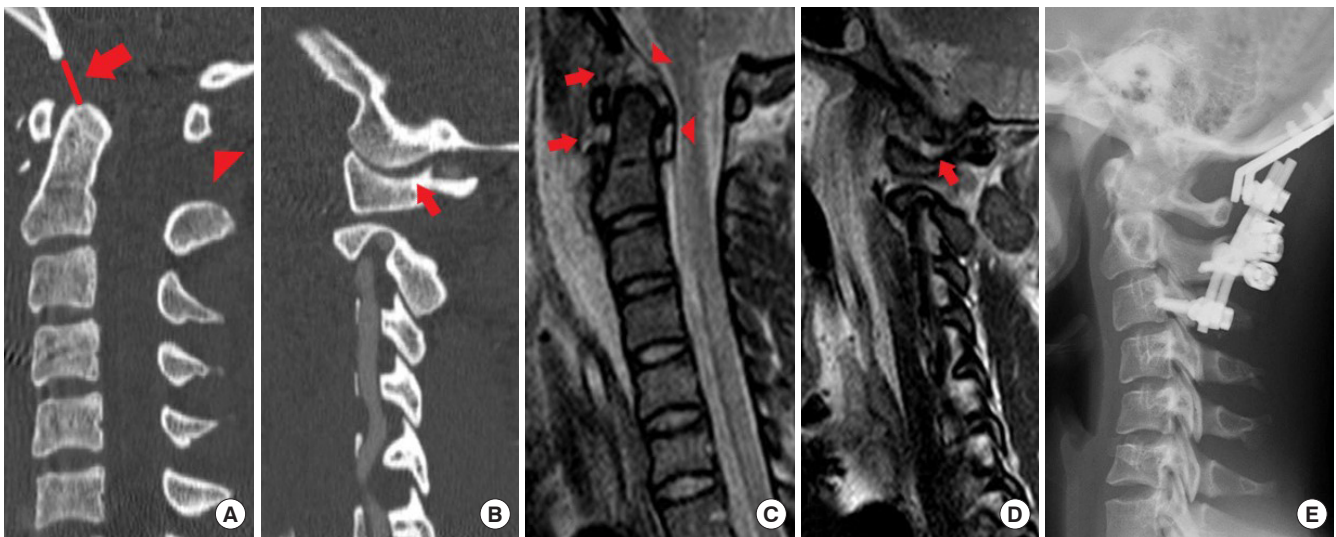


Fig. 1. (Case 5) Preoperative computed tomography scan (A, B), preoperative magnetic resonance imaging (C, D), postoperative x-ray (E). Avulsion fractures of anterior arch of atlas with widening of BDI (A; arrow), cephalad displacement of atlas (A; arrow-head), malalignment of the atlantooccipital joints with posterior widening of the O/C1 facet joints (B; arrow) and C1/2 facet joints. Severe injury of anterior longitudinal ligament and anterior atlantooccipital membrane (C; arrow), tectorial membrane and cruciate ligaments (C; arrowhead). There was apparent distraction of the O/C1 (D; arrow) and C1/2 facet joints with interfacet fluid signal. OC3 fusion was successfully performed (E).

idence of CHI or craniocervical vessel injury. He was found to have right lung pneumothorax and a nondisplaced mandible fracture, both of which were managed conservatively. He had avulsion fractures of anterior arch of C1 with widening of the BAI and BDI. There was posterior widening of the occipitoatlantal facet joints and atlantoaxial facet joints (Fig. 1A, B). Cervical spine MRI showed severe injury of ALL, the tectorial membrane, and cruciate ligament (Fig. 1C) with apparent distraction of the occipitoatlantal and atlantoaxial facet joints with interfacet fluid signal (Fig. 1D). Preoperative diagnosis was occipitoatlantal and atlantoaxial instability with C1 fracture. OC3 fusion was performed (Fig. 1E), however, he developed surgical site infection, which was successfully cured by wound reopening, irrigation, and debridement. He made significant recovery without any neurological symptoms at follow-up in the outpatient clinic.

DISCUSSION

The difficulties in prompt diagnosis of traumatic CCJ injury were highlighted and recognized over the past decade.^{1,5-11} As mortality rates are reportedly extremely low in patients who are correctly diagnosed with CCJ injury on initial trauma evaluation,¹²⁻¹⁴ we need to identify the characteristics of the trauma and imaging clues serving as warning signs for CCJ injury at

the initial trauma assessment. In the present study, all patients were involved in high-energy injuries mainly affecting head and face. Eight patients had transient or protracted loss of consciousness on arrival, indicating severe blow to the brain. Closed head injuries were present in 6 patients (50%) and impaired consciousness with reduced GCS was noticed in 6 cases (50%). Altered level of consciousness due to brain injury, hemodynamic instability, or alcoholic consumption as well as severe pain that distracts from traumatic CCJ injuries contributed to diagnostic difficulties. We also found high rate of scalp or facial injuries, which are suggestive of CCJ injury. Spinal cord deficits were identified in 5 patients on initial evaluation (42%) in the present study; which were AIS grade C or D deficits. Neurological symptoms caused by SCI could facilitate the identification of CCJ injury.

In recent years, the preference of initial imaging has shifted from x-ray to CT scans, since CCJ injuries are often overlooked in x-ray imaging.¹⁵ The analysis of the present study demonstrated generally accepted indexes (BAI, BDI, and ADI) on CT scans were not reliable enough and other CT scan findings such as facet diastasis and facet dislocation were particularly useful findings. Facet diastasis and facet dislocation are closely related to the damage of ligaments.^{15,16} Several important ligaments hold bony structures and facet joints in the CCJ, including the cruciate ligament, the paired alar ligaments, the tectorial mem-

brane, the apical ligament, and the anterior and posterior atlantooccipital membranes.¹⁷⁻¹⁹ Although these ligaments play pivotal roles for stabilization, traumatic CCJ injuries have historically been recognized as osseous fractures.^{20,21} Ligamentous injuries at the CCJ can cause bony dislocations and facet diastasis leading to severe and insidious instability without associated fractures. We encountered several cases with obvious bony dislocations and facet diastasis on CT scans, however, we should emphasize the existence of cases with the ligamentous injuries without clear evidence of osseous displacements on CT scans. Atlantoaxial instability could be made diagnosis solely by detailed analysis of CT scans based on facet dislocations and facet diastasis even with normal values of ADI though the diagnosis should be confirmed using MRI, which more clearly and reliably demonstrated atlantoaxial facet injury and/or cruciate ligament injury. On the other hand, several reports emphasized the existence of trauma patients of occipitoatlantal instability with normal or near-normal CT scans, which were narrowly diagnosed on MRI.^{22,23} It is extremely difficult to detect occipitoatlantal instability solely by CT scans in patients who demonstrate normal values of the BAI, BDI with no clear evidence of occipitoatlantal malalignment or diastasis of the occipitoatlantal facet. These clear differences in the process of diagnosis between occipitoatlantal and atlantoaxial instability may come from the differences of function and range of motion between these facet joints. Atlantoaxial facet joints are structurally more complicated and more mobile with wide range of axial rotation (48.53° on average) than occipitoatlantal facet joints with flexion-extension motion (18.7° on average).²⁴ Therefore, diastasis of the occipitoatlantal facet joints occurring after traumatic CCJ injury may be more likely to spontaneously reduce with normal joint heights even as the patient has significant occipitoatlantal instability. Therefore, CT measurements alone can overlook purely ligamentous injuries, and additional MRI analysis is essential particularly in occipitoatlantal instability. This is especially true of unconscious patients who cannot complain of any subjective symptoms and cannot take neurological assessment.^{25,26} The present study showed occipitoatlantal injury was accompanied by concomitant atlantoaxial injury even as isolated atlantoaxial injury is frequently observed.²⁰ This unique traumatic relationship was clearly verified by MRI assessment. In this context, the possible coexistence of occipitoaxial instability should be born in mind once atlantoaxial dislocation is suspected. MRI is currently an integral part of diagnostic process in CCJ injuries, however, Dyas et al.²⁷ indicated the disruption of alar ligaments, one of the main ligamentous stabilizers in CCJ, was dif-

ficult to be recognized on MRI. The whole ligamentous structure of CCJ needs to be evaluated because identification of individual ligament may be difficult. The ability of MRI to detect the integrity of the ligaments is not always perfect depending on the imaging quality of MRI,^{27,28} therefore comprehensive assessment of mechanism of injury, associated injury, neurological symptoms, and consciousness status is essential to accurately reach the diagnosis.

Rigid cervical orthosis or halo immobilization should be continued until the patient is prepared for surgical intervention. The most appropriate preoperative provisional stabilization has to be decided considering the timing of surgery, the degree of instability, and the patient's general condition, neurological status, and other spine injuries. Traumatic CCJ injury mainly comprises ligamentous disruption and could lead to significant neurological deterioration without surgical intervention.²⁹ Posterior OC fusion is the treatment of choice in most cases³⁰ and the development of plate, rod, and screw system has allowed us to attain successful outcomes without the need for postoperative halo immobilization^{31,32} with high bony fusion rate of more than 90%.³¹

In summary, as CCJ stability is largely dependent on ligamentous integrity,^{33,34} MRI has greater sensitivity for detecting CCJ instability by analysis of disc disruption, facet injuries, and ligament injuries than CT scans or x-ray alone¹ and the addition of MRI to CT scans can alter patient management.^{25,35-37} The classification system where MRI findings are fully integrated needs to be developed particularly for occipitoatlantal instability.

CONCLUSION

We advocate measures to help recognize CCJ injury at an early stage in the present study. Firstly, these measures have put emphasis on the identification of clinical clues (high-energy trauma, transient or protracted loss of consciousness, reduced consciousness level, CHI, scalp, or facial injury). Secondly, careful imaging assessment is necessary based on both CT scan and MRI. Occipitoatlantal instability is carefully investigated on MRI in addition to CT scan with special attention to facet joint and ligament integrity. OC fusion using occipital plate, rod, and screws in a timely manner brings great outcomes. We found that following these measures give great chances to functionally improve even patients with severe neurological symptoms. More cases with CCJ injury are needed to be accumulated to investigate and establish correct diagnostic criteria for CCJ instability.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Original Article

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INTRODUCTION

Cervical spondylotic myelopathy (CSM) is a degenerative disease that causes neurological deficits by spinal cord compression. To halt the dysfunctional progress and initiate neurological recovery, surgical treatment is frequently performed. Numerous studies have demonstrated the usefulness of unilateral open-door laminoplasty for CSM and have reported bene-

Surgical and Functional Outcomes of Expansive Open-Door Laminoplasty for Patients With Mild Kyphotic Cervical Alignment

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Objective: To evaluate the cervical dynamics, neurological function, pain, and quality of life in patients with mild cervical kyphotic alignment who underwent expansive unilateral open-door laminoplasty (ELAP).

Methods: In this retrospective single-center study, we reviewed the surgical outcomes of 80 patients with cervical spondylotic myelopathy who were followed for at least 2 years. The patients were categorized into the preoperative kyphotic group (C2–7 angle $< 0^\circ$) and non-kyphotic group (angle $\geq 0^\circ$). We compared clinical information, radiographic parameters, Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire (JOAC-MEQ) scores, and cervical Japanese Orthopaedic Association (JOA) scores between the groups.

Results: The kyphotic and nonkyphotic groups comprised 17 and 63 patients, respectively. The preoperative C2–7 angles were -3.7° in the kyphotic group and 15.4° in the nonkyphotic group ($p < 0.01$). In the kyphotic group, kyphotic alignment improved to lordosis at the final follow-up (2.6° , $p = 0.01$). The preoperative (16.4° vs. 24.1° , $p < 0.01$) and final follow-up (17.8° vs. 24.5° , $p < 0.01$) C7 slopes were significantly smaller in the kyphotic group. ELAP reduced pain in the arms or hands ($p = 0.02$) and improved the JOA scores ($p < 0.01$) in the kyphotic group. Patient-reported outcomes assessed using the JOACMEQ showed comparable effective rates in both groups.

Conclusion: Patients with mild cervical kyphosis showed smaller C7 slopes as a compensatory mechanism. Kyphotic angles significantly improved to lordosis after ELAP, resulting in favorable clinical outcomes. ELAP is a useful surgical option for patients even if they present mild kyphotic cervical angles.

Keywords: Cervical spondylotic myelopathy, Expansive unilateral open-door laminoplasty, Kyphotic cervical alignment

cial surgical outcomes.¹⁻³

Laminoplasty is a safe and less invasive technique that does not necessitate interspinal fixation surgery. The indication of laminoplasty for patients with CSM should be considered cautiously because preoperative malalignment could affect surgical results.^{1,4-9} Chiba et al.¹ reported that functional recovery was significantly negatively correlated with the degree of preoperative cervical kyphosis. Miyamoto et al.⁶ demonstrated that pos-

terior fixation surgery was more suitable for patients with $>5^\circ$ local kyphosis in view of the acquisition of postoperative lordotic alignment and neurologic improvement. Other studies reported poor neurological improvement after laminoplasty in patients whose C2–7 sagittal angles were $<0^\circ$.^{7,8} In contrast to these adverse effects of preoperative cervical kyphotic alignment, Uchida et al.⁹ evaluated the surgical outcomes of patients who had cervical local kyphosis of $>10^\circ$ preoperatively and underwent either laminoplasty or anterior spondylectomy. They reported comparable recovery of cervical Japanese Orthopaedic Association (JOA) scores in both groups after long-term follow-up despite the fact that cervical kyphosis was maintained in patients who underwent only laminoplasty. The results of these studies suggest that there is no consensus for the treatment of patients with CSM with baseline cervical kyphosis. Although the modified K-line is a useful and convenient method to decide surgical indication of posterior decompression surgery, previous studies targeted only double-door laminoplasty, and there is limited evidence of comprehensive clinical results in terms of cervical alignment changes and patient-reported functional outcomes postoperatively.^{10–12}

Therefore, it is quite meaningful from our therapeutic experience to present the surgical outcomes of patients who had preoperative cervical spinal kyphosis and underwent unilateral open-door laminoplasty. This study aimed to investigate the cervical dynamics, neurological function, pain, and quality of life (QoL) in these patients.

MATERIALS AND METHODS

1. Participants

This study included 80 patients with clinically and radiographically confirmed CSM who were treated using expansive unilateral open-door laminoplasty (ELAP)² at one institution between 2008 and 2014. Nine board-certified spinal surgeons performed the surgeries. Patients were included if they (1) presented with at least one clinical sign of myelopathy, (2) exhibited cervical spinal cord compression on magnetic resonance imaging (MRI) or computed tomography, and (3) had no history of cervical spine surgery. Patients were excluded if they were asymptomatic; were diagnosed with ossification of the posterior longitudinal ligament, active infection, neoplastic spinal disease, rheumatoid arthritis, or ankylosing spondylitis; or had been treated for osteoarthritis of the hip or knee with concomitant lumbar canal stenosis.

The patients were categorized into the preoperative cervical

kyphotic group (C2–7 angle $<0^\circ$) and nonkyphotic group (C2–7 angle $\geq 0^\circ$).

This study received ethical approval from the Institutional Review Board of Keio University School of Medicine (20110142). We certify that all applicable institutional regulations concerning the ethical use of human volunteers were followed during the course of this study.

2. Surgical Procedure

ELAP was performed as described previously.^{2,13,14} Briefly, the laminae were exposed through a midline incision, followed by the dissection of the bilateral paracervical muscles. A gutter was created using a drill at the junction of the lamina and facet joint, and the ventral cortex of the lamina was perforated. Another gutter was created in the opposite side as a hinge, and the laminar door was lifted and fixed in the expanded position using sutures or plates (Centerpiece Plate Fixation System; Medtronic Sofamor Danek, Memphis, TN, USA). The patients began walking without a brace the day after surgery.

3. Data Collection

We retrospectively collected the demographic information, medical history, and imaging data of the patients and evaluated their functional status preoperatively and at the final follow-up (at least 2 years postoperatively) using the cervical JOA scores and JOA Cervical Myelopathy Evaluation Questionnaire (JOA-CMEQ). We did not set a limit for the maximum follow-up duration. Pain, stiffness, and numbness were assessed using the visual analogue scale (VAS) included in the JOACMEQ. Surgery-related events within 30 days postoperatively were defined as perioperative complications. The JOACMEQ defines effective treatment as (1) a posttreatment score of ≥ 20 points above the pretreatment score or (2) a pretreatment score of <90 and a posttreatment score of ≥ 90 .¹⁵ Patients with both pretreatment and posttreatment scores of ≥ 90 were counted but excluded from further analysis. A group's effective rate was calculated as follows: [(number of patients judged "effective") / [(total number of patients in the group) – (number of patients with pre- and posttreatment scores of ≥ 90)]. The postoperative recovery rate (JOA recovery rate), described by Hirabayashi et al.¹⁴ was calculated as follows: recovery rate (%) = (postoperative JOA score – preoperative JOA score) \times 100 / (17 – preoperative JOA score).

4. Imaging

Cervical alignment was assessed by measuring the intermittent C2–7 angles, which were determined by tangential lines on

the posterior edge of the target vertebral bodies, on plain radiographs in the neutral position. We calculated the cervical range of motion (ROM) by subtracting the flexion from the extension C2–7 angles. The C7 slope was measured as the angle between the superior endplate of C7 and a horizontal line. The C7 slope was used as a substitute for the T1 slope.^{16,17} The C2–7 sagittal vertical axis (SVA) was defined as the distance between the C2 plumb line and posterior superior corner of the C7 vertebral body.

5. Statistical Analysis

Continuous variables and frequencies were presented as mean \pm standard deviation, and the unpaired *t*-test was performed to compare these parameters between the groups. Categorical variables were shown as percentages and were compared using the chi-square test. Changes between the preoperative and final JOA scores, VAS scores, and imaging findings were assessed using paired *t*-tests. All statistical analyses were performed using IBM SPSS Statistics ver. 26.0 (IBM Co., Armonk, NY, USA). A *p*-value of <0.05 was considered significant.

RESULTS

1. Demographic Characteristics

Table 1 shows the demographic characteristics of patients who underwent ELAP at our institution. Seventeen patients exhibited preoperative cervical kyphosis (kyphotic group), and 63 pa-

tients exhibited preoperative cervical lordotic alignment (non-kyphotic group). The average age was younger in the kyphotic group (59.5 ± 13.4 years vs. 65.8 ± 11.3 years), although it was not statistically significant ($p=0.053$). There were more men in the kyphotic group (82.4%) than in the nonkyphotic group (71.4%) ($p=0.54$). Body mass index and duration of initial symptoms were not significantly different between the groups. The average follow-up periods were 3.1 ± 0.8 years and 2.8 ± 0.5 years in the kyphotic and nonkyphotic groups, respectively ($p=0.11$). Regarding comorbidities, there were no significant differences in the prevalence of hypertension ($p=0.32$), diabetes mellitus ($p=0.32$), cardiac disease ($p=0.38$), cerebrovascular disease ($p=0.80$), and psychiatric disease ($p=0.80$). No patient had renal, respiratory, or rheumatologic diseases.

2. Surgical Characteristics

Surgical information is presented in Table 2. The average operative duration was 83.4 ± 26.5 minutes in the kyphotic group and 80.1 ± 28.3 minutes in the nonkyphotic group ($p=0.67$). The average numbers of operated laminae were also comparable between the groups (4.7 ± 0.9 vs. 4.6 ± 0.9 ; $p=0.71$). One (5.4%) and 12 patients (19.0%) in the kyphotic and nonkyphotic groups, respectively, underwent laminoplasty with plates ($p=0.28$). For C2 decompression, only laminotomy (not laminoplasty) was performed to drill a caudal portion of the lamina. Only 1 patient (5.4%) in the kyphotic group and 2 (3.2%) in the nonkyphotic group underwent this procedure. At the C3 level, 13 (76.5%) and

Table 1. Demographic characteristics of patients with kyphotic and nonkyphotic cervical alignment

Characteristic	Kyphotic group (n = 17)	Nonkyphotic group (n = 63)	p-value
Age (yr)	59.5 ± 13.4 (32–76)	65.8 ± 11.3 (39–86)	0.05
Sex (% male)	82.4	71.4	0.54
Body mass index (kg/m ²)	24.5 ± 4.6 (18.8–33.5)	24.1 ± 3.6 (17.8–34.2)	0.71
Duration of symptoms (mo)	61.0 ± 88.1 (1–360)	36.6 ± 45.4 (1–240)	0.29
Follow-up period (yr)	3.1 ± 0.8 (2.0–5.0)	2.8 ± 0.5 (2.0–5.0)	0.11
Comorbidities (%)			
Hypertension	23.5	36.5	0.32
Diabetes mellitus	5.9	14.3	0.32
Cardiac disease	5.9	1.6	0.38
Renal disease	0	0	-
Cerebrovascular disease	0	1.6	0.80
Respiratory disease	0	0	-
Rheumatologic disease	0	0	-
Psychiatric disease	0	1.6	0.80

Values are presented as mean \pm standard deviation (range) unless otherwise indicated.

Table 2. Surgical characteristics and perioperative information

Characteristic	Kyphotic group (n = 17)	Nonkyphotic group (n = 63)	p-value
Operative duration (min)	83.4 ± 26.5 (43–137)	80.1 ± 28.3 (32–209)	0.67
Number of operated laminae	4.7 ± 0.9 (3–6)	4.6 ± 0.9 (2–6)	0.71
Use of laminar plates (%)	5.8	19.0	0.28
Duration of hospital stay (days)	15.9 ± 7.4 (9–42)	14.5 ± 3.7 (9–28)	0.29
Perioperative complications (%)			
C5 palsy	0	3.2	0.62
Surgical site infection	5.9	0	0.21
Epidural hematoma	5.9	3.2	0.52
Dural tear	0	1.6	0.79

Values are presented as mean ± standard deviation (range) unless otherwise indicated.

Table 3. Imaging characteristics

Characteristic	Kyphotic group (n = 17)	Nonkyphotic group (n = 63)	p-value
C2–7 angle (neutral)			
Preoperation (°)	-3.7 ± 3.0 (-11.0 to -0.1)	15.4 ± 8.0 (1.2–38.9)	< 0.01
Final follow-up (°)	2.6 ± 10.2 (-15.0 to 22.8)	13.8 ± 9.9 (-4.1 to 37.8)	< 0.01
C2–7 angle (flexion)			
Preoperation (°)	-22.2 ± 10.2 (-43.0 to -1.0)	-9.4 ± 9.8 (-27.3 to 17.9)	< 0.01
Final follow-up (°)	-14.9 ± 9.1 (-30.0 to -2.4)	-2.4 ± 10.4 (-39.1 to 25.1)	< 0.01
C2–7 angle (extension)			
Preoperation (°)	12.5 ± 11.3 (-9.0 to 30.5)	27.1 ± 7.6 (11.6–47.0)	< 0.01
Final follow-up (°)	12.0 ± 11.3 (-6.6 to 31.6)	23.1 ± 10.0 (-0.4 to 44.3)	< 0.01
Cervical range of motion			
Preoperation (°)	34.2 ± 12.8 (14.5–58.2)	36.6 ± 10.6 (11.3–61.3)	0.45
Final follow-up (°)	26.9 ± 10.3 (9.3–47.1)	25.5 ± 8.8 (3.9–44.3)	0.59
C7 slope			
Preoperation (°)	16.4 ± 5.3 (7.7–25.5)	24.1 ± 7.5 (8.6–44.5)	< 0.01
Final follow-up (°)	17.8 ± 6.5 (6.8–25.6)	24.5 ± 8.1 (8.8–53.8)	< 0.01
Intermediate C2–7 sagittal vertical axis			
Preoperation (mm)	26.5 ± 11.8 (7.0–56.3)	22.3 ± 14.1 (-7.5 to 57.5)	0.27
Final follow-up (mm)	22.3 ± 15.0 (-5.8 to 46.4)	25.2 ± 14.8 (-8.3 to 70.0)	0.47

Values are presented as mean ± standard deviation (range) unless otherwise indicated.

52 patients (82.5%) in the kyphotic and nonkyphotic groups, respectively, underwent decompression. In the kyphotic group, 3 of 13 patients underwent laminoplasty, whereas the other 10 patients underwent total laminectomy. In the nonkyphotic group, laminoplasty was performed for 7 of 52 patients, and the other 45 patients underwent laminectomy. For C7 laminae, 12 (70.6%) and 45 patients (71.4%) in the kyphotic and nonkyphotic groups, respectively, underwent surgical decompression. In the kyphotic group, 2 of 12 patients underwent laminoplasty, whereas the other 10 patients underwent laminotomy to decompress a ros-

tral portion of the lamina. In the nonkyphotic group, laminoplasty was performed for only 3 of 45 patients, and the other 42 patients underwent laminotomy.

The length of hospital stay was 15.9 ± 7.4 days in the kyphotic group and 14.5 ± 3.7 days in the nonkyphotic group (p = 0.29). In terms of perioperative complications, the occurrence rates of C5 palsy (p = 0.62), surgical site infection (p = 0.21), epidural hematoma (p = 0.52), and dural tear (p = 0.79) did not show significant differences.

3. Imaging Characteristics

The preoperative intermediate C2–7 angles were $-3.7^\circ \pm 3.0^\circ$ (range, -11.0° to -0.1°) in the kyphotic group and $15.4^\circ \pm 8.0^\circ$ (range, 1.2° – 38.9°) in the nonkyphotic group ($p < 0.01$) (Table 3). This difference was maintained postoperatively at the final follow-up in the kyphotic ($2.6^\circ \pm 10.2^\circ$) and nonkyphotic ($13.8^\circ \pm 9.9^\circ$) groups ($p < 0.01$). With regard to temporal changes in cervical alignment, the kyphotic group presented significant improvement to lordotic alignment at the final follow-up ($p = 0.01$), whereas the nonkyphotic group maintained comparable alignment pre- and postoperatively ($p = 0.16$). The preoperative cervical ROM was $34.2^\circ \pm 12.8^\circ$ in the kyphotic group and $36.6^\circ \pm 10.6^\circ$ in the nonkyphotic group ($p = 0.45$) and changed to $26.9^\circ \pm 10.3^\circ$ and $25.5^\circ \pm 8.8^\circ$, respectively, at the final follow-up ($p = 0.59$). On evaluating ROM temporally, the angle reduced postoperatively in the nonkyphotic ($p < 0.01$) and kyphotic ($p = 0.054$) groups. The C7 slope was significantly smaller in the kyphotic group preoperatively ($16.4^\circ \pm 5.3^\circ$ vs. $24.1^\circ \pm 7.5^\circ$, $p < 0.01$) and at the final follow-up ($17.8^\circ \pm 6.5^\circ$ vs. $24.5^\circ \pm 8.1^\circ$, $p < 0.01$). The preoperative intermediate C2–7 SVAs were 26.5 ± 11.8 mm and 22.3 ± 14.1 mm in the kyphotic and nonkyphotic groups, respectively ($p = 0.27$). The SVA at the final follow-up was similar between the groups (22.3 ± 15.0 mm vs. 25.2 ± 14.8 mm, $p = 0.47$). Temporal changes in the C7 slope and C2–7 SVA did not show significant differences in both groups. The breakdown of each neutral C2–7 alignment in the kyphotic group is shown in Table 4.

4. Surgical Outcomes

The cervical JOA scores, which were used to evaluate neurologic function, were 11.4 ± 3.1 in the kyphotic group and 11.6 ± 2.7 in the nonkyphotic group ($p = 0.82$) (Table 5). Equivalent improvement of neurologic function was observed in both groups at the final follow-up (13.8 ± 2.5 vs. 14.0 ± 2.5 , $p = 0.84$). Each group showed significant functional recovery when comparing the baseline and final JOA scores temporally ($p < 0.01$). The recovery rates of the JOA scores were also similar between the groups (46.7% vs. 46.4%, $p = 0.97$). Linear multiple regression analysis was performed to evaluate the JOA scores at the final follow-up after adjusting for variables, and there was no statistically significant difference between the groups.

Among the 9 attending surgeons, 6 (group A) performed surgeries for patients in both the kyphotic and nonkyphotic groups, and the other 3 (group B) performed surgeries for only patients in the nonkyphotic group. We compared the clinical results between group A ($n = 46$) and group B ($n = 17$) in the nonkyphotic

Table 4. C2–7 angles (neutral) and cervical JOA scores at preoperation and final follow-up in each patient with kyphotic cervical alignment

Patient No.	Neutral C2–7 angles ($^\circ$)		JOA scores	
	Preoperation	Final follow-up	Preoperation	Final follow-up
1	-11.0	-15.0	11	14.5
2	-7.4	7.6	14	15
3	-6.9	-8.5	13.5	15.5
4	-5.9	-13.9	13	14
5	-5.9	-0.8	8.5	12
6	-5.6	5.7	16	17
7	-3.9	2.0	9	16
8	-3	7.7	13	17
9	-2.8	2.3	13	15
10	-2.5	22.8	15	15.5
11	-2.5	18.0	13	16
12	-2.3	7.8	7.5	10
13	-1.6	7.5	9	9
14	-1.3	8.5	11	11
15	-0.5	-7.8	10	14
16	-0.1	3.7	13	13.5
17	-0.1	-4.0	4	10

JOA, Japanese Orthopaedic Association.

group, which revealed no significant differences in JOA scores at preoperation (11.6 ± 2.7 vs. 11.4 ± 2.9 , $p = 0.76$) and final follow-up (13.9 ± 2.4 vs. 14.1 ± 2.6 , $p = 0.85$).

On comparing the surgical outcomes between patients whose cervical alignment progressed to more kyphosis ($n = 5$; patients 1, 3, 4, 15, 17) and improved to lordosis ($n = 12$; all other patients) in the kyphotic group (Table 4), the preoperative C2–7 angles were $-4.9^\circ \pm 4.6^\circ$ and $-3.2^\circ \pm 2.1^\circ$, respectively ($p = 0.48$). The preoperative cervical JOA scores were 10.3 ± 3.8 and 11.8 ± 2.8 ($p = 0.36$), respectively, and this difference was comparable at the final follow-up (13.6 ± 2.1 vs. 13.9 ± 2.8 , $p = 0.82$).

The following 4 aspects were evaluated using VAS: pain or stiffness in the neck or shoulders, tightness in the chest, pain or numbness in the arms or hands, and pain or numbness from the chest to toe.¹⁵ The results were comparable for all aspects between the groups both pre- and postoperatively (Table 5). In the kyphotic group, the VAS scores for pain or numbness in the arms or hands significantly reduced postoperatively (58.8 ± 33.0 mm to 39.4 ± 31.5 mm, $p = 0.02$). In the nonkyphotic group, the VAS scores significantly reduced for pain or numbness in the

Table 5. Clinical outcomes

Variable	Kyphotic group (n = 17)	Nonkyphotic group (n = 63)	p-value
Cervical JOA score			
Preoperation	11.4 ± 3.1 (4.0–16.0)	11.6 ± 2.7 (4.5–16.5)	0.82
Final follow-up	13.8 ± 2.5 (9.0–17.0)	14.0 ± 2.5 (8.0–17.0)	0.84
Recovery rate (%)	46.7 (0–100)	46.4 (0–100)	0.97
VAS score for neck or shoulder			
Preoperation (mm)	44.7 ± 36.3 (0–100)	45.8 ± 28.9 (0–100)	0.90
Final follow-up (mm)	34.1 ± 33.7 (0–100)	37.5 ± 30.8 (0–100)	0.70
VAS score for chest			
Preoperation (mm)	3.5 ± 10.0 (0–40)	10.2 ± 22.3 (0–80)	0.08
Final follow-up (mm)	9.4 ± 18.9 (0–70)	9.0 ± 20.8 (0–100)	0.95
VAS score for arms or hands			
Preoperation (mm)	58.8 ± 33.0 (0–100)	61.0 ± 31.4 (0–100)	0.81
Final follow-up (mm)	39.4 ± 31.5 (0–100)	39.7 ± 32.3 (0–100)	0.98
VAS score from chest to toe			
Preoperation (mm)	38.2 ± 30.1 (0–100)	39.8 ± 33.5 (0–100)	0.86
Final follow-up (mm)	27.6 ± 33.6 (0–100)	31.7 ± 35.2 (0–100)	0.67
Effective rate for the JOACMEQ (%)			
Cervical spine	36.4	58.5	0.16
Upper extremity	30.8	43.2	0.42
Lower extremity	46.2	34.7	0.33
Bladder	16.7	20.0	0.58
QoL	18.8	31.7	0.24

JOA, Japanese Orthopaedic Association; VAS, visual analogue scale; JOACMEQ, Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire; QoL, quality of life.

arms or hands (61.0 ± 31.4 mm to 39.7 ± 32.3 mm, $p < 0.01$) and from the chest to toe (39.8 ± 33.5 mm to 31.7 ± 35.2 mm; $p = 0.02$). Other scales did not show statistically significant changes.

The JOACMEQ results revealed effective rates of 36.4% (4 of 11) and 58.5% (31 of 53) for cervical spine function, 30.8% (4 of 13) and 43.2% (19 of 44) for upper extremity function, 46.2% (6 of 13) and 34.7% (17 of 49) for lower extremity function, 16.7% (2 of 12) and 20.0% (10 of 50) for bladder function, and 18.8% (3 of 16) and 31.7% (20 of 63) for QoL in the kyphotic and nonkyphotic groups, respectively (Table 5). None of the rates differed significantly between the groups. Binomial logistic regression analysis was performed to evaluate the effective rates after adjusting for variables, and there was no significant difference between the groups.

5. Case Presentation

1) Patient 2

A 37-year-old man who was diagnosed with CSM was re-

ferred to our institution for surgical treatment. He complained of hand clumsiness and gait impairment, and his cervical JOA score was 14. In radiographic findings, the C2–7 angle was -7.4° , and the C7 slope was 16.2° (Fig. 1A). T2-weighted MRI revealed multiple cervical canal stenosis from C3 to C7 and intramedullary high signal intensity at the C6/7 spinal level (Fig. 1B). Because dynamic canal stenosis was identified at the C4/5 and C5/6 levels, he underwent ELAP from the C3 to C7 laminae. His symptoms improved postoperatively, and at 5 years postoperatively, his JOA score recovered to 15, C2–7 angle was 7.6° , and C7 slope was 17.1° (Fig. 1C). MRI showed expanded cervical canal space and maintenance of favorable decompression (Fig. 1D).

2) Patient 10

A 66-year-old man complained of bilateral hand clumsiness and numbness of the upper extremities. His cervical JOA score was 15. Radiographic findings showed a C2–7 angle of -2.5° and

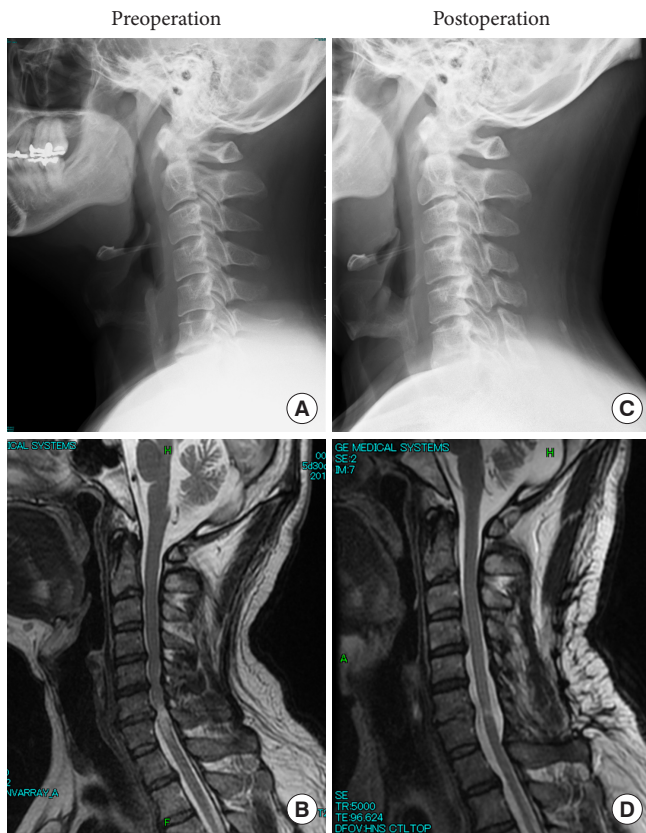


Fig. 1. Case presentation of a 37-year-old man. (A) The preoperative C2–7 angle was -7.4° in an x-ray image. (B) Sagittal T2-weighted magnetic resonance imaging revealed cervical canal stenosis at multiple intervertebral levels. (C) After laminoplasty, the C2–7 angles improved to a lordotic angle of 7.6° . (D) Appropriate spinal cord decompression was observed postoperatively.

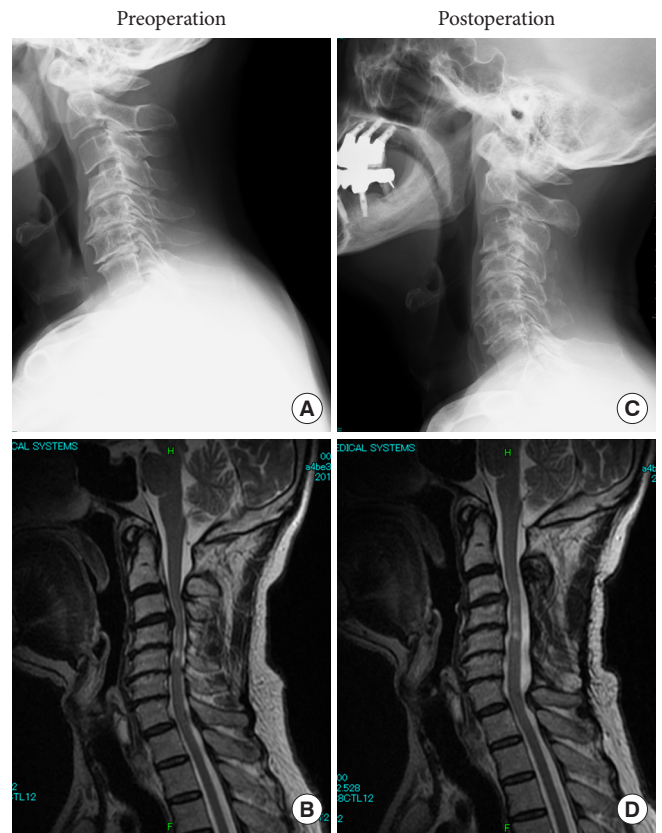


Fig. 2. Case presentation of a 66-year-old man. (A) The preoperative C2–7 angle was -2.5° in an x-ray image. (B) Sagittal T2-weighted magnetic resonance imaging revealed cervical canal stenosis at multiple intervertebral levels with intramedullary high signal intensity. (C) After laminoplasty, the C2–7 angles improved to a lordotic angle of 22.8° . (D) Appropriate spinal cord decompression was observed postoperatively.

C7 slope of 22.6° (Fig. 2A). T2-weighted MRI revealed multiple canal stenosis with intramedullary high signal intensity (Fig. 2B). He underwent ELAP from the C3 to C7 laminae. His postoperative course was uneventful. At 5 years postoperatively, his JOA score recovered to 15.5, C2–7 angle was 22.8° , and C7 slope was 25.1° (Fig. 2C). MRI revealed decompression of the cervical spinal cord (Fig. 2D).

DISCUSSION

In this study, ELAP was performed for patients with CSM with kyphotic cervical alignments, which were $\leq -11^\circ$ in C2–7 angles. This kyphotic angle was sustained by compensatory lower angle of the C7 slope compared with that in patients with preoperative C2–7 lordotic alignment (Table 3). However, even in patients with cervical kyphosis, the alignment significantly im-

proved to lordotic angle postoperatively. Regarding clinical outcomes, perioperative complications equivalently developed in the kyphotic and nonkyphotic groups (Table 2). The surgical treatment reduced pain in the arms or hands and recovered the neurologic status, which was evaluated using JOA scores (Table 5). The patient-reported outcomes assessed using the JOAC-MEQ also revealed comparable effective rates of cervical spine, extremity, and bladder functions and QoL in both groups. These results indicate that ELAP is a useful surgical option for patients even if they present mild kyphotic cervical angles.

Several studies have reported the progression of kyphotic angles after laminoplasty.⁵⁻⁷ Although we targeted patients with only mild kyphotic angles, our findings indicate that patients with cervical spinal kyphosis had the potential to attain lordotic angles postoperatively. In corroboration, Kim et al.¹⁸ reported that the subpopulation of patients who had kyphotic cervical

alignment did not show development of kyphosis even after laminoplasty. These patients had radiographically reducible lordotic alignment before surgery at the extension view of the cervical spine. In our patients with preoperative cervical kyphosis, the average baseline C2–7 angles at extension was 12.5° (Table 3), which was within the acceptable range as reducible lordotic alignment. Therefore, patients with mild cervical kyphosis in our study were deemed to have favorable radiographical and functional outcomes after ELAP. Thus, if surgical treatment is necessary for patients with cervical spinal kyphosis, the evaluation of alignment at extension could be an important indicator to decide the actual operative technique.

In the present study, the C7 slope was significantly smaller in patients with preoperative cervical kyphosis than in patients with lordotic alignment (Table 3). Although Ames et al. used the T1 slope as a substitute parameter of the C7 slope, they reported that lower T1 slope was significantly correlated with smaller C2–7 lordosis.¹⁹ In their study, they demonstrated that cervical alignment showed adaptive characteristics and changes relative to the other thoracic and lumbar spinal segments to maintain the head over the pelvis and horizontal gaze. Therefore, we believe that kyphotic cervical curvature in our study was not the cause but rather the result of a smaller C7 slope by a compensatory mechanism of spinal dynamics. With regard to postoperative cervical alignment, Kim et al.²⁰ reported that patients with larger preoperative T1 slopes presented more kyphotic alignment changes after cervical laminoplasty. In contrast, C7 slopes in patients with cervical kyphosis in the present study were comparable before and after surgery within the ranges of lower angles (Table 3), and these results led to the prevention of kyphotic changes. However, because the C7 slope gradually increases with age,¹⁷ cervical kyphosis may progress in the future after surgical intervention. Therefore, careful attention should be paid regarding changes in cervical alignment with longer follow-up periods.

Based on our results, we did not conclude the limitation of the indication for ELAP in patients with kyphotic cervical alignment due to the lack of patients who had hyperkyphosis. Generally, the current therapeutic strategy for cervical deformity is spinal fixation surgery²¹; therefore, we avoided ELAP for patients with excessive kyphotic angles of the cervical spine preoperatively. Several studies have reported that kyphotic angles of > 5°–10° increase the risk of malalignment progression and functional deterioration if laminoplasty is performed.^{4,6–8} The average kyphotic angle in our subjects was 3.7° in the kyphotic group, and this small angle resulted in the prevention of wors-

ening kyphotic deformity postoperatively. Further evidence is needed to achieve a consensus regarding the indication of surgical techniques with and without spinal fixation for cervical kyphosis.

Several limitations were noted in this study. First, this was a retrospective study, which inevitably has a low evidence level. Second, we did not analyze global spinal alignment, which could affect cervical dynamics after laminoplasty.²² Third, differences in postoperative medication and rehabilitation, which were left to the surgeon's discretion, could have affected the clinical outcomes. Finally, the results should be carefully interpreted because this study was performed using a single surgical technique and assessment questionnaire at a single institution.

CONCLUSION

We evaluated the cervical spinal dynamics and functional outcomes of patients with mild kyphotic cervical alignment who underwent ELAP. The average preoperative C2–7 angle in the kyphotic group was -3.7°, and these patients presented favorable surgical outcomes regarding neurologic function, pain, and QoL, with a reduction in the cervical alignment to lordotic angle. However, this beneficial result was achieved in patients who had cervical alignment within -10° and were followed up for only a few years. Further studies are necessary to evaluate the efficacy of ELAP for more kyphotic alignment with a longer observational period.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Editorial



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See the article “Surgical and Functional Outcomes of Expansive Open-Door Laminoplasty for Patients With Mild Kyphotic Cervical Alignment” via <https://doi.org/10.14245/ns.2142792.396>.



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Commentary on “Surgical and Functional Outcomes of Expansive Open-Door Laminoplasty for Patients With Mild Kyphotic Cervical Alignment”

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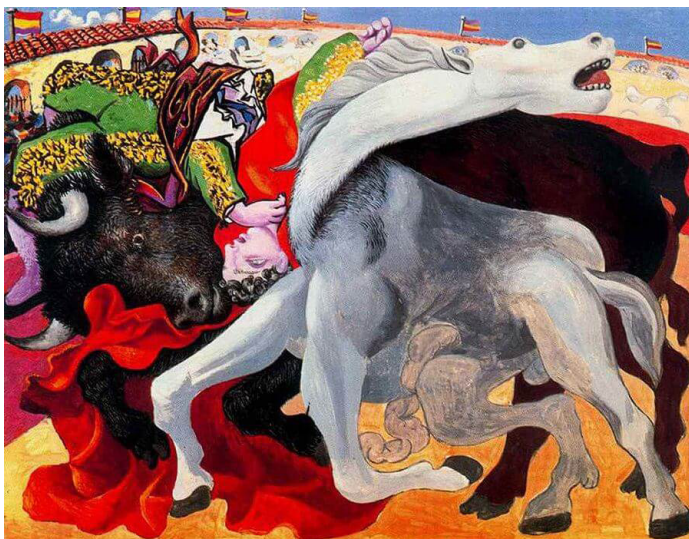
I read the article titled “Surgical and functional outcomes of expansive open-door laminoplasty for patients with mild kyphotic cervical alignment”¹ with interest that raised questions about the preoperative kyphotic alignment, which is a contraindication to laminoplasty. In the World Federation of Neurosurgical Society (WFNS) recommendation, preoperative straight or lordotic alignment is the candidate for laminoplasty, and anterior cervical discectomy and fusion (ACDF) or laminectomy and posterior fusion are recommended for kyphotic alignment for cervical spondylotic myelopathy (CSM).²⁻⁶ However, ACDF and posterior fusion are expected to have high complications in elderly patients with poor bone quality.^{7,8} Clinically, there was a demand to expand laminoplasty to broader indications, such as mild kyphotic alignment. I read impressively the results of over 14 years of laminoplasty from the author's institution. They reported no significant differences in the final average recovery rates among those with different preoperative alignments in the CSM group, but patients with preoperative kyphosis in the OPLL (ossification of the posterior longitudinal ligament) group had much lower recovery rates than those with lordotic and straight alignments although statistical significance was not detected due to the small sample size.⁹ However, in this study, the authors could find the efficacy of laminoplasty on mild kyphotic alignment in more cases. Recently, many dynamic concepts, not static concepts, have been presented in laminoplasty studies.^{10,11} Now, we need to develop an extended indication that can be safely applied laminoplasty to more patients, rather than simply limiting mild kyphotic alignment as a contraindication. Dr Nagoshi and colleagues¹ well explained the tendency of mild kyphosis patients to change to a lordotic curve after laminoplasty and relatively good clinical results. These results may provide more options for the treatment of elderly osteoporotic and mild kyphosis patients. Lastly, as in the author's conclusion, I fully agree with the phrase “laminoplasty is not all possible in mild kyphotic alignment patients.” We still need to pay attention to the severe postoperative kyphotic alignment that occurs after laminoplasty and make efforts to find an appropriate indication.

CONFLICT OF INTEREST

The author has nothing to disclose.

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Title: Bullfight: Death of the Toreador
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Year: 1933
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Original Article

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Five-Repetition Sit-to-Stand Test Performance in Healthy Individuals: Reference Values and Predictors From 2 Prospective Cohorts

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Objective: The 5-repetition-sit-to-stand (5R-STs) test is an objective test of functional impairment- commonly used in various diseases, including lumbar degenerative disc diseases. It is used to measure the severity of disease and to monitor recovery. We aimed to evaluate reference values for the test, as well as factors predicting 5R-STs performance in healthy adults.

Methods: Healthy adults (> 18 years of age) were recruited, and their 5R-STs time was measured. Their age, sex, weight, height, body mass index (BMI), smoking status, education level, work situation and EuroQOL-5D Healthy & Anxiety category were recorded. Linear regression analysis was employed to identify predictors of 5R-STs performance.

Results: We included 172 individuals with mean age of 39.4 ± 14.1 years and mean BMI of 24.0 ± 4.0 kg/m². Females constituted 57%. Average 5R-STs time was 6.21 ± 1.92 seconds, with an upper limit of normal of 12.39 seconds. In a multivariable model, age (regression coefficient [RC], 0.07; 95% confidence interval [CI], 0.05/0.09; $p < 0.001$), male sex (RC, -0.87; 95% CI, -1.50 to -0.23; $p = 0.008$), BMI (RC, 0.40; 95% CI, 0.10-0.71; $p = 0.010$), height (RC, 0.13; 95% CI, 0.04-0.22; $p = 0.006$), and houseworker status (RC, -1.62; 95% CI, -2.93 to -0.32; $p = 0.016$) were significantly associated with 5R-STs time. Anxiety and depression did not influence performance significantly (RC, 0.82; 95% CI, -0.14 to 1.77; $p = 0.097$).

Conclusion: The presented reference values can be applied as normative data for 5R-STs in healthy adults, and are necessary to judge what constitutes abnormal performance. We identified several significant factors associated with 5R-STs performance that may be used to calculate individualized expected test times.

Clinical Trial Registration: ClinicalTrials.gov Identifier: NCT03303300 and NCT03321357

Keywords: Sit-to-stand, Objective test, Degenerative disc disease, Lumbar stenosis, Lumbar disc herniation, Functional impairment



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INTRODUCTION

The sit-to-stand (STS) action is very common and performed by individuals of all ages up to 60 times a day or more.¹ This movement is an important determinant of physical function

and independence.² In 1985, Csuka and McCarty³ were among the first to introduce the 5-repetition-sit-to-stand test (5R-STs) as a way of measuring lower leg strength. It involves measuring how quickly an individual will repeat the sitting-to-standing action 5 times.³⁻⁵ Since then, it has been applied to patients with

a range of medical conditions, including lumbar degenerative spine disease, stroke, chronic obstructive pulmonary disease (COPD), Parkinson disease, rheumatoid arthritis, postkidney transplant, and posttotal knee replacement to not only objectively assess functional impairment, but also to monitor recovery and progress.⁴⁻¹² It is also used in the pediatric setting.¹³ Objective functional tests can eliminate subjectivity that is at times captured in questionnaires, and account for symptoms such as foot drop missed by common Patient-Reported Outcome Measures.¹⁴ The popularity of tests for objective functional impairment (OFI) has increased rapidly during the past years.¹⁵ Other OFI tests include the Timed Up and Go (TUG) test and the 6-minute walk test (6MWT).¹⁵

To assess what should be considered as a pathological performance in any test for OFI, normative reference values from a healthy population need to be established. Only few data are available on normative values for the 5R-STS in healthy individuals, only focusing on elderly individuals.¹⁶ In addition, it is important to understand which factors govern test performance. For example, if body height significantly influences test performance because of a standardized chair height that may benefit shorter individuals, this effect needs to be considered. In addition, knowledge of these predictive factors allows generation of individualized expected test statistics for patients with e.g., degenerative disease of the lumbar spine. Lower extremity muscle strength and sense of balance are the mostly commonly studied predictive factors, although only few studies analyzed variables such as age, sex, or height as determinants of the 5R-STS test time.^{7,17-22} Additionally, the majority of 5R-STS studies concentrate on patients with specific diseases or elderly patients, creating a gap in understanding the younger adult population. In addition, sociodemographic factors such as work status, education level, and anxiety and depression are frequently not considered.²³ We aimed to evaluate reference values for the test, as well as factors predicting 5R-STS performance in healthy adults.

MATERIALS AND METHODS

1. Study Design

In 2 prospective studies, carried out between October and December of 2017 and between December 2017 and June 2018, healthy volunteers were seen at a Dutch specialized short-stay outpatient spine surgery clinic. The prospective studies (ClinicalTrials.gov Identifier: NCT03303300 and NCT03321357) were approved by the local Institutional Review Board (Medical Research Ethics Committees United, Registration Number: W17.107

and W17.134) and were conducted according to the Declaration of Helsinki. Informed consent was obtained from all participants.

2. Study Population

Healthy individuals aged > 18 years were recruited and were either volunteers or employees of the department. Most volunteers were partners of patients scheduled for surgery, and thus demonstrated comparable sociodemographic features. Some volunteers were also acquaintances and relatives of authors. Participants disclosing spinal conditions, hip- or knee replacements, other lower extremity-related complaints, or that required walking aides were excluded.

3. Testing Protocol

The 5R-STS test was performed as previously described.^{4,5,8,12,15,24-26} Participants were asked to sit down on an armless chair of standard height (48 cm) with a hard seat, firmly placed against a wall. The participants were instructed to fold their arms across their chest, and to keep their feet flat on the ground. Participants were required to wear stable shoes for this test. To become familiar with the maneuver, participants were asked to stand up fully and sit back down again once without using their upper limbs. If assistance was required, or if the maneuver could not be completed, the test was abandoned. Otherwise, the patients were asked to stand up fully and sit down again, landing on the seat firmly, 5 times as fast as possible, starting on the command “go.” Using a stopwatch, the 5 repetitions were timed from the initial command to the completed fifth stand. This time was recorded as the participant’s score. If the patient was unable to perform the test in 30 seconds, or not at all, this was captured, and the test score was recorded as 30 seconds. Volunteers and patients were also asked to complete questionnaires containing baseline sociodemographic data: age, sex, body mass index (BMI), height, weight, smoking status, education level, work situation, and EuroQOL-5D (EQ-5D) questionnaire – containing the EQ-Anxiety and Depression category, which has been demonstrated to correlate adequately with anxiety and depression.²⁷ Participants filled in the questionnaires right after initially performing the test.

4. Statistical Analysis

Continuous variables are reported as mean ± standard deviation, and categorical variables as numbers and percentages. The 2 cohorts were pooled. The upper limit of normal (ULN) was arrived at by calculating the 99th percentile of this normative

population.^{5,28} Missing data, which was presumed to be missing at random, was imputed using 5-nearest neighbor imputation.²⁹ To identify univariable predictors of 5R-STS performance in healthy individuals, linear regression models were fitted for each of the baseline variables. Subsequently, a multivariable linear regression model was fitted to identify factors independently associated with 5R-STS performance. The primary analysis was based on the purposeful variable selection procedure described by Bursac et al.³⁰ In more detail, variables were considered for primary inclusion at univariable $p \leq 0.25$. Subsequently, an initial multivariable model was built, and variables that did not have a significant effect (defined as $p \leq 0.1$) or that did not demonstrate confounding (defined using a change-in-estimate criterion of 20% or greater) were iteratively removed from the model. Finally, any variable not eligible for the initial multivariable model was added iteratively, and the model was subsequently reduced in the same way as described above by iterative removal of only those variables that were additionally added.²⁹ Spearman rank correlation was applied to describe the correlation among continuous variables and 5R-STS performance. All analyses were carried out using R version 3.6.2 (The R Foundation for Statistical Computing, Vienna Austria).³¹ A 2-tailed $p \leq 0.05$ was considered significant. The statistical code is provided (Supplementary Content 1).

RESULTS

1. Cohort

The cohort consisted of 172 healthy adult participants (Table 1) with a mean age of 39.4 ± 14.1 years. The ratio of females to males was 57:43. A mean BMI of 24.0 ± 4.0 kg/m² was observed. Only 13.4% were active smokers. In terms of work situation, 35.5% of participants were students, 39.5% of participants were employed, and 13% were retired, among others. A vast majority (94.2%) of the cohort scored 1 in EQ-5D Anxiety & Depression, indicating no signs of anxiety or depression, while the rest scored at 2 indicating mild anxiety or depression.²⁷ Fifteen indi-

viduals (8.7%) had missing data on anxiety and depression.

2. Reference Values

A detailed account of normative reference values for healthy adults is provided in Table 2, including stratifications for male

Table 1. Basic demographic data for healthy adult participants

Characteristic	All participants (n = 172)	Female (n = 98)	Male (n = 74)
Age (yr)	39.4 ± 14.1	63.3 ± 18.5	41.7 ± 19.5
Sex			
Female	98 (57.0)	-	-
Male	74 (43.0)	-	-
BMI (kg/m ²)	24.0 ± 4.0	23.3 ± 4.5	25.0 ± 3.0
Height (cm)	171.0 ± 10.0	164.9 ± 6.6	179.2 ± 7.7
Weight (kg)	70.5 ± 14.1	63.3 ± 11.7	80.0 ± 11.1
Smoking status			
Active smoker	23 (13.4)	10 (10.2)	13 (17.6)
Ceased smoking	37 (21.5)	19 (19.4)	18 (24.3)
Never smoked	112 (65.1)	69 (70.4)	43 (58.1)
Education level			
Elementary	6 (3.4)	2 (20.0)	4 (50.4)
High-school	59 (34.3)	34 (34.7)	25 (33.8)
Higher	103 (60.0)	59 (60.2)	44 (59.5)
Postdoctoral	4 (2.3)	3 (30.1)	1 (1.3)
Work situation			
Employed	68 (39.5)	37 (37.8)	31 (41.9)
Self-employed	13 (7.6)	3 (3.1)	10 (13.5)
Retired	22 (12.8)	11 (11.2)	11 (14.9)
Houseworker	5 (2.9)	5 (5.1)	0 (0.0)
Unemployed	3 (1.7)	1 (1.0)	2 (2.7)
Student	61 (35.5)	41 (41.8)	20 (27.0)
EQ5D Anxiety & Depression			
1	162 (94.2)	90 (91.8)	72 (97.3)
2	10 (5.8)	8 (8.2)	2 (2.7)

Values are presented as mean ± standard deviation and number (%). BMI, body mass index.

Table 2. Reference values for the 5R-STS test time (second) in healthy individuals

Age (yr)	Male		Female		Overall	
	Mean ± SD	ULN	Mean ± SD	ULN	Mean ± SD	ULN
≤ 60	5.98 ± 1.54	8.7	5.60 ± 1.43	9.31	5.76 ± 1.50	9.11
> 60	8.23 ± 2.26	11.85	9.00 ± 1.98	13.36	8.63 ± 2.12	13.36
Overall	6.38 ± 1.88	11.10	6.09 ± 1.95	13.36	6.21 ± 1.92	12.39

Mean ± standard deviation (SD) and ULN (upper limits of normal) are provided for each subpopulation. 5R-STS, 5-repetition sit-to-stand test.

and female individuals, for those aged under and over 60 years, as well as for combinations of these factors. In the overall population, the average 5R-STS test time was 6.21 ± 1.92 seconds, with an ULN of 12.39 seconds.

We have additionally provided normative reference values for healthy adults further stratified by age groups ≤ 60 years of age (Supplementary Table 1).

3. Factors Associated With 5R-STS Performance

Results of the univariable analysis are demonstrated in Table 3. In the multivariable model (Table 4) including confounders,

Table 3. Univariable linear regression analysis of predictive factors for the 5R-STS in healthy adult individuals

Variable	Univariate analysis		
	RC	95% CI	p-value
Age	0.06	0.05 to 0.08	< 0.001*
Sex			
Male	0.29	-0.29 to 0.87	0.335
Female		Reference	
BMI (kg/m ²)	0.21	0.14 to 0.27	< 0.001*
Height (cm)	0.02	-0.01 to 0.04	0.265
Weight (kg)	0.05	0.03–0.07	< 0.001*
Smoking status			
Active smoker	-0.20	-1.06 to 0.67	0.653
Ceased smoking	0.07	-0.64 to 0.79	0.838
Never smoked		Reference	
Education level			
Elementary	3.03	-8.08 to 2.86	< 0.001*
High-school	-0.37	-0.58 to 2.94	0.224
Higher		Reference	
Postdoctoral	0.56	-4.49 to 4.13	0.553
Work situation			
Employed		Reference	
Self-employed	0.72	-0.28 to 1.72	0.158
Retired	2.30	1.49–3.10	< 0.001*
Houseworker	-0.15	-1.68 to 1.37	0.846
Unemployed	-0.17	-2.11 to 1.77	0.862
Student	-0.81	-1.39 to -0.23	0.007
EQ-5D Anxiety & Depression			
1		Reference	
2	2.04	0.85–3.23	< 0.001*

5R-STS, 5-repetition sit-to-stand test; RC, regression coefficient; CI, confidence interval; BMI, body mass index; EQ-5D, EuroQOL-5D.

higher age (regression coefficient [RC], 0.07; 95% confidence interval [CI], 0.05/0.09; $p < 0.001$) (Fig. 1), higher BMI (RC, 0.40; 95% CI, 0.10–0.71; $p = 0.010$), and greater height (RC, 0.13; 95% CI, 0.04–0.22; $p = 0.006$) were significantly associated with a higher 5R-STS test time, and thus with worse performance. In contrast, male sex (RC, -0.87; 95% CI, -1.50 to -0.23; $p = 0.008$) (Fig. 2) and houseworker status (RC, -1.62; 95% CI, -2.93 to -0.32; $p = 0.016$) were associated with lower 5R-STS test time, and thus with greater performance. Body weight and education level were included in the model as confounding variables – as was anxiety and depression, which did not influence 5R-STS performance significantly (RC, 0.82; 95% CI, -0.14 to 1.77; $p = 0.097$). The *post hoc* power analysis demonstrated a power of $1 - \beta$ approaching 1.

Table 4. Multivariable linear regression analysis of predictive factors for the 5R-STS in healthy adult individuals

Variable	Multivariate analysis		
	RC	95% CI	p-value
Age	0.07	0.05–0.09	< 0.001*
Sex			
Male	-0.87	-1.50 to -0.23	0.008*
Female		Reference	
BMI (kg/m ²)	0.40	0.10–0.71	0.010*
Height (cm)	0.13	0.04–0.22	0.006*
Weight (kg)	-0.10	-0.21 to 0.01	0.088
Education level			
Elementary	1.07	-0.12 to 2.26	0.081
High-school	-0.02	-0.48 to 0.43	0.918
Higher		Reference	
Postdoctoral	-0.03	-1.39 to 1.34	0.971
Work situation			
Employed		Reference	
Self-employed	0.02	-0.83 to 0.87	0.967
Retired	-0.17	-1.15 to 0.80	0.731
Houseworker	-1.62	-2.93 to -0.32	0.016*
Unemployed	-0.21	-1.83 to 1.41	0.802
Student	0.71	0.11–1.31	0.022*
EQ-5D Anxiety & Depression			
1		Reference	
2	0.82	-0.14 to 1.77	0.097

Variables for inclusion in this final model were selected according to the purposeful variable selection algorithm.

5R-STS, 5-repetition sit-to-stand test; RC, regression coefficient; CI, confidence interval; BMI, body mass index; EQ-5D, EuroQOL-5D.

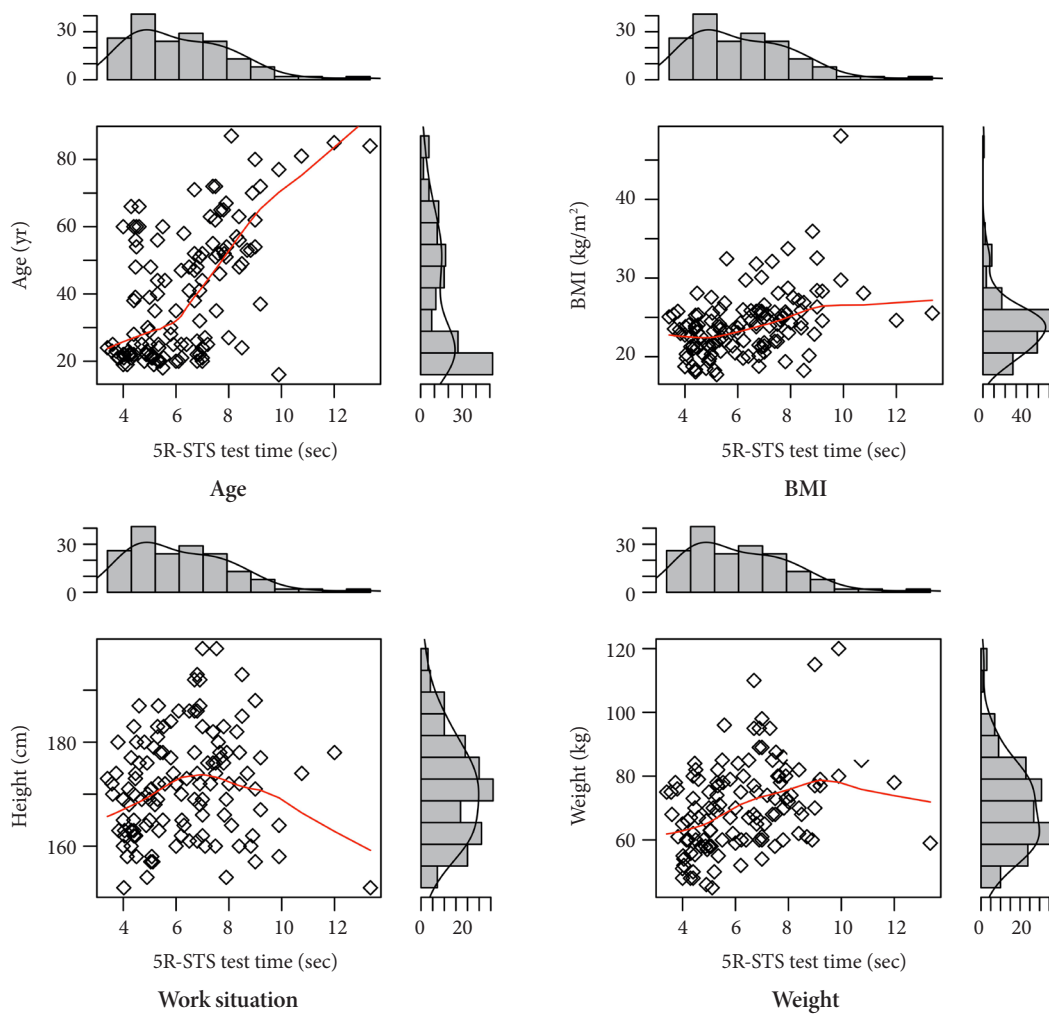


Fig. 1. Scatter plots with marginal histograms demonstrating continuous factors associated with 5-repetition sit-to-stand test (5R-STST) test time in healthy adult individuals using Spearman rank correlation. BMI, body mass index.

DISCUSSION

The purpose of this study was to describe reference values and to identify predictive factors of 5R-STST test time in healthy individuals. It was found that age, BMI, and body height correlated positively with 5R-STST test time, while male sex and houseworker status correlated negatively with test times. Anxiety and depression, body weight, and education level were identified as confounders of 5R-STST performance and were thus included in the multivariable model, however without a significant influence on performance.

Establishing normative data in the form of reference values—derived from healthy “normal” population—is crucial for 2 reasons: First, it allows judgement of what is normal and what is abnormal. Commonly, the ULN is calculated to base this deci-

sion on. Our reference values (Table 2) allow application of the 5R-STST in most pathological populations, as the age- and sex-stratified ULNs can determine what is objectively normal and what is pathological performance. The degree to which abnormal 5R-STST performance correlates with disease progression (construct validity) for particular diseases such as COPD or lumbar degenerative disease can however only be judged after validation in those specific populations. Second, these data allow generation of models that can calculate expected 5R-STST test times for each individual, even if their performance is pathological – Much akin to spirometry reporting in pulmonary functional testing or t-scores for bone density in osteoporosis. This can both help to quantify the degree of abnormality, as well as enable setting targets, for example when it comes to recovery of functional status after lumbar spine surgery or pro-

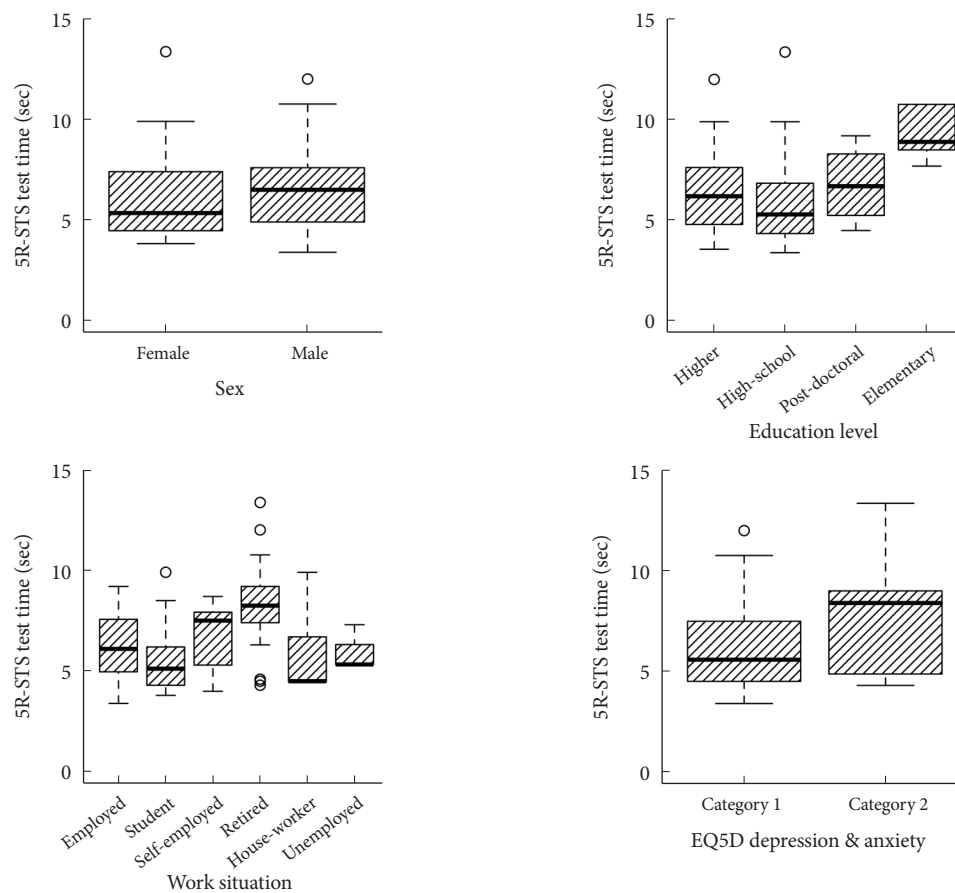


Fig. 2. Boxplots of categorical factors associated with 5-repetition sit-to-stand test (5R-STST) test time in healthy adult individuals.

longed intensive care unit stays.

The statistical analysis of factors associated with 5R-STST performance was performed using the purposeful variable selection algorithm, which substantiates that variables included in the final model significantly influence the 5R-STST test time either by statistical significance of a low p-value or by providing adjustment for other variables, known as confounding.³⁰ This method is often deemed superior to forward and backward stepwise selection models, or those based on simple univariate filtering, as it reduces the risk of missing meaningful variables that failed to have a p-value of <0.05 —or any other threshold for that matter—initially.^{30,32,33} Many question the validity of the commonly used p-value cutoff of <0.05 , often suggesting that it is an arbitrary threshold creating a fallacious reassurance of significance.^{34,35} Through the use of this approach in this study, all relevant variables that were collected are ascertained to be included in the multivariable model, without missing out on important confounders.

The identified age-associated increase in 5R-STST test time is multifactorial and is in agreement with available literature.¹⁷⁻¹⁹

Firstly, older individuals experience progressive loss of skeletal muscle mass and power.³⁶⁻³⁸ Multiple studies confirmed that the quadriceps strength is one of the most important determinants of the test performance.^{10,19,22,39} On the other hand, some data suggested that sense of balance is as crucial while other found no significant association between the 5R-STST test and the Berg Balance Scale.^{10,19,20,40} Nonetheless, all of the aforementioned components including sensorimotor and cognitive status decline with age may contribute not only to increased 5R-STST test time, but also to poorer performance across other OFI tests such as 6MWT.^{18,41-43} Therefore, it is highly recommended to include age in any proposed baseline severity stratification, or in algorithms predicting individual expected 5R-STST test time.⁵

We found that higher BMI was associated with longer 5R-STST test times. Albeit this is contrary to what Lord et al. reported in their study in an elderly population—the mean age of their participants was 80 years—this difference in results may be rationalised by increased weight in younger individuals reflecting muscle mass.^{19,21,22} Currently, there is no consensus on the independent impact of height on OFI test's, such as the 5R-STST test.^{19,25,44}

Performance related to height appears dependent also on standardized seat height—in our population, a standardized seat with 48-cm height was used, corresponding to a normal seat height in continental Europe. As decreased chair height increases test time, some testing protocols strongly recommended to seat an individual at their knee height to optimize the test.^{45,46}

In our study, level of education did not significantly influence test performance, although it was included as a confounding variable, with elementary-level education leading to marginally longer test times. It has been previously demonstrated that less educated individuals were at greater risk of decreasing their physical activity.⁴⁷ This finding was suggested to be linked to perceived control, where participants with lower education had lower self-esteem and less confidence in achieving a desired outcome, as well as being more likely to face challenges of multiple-child families and financial struggles.^{43,47}

There is a bidirectional relationship between mood and functional mobility.⁴⁸ Multiple sources have found that increased physical activity positively affects people's mental health, while other studies demonstrated presence of depressive symptoms as a strong predictor of decreased mobility and indirectly functional impairment.⁴⁸⁻⁵² In this study, the EQ-5D was utilized—a validated tool for depression and anxiety symptoms assessment that is commonly used to assess patients' psychological status.^{27,53} In patients with degenerative disease of the lumbar spine, a stepwise increase in OFI measured by the TUG test demonstrated a drop in EQ-5D by -0.073 .⁵⁴ A similar relationship was identified between the 6MWT and psychological status.^{19,55,56} While the influence of depression and anxiety on the 5R-STS performance in our study was minimal in the multivariable model—suggesting that the 5R-STS test is relatively robust towards mood factors, in contrast to many subjective questionnaires—the univariable analysis demonstrated a weak influence of depression and anxiety on 5R-STS test performance. However, this statistically significant influence disappeared after inclusion in a multivariable model.

In contrast to results of Bohannon et al.¹⁷ and Lord et al.¹⁹ in elderly patients, findings of this study—at least in the multivariable model—demonstrated a strong relationship between male sex and lower 5R-STS test times. Interestingly, studies on the 6 MWT did not identify gender differences.^{44,57} The gender difference identified in our study may be partially explained through the 5R-STS's more prominent focus on rapid lower limb muscle torque and knee extension strength, which undergoes more accelerated age-related decline in women compared to men.^{58,59}

Intriguingly, the smoking status was not a significant predictive factor for the 5R-STS test time in healthy individuals. A cross-sectional study by Heydari et al.⁶⁰ demonstrated that smokers were 4.88 more likely to experience decreased physical function compared to nonsmokers. However, they did not differentiate between 'never smokers' and 'ex-smokers,' as we did – an important distinction as irreversible airway gene expression changes persist years after smoking cessation.⁶¹ The relatively quick performance of the 5R-STS test may not be sufficient to elicit decreased physical function as a result of smoking, although it has been effectively used in COPD.⁴ Additionally, it is crucial to highlight that this study's cohort comprised of healthy individuals only without mobility issues. Smoking is said to affect physical function as result of developing severe chronic conditions which were not applicable for this cohort.⁶²

First, some categories were low in sample size. Only 3.4% of the cohort had elementary-level education, while around 63% had a higher or postdoctoral education. This statistical power may have influenced the effect size. This also applies to work situation and anxiety and depression – future studies should include a higher number of patients with anxious and depressive symptoms to more accurately study the robustness of the 5R-STS in this population. In addition, the presence of chronic conditions in volunteers was not clearly reported, which may have influenced their 5R-STS performance. However, our criteria for inclusion led to an exclusion of individuals with comorbidities typically influencing 5R-STS performance markedly. Also, we were limited in our analysis to the variables collected within the 2 prospective cohorts – any other variables such as presence of regular exercise or polypharmacy could thus not be considered. We did not include any individuals aged under 18, although the test could potentially also be used in adolescents. Finally, our data may only generalize to a Dutch population. As has been observed for other measurements, such as the EQ-5D or the 6MWT, different populations may require different normative values. Further studies should aim to distinguish between different nationalities and ethnicities.^{63,64}

CONCLUSION

The presented reference values can be applied as normative data for the 5R-STS in healthy adult individuals of all age groups, and are necessary to judge what constitutes abnormal performance. We identified several factors associated with 5R-STS performance that must be taken into account and that may be applied to calculate individualized expected test times. Notably,

the 5R-STS does not appear to be significantly influenced by anxiety and depression.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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SUPPLEMENTARY MATERIALS

Supplementary Content 1 and Table 1 can be found via <https://doi.org/10.14245/ns.2142750.375>.

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Supplementary Content 1. Statistical code. R Code for the statistical analysis figure rendering. The code was executed in R Version 3.5.2 (The R Foundation for Statistical Computing, Vienna, Austria) on a machine running macOS Catalina Version 10.15.6. The raw data will be made available by the authors on request.

Supplementary Table 1. Reference values for the 5R-STS test time (second) in healthy individuals ≤ 60 years of age


Age (yr)	Male		Female		Overall	
	Mean \pm SD	ULN	Mean \pm SD	ULN	Mean \pm SD	ULN
20-30 yr	5.24 \pm 1.36	8.15	5.18 \pm 1.08	7.59	5.20 \pm 1.18	8.13
31-40 yr	5.89 \pm 1.10	7.49	5.60 \pm 1.68	9.01	5.73 \pm 1.47	9.0
41-50 yr	7.01 \pm 1.88	8.49	5.91 \pm 1.19	7.66	6.46 \pm 1.25	8.48
51-60 yr	7.02 \pm 1.44	8.91	6.64 \pm 1.82	8.83	6.83 \pm 1.63	8.95

Mean \pm standard deviation (SD) and ULN (upper limits of normal) are provided for each subpopulation. 5R-STS, 5-repetition sit-to-stand test.

Original Article

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INTRODUCTION

Vertebral artery (VA) injury is one of the most serious complications during cervical spine surgeries, which may result in problems such as cerebral vascular disturbance, neurological deficit, and even death.¹⁻⁷ When atlantoaxial dislocation (AAD) is combined with atlas occipitalization and C2-3 fusion, we consider it as a special subgroup of AAD cases with prominent

Vertebral Artery Variations at the Craniovertebral Junction in “Sandwich” Atlantoaxial Dislocation Patients

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Objective: To summarize the vertebral artery (VA) pattern of 96 “sandwich” atlantoaxial dislocation (AAD) patients and to describe the strategies of reducing the injury of VA during surgery.

Methods: From 2009 to 2020, we retrospectively reviewed the 3-dimensional computed tomography angiography data of 96 AAD patients combined with atlas occipitalization and C2-3 fusion, which were diagnosed as “sandwich” AAD and 96 patients as control group patients who were without atlas occipitalization, C2-3 fusion and any other cervical bone deformity at our institution. The variations of each side of VA were described in 3 different parts (C0-1, C1-2, and C2-3) according to the characteristics of the 3-part pathological structures in “sandwich” subgroup.

Results: One hundred ninety-two sides of VAs in every group of patients were analyzed and every VA was described separately at 3 different level regions. There were different variations in these 3 different regions: 4 variations in the upper fusion region, 5 variations in the sandwiched region, and 6 variations in the lower fusion region in sandwich AAD patients. And the rate of VA deformity in sandwich AAD patients was much higher and more types of VA variations existed.

Conclusion: In “sandwich” AAD patients, deformities of vertebral arteries in craniovertebral junction are more common, and the same VA may have deformities at different levels that severely affect surgical procedures. Therefore, preoperative imaging examination of VA for “sandwich” AAD patients is vital of guiding surgeons to avoid injury of VA during surgery.

Keywords: Sandwich atlantoaxial dislocation, Vertebral artery variations, Craniovertebral junction, Atlantoaxial dislocation, Craniovertebral fixation

clinical features including younger onset age, increased probability of concomitant Chiari deformity, syringomyelia and cranial neuropathy, and a lower rate of myelopathy improvement compared with typical AAD patients, which have been reported as “sandwich” AAD.⁸ The 3 deformities included in “sandwich” AAD were classified into 3 parts: the upper fusion region (C1 occipitalization), the sandwiched region (AAD), and the lower fusion region (C2-3 fusion) (Fig. 1). Neurologic deterior-

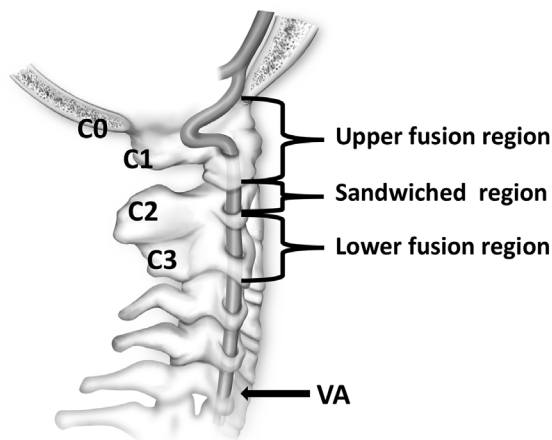


Fig. 1. Illustration of the 3 parts of vertebral artery (VA) in the “sandwich” atlantoaxial dislocation.

ration in such patients commonly presents in the third or fourth decade of life, which requires surgical treatment. However, such osseous deformities as atlas occipitalization and C2–3 fusion are often accompanied by severe VA variations. To understand VA malformations are particularly important in the treatment of sandwich AAD patients.

A normal VA is divided into 4 segments: V1 segment (It originates from the subclavical artery and enters the C6 transverse process), V2 segment (walks through C6–2 transverse process), V3 segment (the segment courses from C2 to the foramen magnum), and V4 segment is coursing from entering the cranium to attending the basilar artery.⁹ Wang et al.¹⁰ has previously reported anatomical V3 segment variations of VA in patients with atlas occipitalization. The bone deformity of “sandwich” AAD patients was more serious than mere atlas occipitalization, and the combined VA deformities may be more complex, which have not been reported yet. In this current group, due to the existence of 3 deformities ranging from occipital bone to C3, we would like to focus on summarizing VA variations of segment from C3 level to the foramen magnum, to help the planning for surgical strategies.

Here, we summarized the VA pattern of 96 sandwich AAD patients to describe their variations and to set up strategies of how to reduce the injury of VA during surgery.

MATERIALS AND METHODS

This study was a retrospective study and no formal ethics approval was required as ruled by the ethics committee of Peking University Third Hospital. From 2009 to 2020, we retrospec-

tively reviewed 3-dimensional computed tomography angiography (3D-CTA) data of 96 AAD patients combined with atlas occipitalization and C2–3 fusion at our institution, which were diagnosed as “sandwich” AAD. Based on the dynamic radiographs (flexion and extension) and computed tomography (CT) scan evidence, the diagnosis of AAD was defined as an abnormal local relationship between the atlas and axis, with an atlantodental interval >3 mm in adults and >5 mm in children (<18 years of age). Patients were excluded if adequate radiographs were unavailable or they did not undergo surgical treatment. All of the patients’ 3D-CTA data were evaluated to identify the VA variations from C3 level to the foramen magnum before surgery. The average age of the patients was 39.6 years (range, 5–67 years), with 45 males and 51 females. Nonionic contrast material was intravenously administered to all patients via the antecubital vein. Then 3D-CTA were performed on all 96 cases, using a 64-slice scanner (lightspeed VCT, GE Healthcare Systems, Chicago, IL, USA) with the scanning parameters: 120 kV, 500 mA, 0.6 seconds/rotation, table speed with 0.516 mm/rotation and 0.625 mm slice thickness. Three-dimensional images were obtained and analyzed by 2 spine surgeons.

According to the characteristics of the 3-part pathological structures in “sandwich” subgroup, we described the variations of each VA in 3 different parts. In the upper fusion region, the classification of VA variation was based on the position of VA entering the cranial or spinal canal and the relationship with atlas; in the sandwiched region, the VA variations were described according to the morphology of VA in this region; in the lower fusion region—the VA variations were classified for the shape of VA in the transverse foramen of C2 and C3 and its relationship with adjacent bone. Besides, the diameter of bilateral VA in each patient was measured at C2 level, then a dominant VA was defined if it was at least 30% larger than the other side.

Then, we also retrospectively reviewed 3D-CTA data of 96 patients as control group patients who were without atlas occipitalization, C2–3 fusion, and any other cervical bone deformity at our institution at the same time (from 2009 to 2020). The average age of the patients was 42.3 years (range, 11–69 years), with 47 males and 49 females. And there was no statistical difference in the age and sex distribution between the 2 patient groups using chi-square test ($p > 0.05$). Their 3D-CTA data were evaluated to identify the VA variations following the 3-part classification method. Chi-square test was also performed for statistical analyses using IBM SPSS Statistics ver. 23.0 (IBM Co., Armonk, NY, USA) to compare the difference of the rate of VA deformity between these 2 different groups of patients.

RESULTS

1. The VA Variations in Sandwich AAD Patients

In our study, 192 sides of VAs were analyzed. The VA variations of sandwich AAD patients in 3 regions were summarized separately and presented in Table 1.

1) The upper fusion region: (U-region)

Type I: The VA passes through the transverse foramen of the C1 and enters an extraosseous canal created in the assimilated atlas before reaching the cranium (101 sides, 52.6%) (Fig. 2A, a); Type II: The VA enters the spinal canal directly under the posterior arch of atlas without passing through the transverse foramen of C1 (69 sides, 35.9%) (Fig. 2B, b; red arrow); Type III: The VA passes through the transverse foramen of the C1

and is exposed partly when passing through the VA sulcus due to incomplete occipitalization of the C1 posterior arch (17 sides, 8.9%) (Fig. 2C, c); Type IV: Absent VA (5 sides, 2.6%) (Fig. 2B; yellow arrow).

2) The sandwiched region: (S-region)

Type I: The VA goes through the C2 transverse foramen and ascends directly into the C1 transverse foramen without tortuosity (113 sides, 58.9%) (Fig. 3A, a); Type II: The VA courses above the axis facet or makes a curve below the atlas lateral mass and then turns directly medially towards the spinal canal after leaving the C2 transverse foramen without going through the C1 transverse foramen (first intersegmental artery [FIA]) (66 sides, 34.4%) (Fig. 3B, b); Type III: The VA is duplicated after emerging from the C2 transverse foramen; one branch passes

Table 1. The VA variations of sandwich AAD patients in 3 regions

Region	Variations	Number	Proportion	Surgical strategies
Upper fusion region (C0-1)	I: The VA passes through the C1 foramen and enters an extraosseous canal created in the assimilated atlas before reaching the cranium.	101	52.6%	Evaluating the shape of VA in osseous foramen and the location of the osseous foramen preoperatively
	II: The VA enters the spinal canal directly under the C1 posterior arch without passing through the C1 transverse foramen.	69	35.9%	Small risk of injury with C1LMS in this region
	III: The VA is exposed partly when passing through the vertebral artery sulcus due to incomplete occipitalization of the C1 posterior arch.	17	8.9%	Taking special care during the exposure of the posterior arch of C1
	IV: Absent VA	5	2.6%	Avoiding injuring the contralateral side VA
Sandwiched region (C1-2)	I: The VA goes through the C2 transverse foramen and ascends directly into the C1 transverse foramen without tortuosity.	113	58.9%	Small risk of injury in this region
	II: The VA courses above the axis facet or makes a curve below the atlas lateral mass and then turns directly medially towards the spinal canal.	66	34.4%	Preoperative evaluation and caution during the lateral mass joint operation
	III: The VA is duplicated after emerging from the C2 transverse foramen.	6	3.1%	Preoperative evaluation and caution during the lateral mass joint operation
	IV: Absent VA	5	2.6%	Avoiding injuring the contralateral side VA
	V: The posterior inferior cerebellar artery originates from the level C1/2.	2	1.0%	Preoperative evaluation and caution during the lateral mass joint operation
Lower fusion region (C2-3)	I: The VA travels normally in the C2/3 transverse foramen.	138	71.9%	Small risk of injury in this region
	II: Tortuosity or medial loop formation can be seen in the C2 or C3 transverse foramen (loop).	21	10.9%	Evaluating the location of the loop and its subsequent bone deformity
	III: The VA is anomalously located too medially, too posteriorly, and/or too high with a C2 isthmus height of ≤ 5 mm (HRVA).	20	10.4%	Using alternative fixation methods instead of C2 pedicle screw
	IV: Loop and HRVA are concurrent at the same time.	7	3.6%	Alternative fixation methods and evaluation of the loop location
	V: Absent VA	5	2.6%	Avoiding injuring the contralateral side VA
	VI: The VA emerges from the C3 transverse foramen and ascends directly without passing through C2 transverse foramen.	1	0.5%	Careful operation during the exposure of C2 pedicle

VA, vertebral artery; AAD, atlantoaxial dislocation; C1LMS, C1 lateral mass screw; HRVA, high-riding VA.

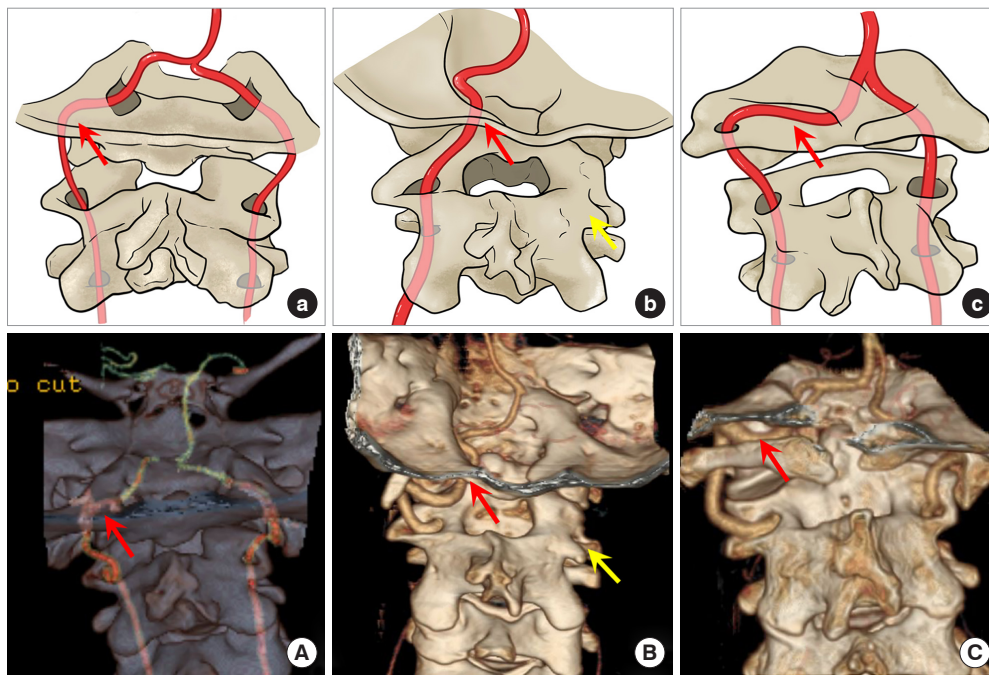


Fig. 2. Vertebral artery (VA) variations in U-region. (A, a) Type I of passing through an extraseous canal created by the assimilated atlas (red arrow). (B, b) The red arrow shows the type II of entering the spinal canal directly under the C1 posterior arch; The yellow arrow shows the absent VA. (C, c) Type III of exposed partly by the incomplete occipitalization of the C1 posterior arch (red arrow).

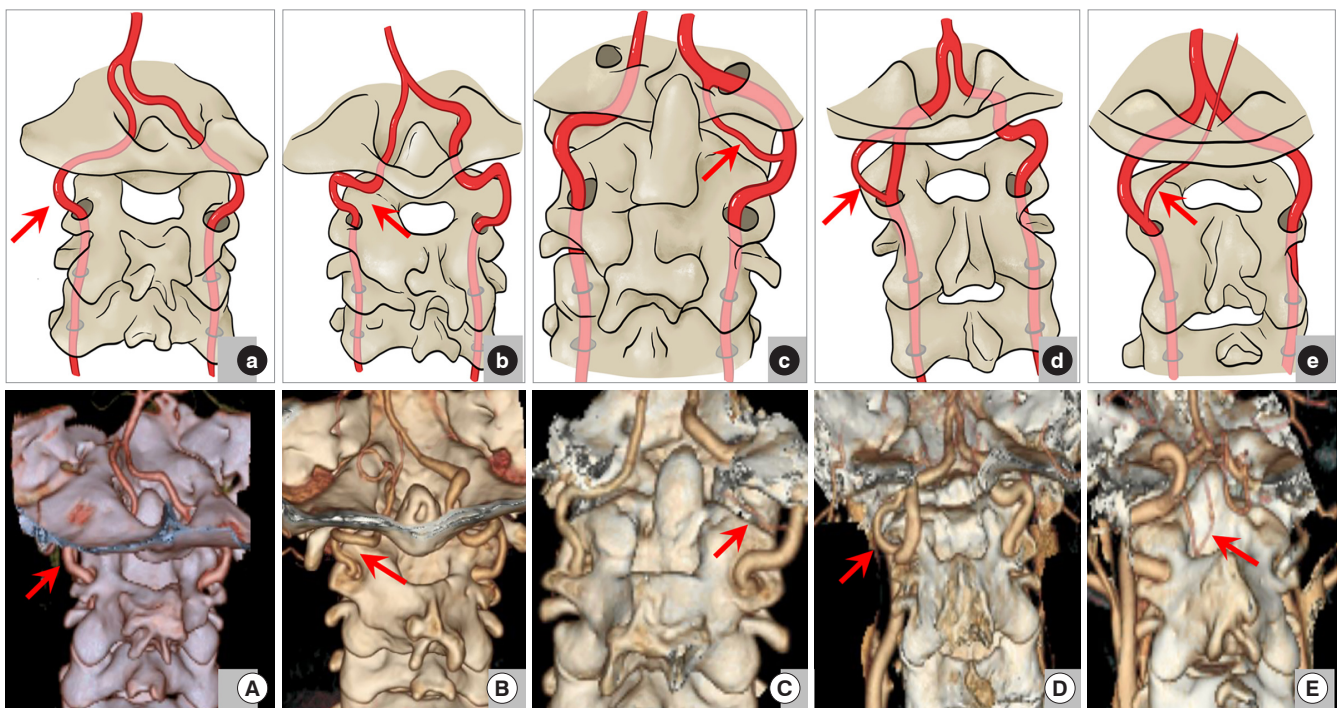


Fig. 3. Vertebral artery (VA) variations in S-region. (A, a) Type I in this region of going through the C2 and C1 transverse foramina without tortuosity. (B, b) Type II of coursing above the axis facet or making a curve below the atlas lateral mass illustrated by the red arrow. (C, c) Type III of duplicated VA. (D, d) A special subtype of type III of the 2 branches converge under the C1 posterior arch and then goes in spinal canal. (E, e) Type V of the posterior inferior cerebellar artery originating from the level C1/2. All the variations were marked by the red arrow.

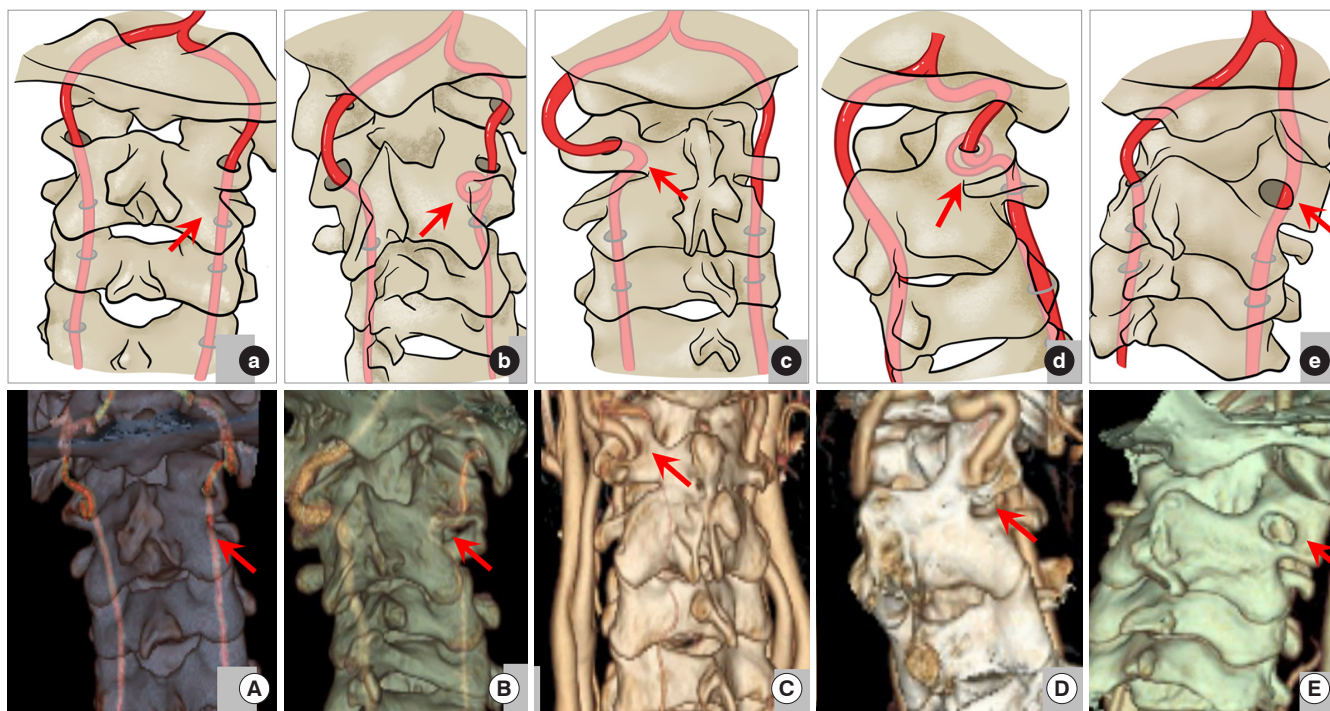


Fig. 4. Vertebral artery (VA) variations in L-region. (A, a) Type I in this region of traveling normally in the C2/3 transverse foramen. (B, b) Type II of tortuosity or medial loop formation in the C2 or C3 transverse foramen (loop). (C, c) Type III of high-riding VA (HRVA). (D, d) Type IV of Loop and HRVA existing at the same time. (E, e) Type VI of emerging from the C3 transverse foramen and ascending directly without passing through C2 transverse foramen. All the variations were marked by the red arrow.

through the C1 transverse foramen; the other branch enters the spinal canal between C1 and C2 before joining the former (fenestration of the VA above and below C1 [FEN]) (6 sides, 3.1%) (Fig. 3C, c). One special type of them is that the 2 branches converge under the C1 posterior arch and then goes in spinal canal (Fig. 3D, d); Type IV: Absent VA (5 sides, 2.6%); Type V: The posterior inferior cerebellar artery (PICA) originates from the level C1/2 (2 sides, 1.0%) (Fig. 3E, e).

3) The lower fusion region(L-region)

Type I: The VA travels normally in the C2 and C3 transverse foramen (138 sides, 71.9%) (Fig. 4A, a); Type II: Tortuosity or medial loop formation can be seen in the C2 or C3 transverse foramen (loop) (21 sides, 10.9%) (Fig. 4B, b); Type III: The VA is anomalously located too medially, too posteriorly, and/or too high with a C2 isthmus height of ≤ 5 mm (HRVA) (20 sides, 10.4%) (Fig. 4C, c); Type IV: Loop and HRVA are concurrent at the same time (7, 3.6%) (Fig. 4D, d); Type V: Absent VA (5 sides, 2.6%); Type VI: The VA emerges from the C3 transverse foramen and ascends directly without passing through C2 transverse foramen (1, 0.5%) (Fig. 4E, e).

Table 2. The rate of VA deformity between sandwich AAD patients and control group patients

Region	Rate of VA deformity (%)		
	Sandwich AAD (n=192)	Control group (n=192)	p-value
U-Region	38.5	2.1	<0.001
S-Region	41.1	4.2	<0.001
L-Region	28.1	3.1	<0.001

VA, vertebral artery; AAD, atlantoaxial dislocation.

2. The Dominance of VA In Sandwich AAD patients

Forty-six cases of 96 patients had unilateral-side VA dominance, accounting for 48.0%. Twenty-three cases were left-side VA dominance (including 1 right-side absence), while 23 cases were right-side VA dominance (including 4 left-side absence).

3. The Difference of VA Deformity Between Sandwich AAD Patients and Control Group Patients

Following the 3-part classification method, 4 sides of VA were abnormal (3 sides of type II, 1 absent side of type IV) in U-region, 8 sides were abnormal (3 sides of type II, 3 sides of type III, 1 side of type IV and 1 side of type V) in S-region and 6

sides (3 sides of type II, 2 sides of type III and 1 side of type V) were abnormal in L-region in control group patients. The specific rate of VA deformity between sandwich AAD patients and control group patients was shown in Table 2. The rate of VA deformity in sandwich AAD patients was much higher than that in control group patients ($p < 0.001$). Besides, 48 cases of 96 patients had unilateral-side VA dominance (24 cases of left-side dominance, 24 cases of right-side dominance) in control group patients (50.0% vs 48.0%, $p = 0.77$, no statistically significant difference).

DISCUSSION

VA variations in different patients series have been reported. Wakao et al.¹¹ reported 387 cases of VA variations at C1–2 level without osseous deformities in craniovertebral junction in 2014, including high-riding VA (HRVA, 10.1%), persistent FIA (1.8%), fenestration of the VA above and below C1 (FEN 1.3%), PICA from C1/2 (PICA, 1.3%) and the ponticulus posticus (6.2%). Wang et al.¹⁰ have reported the variations of V3 segment of VA in 36 patients with atlas occipitalization in 2009, which was divided into 4 categories: Type I (8.3%), the VA enters the spinal canal below the C1 posterior arch, and courses below the occipitalized C1 lateral mass. Type II (25%), the VA enters the spinal canal below the C1 posterior arch, and the course of VA is on the posterior surface of the occipitalized C1 lateral mass, or makes a curve on it. Type III (61.1%), VA ascends laterally after leaving the C2 transverse foramen, enters an osseous foramen created between the atlas and occiput, then reaches the cranium. Type IV (5.6%), the VA is absent. Here, we regarded types I and II in the article of Wang et al.¹⁰ as different subtypes of FIA as reported by Wakao et al.,¹¹ but their proportion is much higher than that of Wakao's in normal people, and the proportion of type III of entering an osseous foramen in Wang's article was also high. This result might mean that different bone deformities may lead to an increased incidence of associated VA deformities. From the 2 different group of patients in our research, the rate of VA deformity in sandwich AAD patients was much higher and more types of VA variations existed.

1. The Characteristics of VA Variations in Sandwich AAD Patients

In our case series, due to the existence of the upper and lower fusion regions in sandwich AAD patients, we first proposed a 3-part formula to describe the variations of VA in more detail. In this article, we further divided the VA segment at craniover-

tebral junction of sandwich AAD patients into 3 regions—U, S, and L regions. Since there were different surgical operations in different regions, this division of the VA was conducive to the operators to make detailed preoperative planning.

As can be seen from our results, due to the atlas occipitalization in the U-region, the highest incidence of deformity was the type I of VA entering an osseous foramen, with proportion as high as 52.6%; Type III of coursing an incomplete osseous canal has not been reported before, and their occurrence was due to incomplete ossification of C1 posterior arch. So, the electronic exposure needs to be careful with this type during the posterior procedure, to protect the partial lie-open VA.

The highest occurrence of VA malformation in the S-region was type II of VA making a curve and turning directly medially towards the spinal canal below the C1 posterior arch (34.4%), and it was mostly tortuous on the surface of C1-2 lateral mass joint. As for duplicated type III, 5 of the 6 cases was that one branch ascended under the posterior arch of C1 and merged with another branch passing through the transverse foramen of C1, while 1 case was unique that both branches merged and entered the spinal canal directly under the posterior arch of C1 without passing through the C1 transverse foramen (Fig. 3D, d). This unique duplicated variation has not been reported before.

In the L-region, high-riding VA and VA loop were high incidence, accounting for 10.4% and 10.9% respectively, and these 2 deformities both occurred simultaneously in 7 cases, which was vital to guide our selection of surgical methods. To our knowledge, VA Loop has been rarely reported in the upper cervical spine previously. Ekşi et al.¹² have mentioned in his article that VA loops were more commonly observed at V2 segment (90.5%), while they were less common at V1 (7.6%) and V3 (1.9%) segments in the literature. And in his report, the occurrence segments of Loop were C4–5 (31.4%), C3–4 (20%), and C5–6 (18.1%), respectively.

2. Special Surgical Strategies for the Variations

As for the surgical treatment, VA malformations in different parts also lead to different risks.

In the U-region, the risk of injury to the VA during the posterior C1 lateral mass screw (C1LMS) was highlighted. Hong et al.¹³ has suggested that C1 lateral mass screw insertion can be dangerous in cases of a persistent FIA where the VA courses abnormally below the C1 posterior arch. But Wang et al.¹⁰ proposed that not all FIAs were at risk during C1LMS placement, and the high risk of VA injury was only for those FIAs that were tortuous on the surface of the C1 lateral mass, and the FIAs that

went under the C1 lateral mass were relatively safe during placement of the C1LMS. Li et al.¹⁴ reported 120 cases of VA malformations in patients with BI and atlas occipitalization in 2018. In his classification, 2 types of variations that would increase the risk of VA injury with C1LMS were type of entering an osseous foramen and FEN, and he proposed to reduce the risk of VA injury by changing the entry point and direction of C1MS. In our classification of the upper fusion region, we believed that type I of passing through an osseous foramen and type III of being exposed partly due to incomplete occipitalization of the C1 posterior arch had an increased risk of injury during C1LMS placement. In type I, it was important to evaluate the shape of VA in the osseous foramen and the location of the osseous foramen preoperatively. In type III, due to the incomplete ossification of the posterior arch of the atlas, there is no bone protection on part of the surface of the VA, so special care should be taken during the exposure of the posterior arch of C1. For type II of VA entering the spinal canal directly under the posterior arch of atlas, in our cases, since they did not perforate the C1 transverse foramen, most of their course was tortuous on the joint surface of the lateral mass joint of C12, so the risk of injury with C1LMS was relatively small.

In the S-region, VA injury is mainly caused during the operation of the lateral mass joint. Li et al.¹⁴ have mentioned that VA could be much more easily injured during the surgical manipulations around the facets, such as the placement of spacers or Titanium Cages between the C1–2 facets. In our classification, we have similar opinions. Type II of VA in this region is tortuous on the surface of the C1–2 lateral mass facets, so the risk of VA injury is greatly increased when handling the lateral mass joint. In addition, type III and type V of this region have the same risk in the lateral mass joint operation, especially type V with C1–2 level PICA which may lead to serious consequences such as postoperative cerebellar infarction after injury.

In the L-region, we should focus on the presence of high-riding VA and VA loop during C2 pedicle screw (C2PS) insertion. The risk of injury to VA caused by C2PS insertion due to high-riding VA has been reported,¹⁵ but the risk of VA loop in upper cervical spine during surgery have not been reported before. Park et al.¹⁶ reported the incidence of VA loop as 0.6% in patients with vertebral bone erosion or widened transverse foramen. Then, the enlargement of the transverse foramen leads to the hypoplasia pedicle, which is too thin to accommodate C2PS. Moreover, when the VA loop curves inwards the spinal canal, it results in a significantly increased risk of injury during posterior surgical procedures. Therefore, either of these 2 VA deformi-

ties increases the risk of injury to the VA during surgery at the lower fusion region, especially for the VA with these 2 deformities together. Besides, in this region, we found a case where the VA went from the C3 transverse foramen to the C1 transverse foramen without passing through the C2 transverse foramen, which might increase the risk of VA injury during the operation of the exposure of the C2 pedicle.

3. The Dominance of VA in Sandwich AAD and Its Clinical Solutions

For the dominance of VA, this type of malformation was through 3 regions. The diameters of the VA are of equal size in only 6%–26% of patients in angiographic reported in post studies, and the left VA is often larger than the right VA, this is called the VA dominance (VAD) because of asymmetric VA.^{17,18} Individual with VAD usually do not have symptoms of Vertebrobasilar insufficiency.¹⁹ Smith and Bellon²⁰ have reported that the diameter of the dominant VA should be at least 30% larger than the other side. We followed this standard and considered the unilateral absence type as the contralateral dominant type in our cases. And we found that there was no statistically significant difference in the rate of unilateral-side VAD between the 2 group patients. But there might be a relationship between the side of VA variation and the VAD. We chose a subgroup including 31 patients with VAD and unilateral VA variation from the sandwich AAD patients to analyze if there was a relationship between the side of VA variation and VAD using chi-square test. The statistical results showed that the rate of variation in the dominant side of VA was significantly higher than in the recessive side ($p < 0.05$) (Table 3). Although VA variation may occur in the case without VAD and there were bilateral VA variations or bilateral regular VA in the case with VAD, we still found that the dominant side of VA has a higher rate of VA variation, which reminded us to pay high attention to the dominant VA during surgery. Besides, the VAD was same at the risk of injury as unilateral absence type VA during the surgery. Then we have to evaluate the dominant VA carefully preoperatively to avoid the occurrence of disastrous results.

Table 3. Relationship between the side of VA variation and the VAD

VAD	Variation in the dominant side of VA (n = 31)		
	Yes	No	p-value
Left VAD	13 (41.9)	3 (9.7)	<0.05
Right VAD	13 (41.9)	2 (6.5)	<0.05

VA, vertebral artery; AAD, atlantoaxial dislocation.

CONCLUSION

In sandwich AAD patients, deformities of vertebral arteries in the upper cervical spine region are more common, and the same VA may have deformities at different levels that severely affect surgical procedures. Therefore, for these patients, preoperative imaging examination of VA is very important, which is essential to guide us to avoid injury of VA during surgery.

CONFLICT OF INTEREST

The authors have nothing to disclose.


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Original Article

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Complications of Posterior Fusion for Atlantoaxial Instability in Children With Down Syndrome

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Objective: To clarify the complications of posterior fusion for atlantoaxial instability (AAI) in children with Down syndrome and to discuss the significance of surgical intervention.

Methods: Twenty pediatric patients with Down syndrome underwent posterior fusion for AAI between February 2000 and September 2018 (age, 6.1 ± 1.9 years). C1–2 or C1–3 fusion and occipitocervical fusion were performed in 14 and 6 patients, respectively. The past medical history, operation time, estimated blood loss (EBL), duration of Halo vest immobilization, postoperative follow-up period, and intra- and perioperative complications were examined.

Results: The operation time was 257.9 ± 55.6 minutes, and the EBL was 101.6 ± 77.9 mL. Complications related to the operation occurred in 6 patients (30.0%). They included 1 major complication (5.0%): hydrocephalus at 3 months postoperatively, possibly related to an intraoperative dural tear. Other surgery-related complications included 3 cases of superficial infections, 1 case of bone graft donor site deep infection, 1 case of C2 pedicle fracture, 1 case of Halo ring dislocation, 1 case of pseudoarthrosis that required revision surgery, and 1 case of temporary neurological deficit after Halo removal at 2 months postoperatively. Complications unrelated to the operation included 2 cases of respiratory infections and 1 case of implant loosening due to a fall at 9 months postoperatively.

Conclusion: The complication rate of upper cervical fusion in patients with Down syndrome remained high; however, major complications decreased substantially. Improved intra- and perioperative management facilitates successful surgical intervention for upper cervical instability in pediatric patients with Down syndrome.

Keywords: Pediatric Down syndrome, Surgical complication, Atlantoaxial instability, Posterior fusion, Atlantodental interval, Cervical spine



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INTRODUCTION

Atlantoaxial instability (AAI) occurs in 14.6%–22.2% of individuals with Down syndrome,¹⁻⁴ which is more frequent than that in normal children and results from ligament laxity and odontoid dysplasia.³ Surgical treatment of AAI in children with Down syndrome is challenging because of the small bony structures, anatomical variety, and high complication rate. Posterior arthrodesis of the upper cervical spine in patients with Down

syndrome had 73.3%–100% of complications in the 1990s.^{5,6} While surgeries have been recommended in AAI patients with associated neurological symptoms, prophylactic arthrodesis for asymptomatic cases has been controversial.⁷⁻¹⁰ However, perioperative management, including radiographic evaluations, surgical techniques with spinal instrumentation, and anesthesia, has progressed markedly, enabling safer surgery. After posterior fusion with C1–2 transarticular screws was first reported in 1992,¹¹ C1 lateral mass screws and C2 pedicle screws have been

developed and utilized.^{12,13} These techniques have been applied in pediatric patients and have demonstrated improved stabilization and fusion rate.¹⁴⁻¹⁸ Although several reports have shown acceptable outcomes in pediatric upper cervical spine surgeries since 2000,^{15,16,19-22} they included small populations of Down syndrome. Therefore, the complication rate is difficult to estimate. The purpose of this study was to clarify the complications of posterior fusion for AAI in children with Down syndrome and the significance of surgical intervention.

MATERIALS AND METHODS

This study was approved by the Institutional Review Board (IRB) of Kobe University Graduate School of Medicine (IRB No. B190002). Written informed consent was obtained from each patient and family. Further, they were informed that data from the cases would be submitted for publication and gave their consent. This study was conducted following the principles of the Declaration of Helsinki and with the laws and regulations of Japan.

A total of 20 pediatric patients with Down syndrome underwent posterior fusion for AAI in the authors' hospitals between February 2000 and September 2018 (7 men and 13 women; age, 6.1 ± 1.9 [3–9] years) (Table 1). Prior to surgery, a combination of lateral cervical radiography, computed tomography (CT), and magnetic resonance imaging (MRI) were performed. The surgical indication was an atlantodental interval (ADI) larger than 7.0 mm with smaller space available for the cord (SAC) than 10.0 mm and os odontoideum even without symptoms. All screws and plates were placed under fluoroscopic guidance. The constructs included C1 lateral mass screws, C2 or C3 pedi-

cle screws, C2 laminar screws, C2 or C3 hooks, rectangular rods with sublaminar wiring, and occipital plates.

The past medical history, operation time, estimated blood loss (EBL), duration of postoperative Halo vest immobilization, postoperative follow-up period, and intra- and perioperative complications of these patients were examined. Values are expressed as the mean \pm standard deviation. Fisher exact test was used to assess the complication rate between rod-wiring/hook constructs and rod-screw constructs.

RESULTS

C1–2 or C1–3 fusion and occipitocervical (O-C) fusion were performed in 14 and 6 patients, respectively. All patients underwent primary surgeries performed by a single surgeon. Preop-

Table 1. Summary of patients' characteristics and past medical history

Characteristic	Value
Sex, men:women	7:13
Age (yr), mean \pm SD (range)	6.1 ± 1.9 (3–9)
Height (cm), mean \pm SD	103.5 ± 10.6
Weight (kg), mean \pm SD	17.9 ± 4.5
Past medical history	
Cardiovascular diseases	17
Hypoacusis, serous otitis media	5
Dysopia	4
Gastrointestinal anomalies	3

SD, standard deviation.

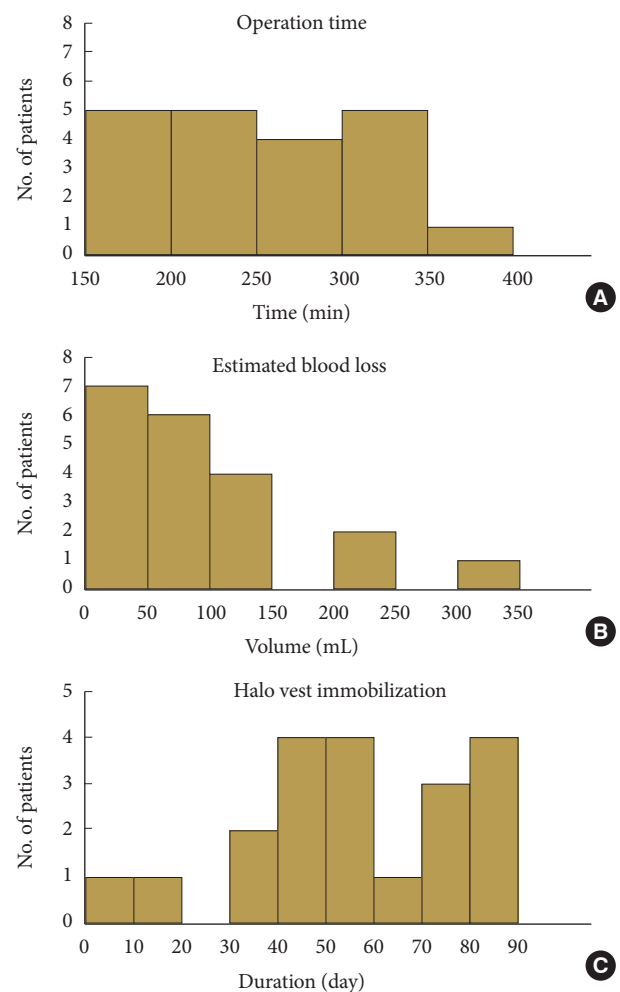


Fig. 1. Distribution of intraoperative data and postoperative Halo immobilization. (A) Operation time. (B) Intraoperative estimated blood loss. (C) Duration of Halo vest immobilization.

erative ADI was 7.6 ± 1.5 mm and SAC was 9.0 ± 2.1 mm. Lateral radiography revealed 1 case of odontoid hypoplasia and the other 19 of os odontoideum. One patient had a hypoplastic posterior arch of the atlas. None of the patients had subaxial instability according to the lateral flexion-extension images. No pa-

tients presented abnormal neurological findings preoperatively.

Seventeen patients had past medical history of cardiovascular diseases, such as atrial septal defect (ASD), endocardial cushion defect, patent ductus arteriosus, and ventricular septal defect (VSD); however, their cardiac functions were maintained to

Table 2. Clinical and surgical characteristics

Case No.	Age (yr)	Sex	Past medical history	Fusion levels	Instrumentation	Complication
1	4	W	ECD, pulmonary atresia, bilateral equinus feet, scoliosis, developmental dysplasia of left hip	O–C2	Rectangular rod+sublaminar wiring	Superficial infection, pseudoarthrosis (resulting in revision surgery)
2	4	M	ASD, PDA, pulmonary hypertension	O–C3	Rectangular rod+sublaminar wiring	Bronchitis
3	9	W	ECD (postoperative brain infarction resulting in left hemiparesis)	O–C3	Occipital plate+C2 and C3 hook	Temporary muscle weakness of right upper and lower limbs after Halo removal
4	8	M	Common atrioventricular valve port, Hirschsprung's disease	O–C2	Occipital plate+C2 PS	None
5	8	W	ASD, VSD	O–C2	Occipital plate+C2 PS	None
6	5	M	ASD, VSD	C1–2	C1 LMS+C2 PS	Implant loosening due to fall
7	6	W	ASD, VSD	C1–3	C1 LMS+C2 Left PS+C3 right PS	None
8	6	W	ASD, VSD	C1–2	C1 LMS+C2 PS	None
9	4	W	ASD, hypoacusis, glaucoma	C1–2	C1 LMS+C2 PS	Hydrocephalus (related to intraoperative dural tear), superficial infection
10	8	M	VSD, aberrant right subclavian artery, pulmonary hypertension	C1–2	C1 LMS+C2 laminar screw	Halo ring dislocation, deep infection (iliac crest)
11	5	W	VSD, hypoacusis, retinopathy of prematurity, strabismus	C1–2	C1 LMS+C2 laminar screw	None
12	8	W	Recurrent pneumonia and bronchitis	C1–2	C1 LMS+C2 right PS and laminar screw	None
13	7	W	Atrioventricular septal defect, tricuspid valve insufficiency	C1–2	C1 LMS+C2 PS	Influenza
14	8	M	congenital esophageal atresia, recurrent laryngeal nerve paralysis, epilepsy, hypoacusis	C1–2	C1 LMS+C2 PS	None
15	7	W	ASD, duodenal atresia	C1–2	C1 LMS+C2 PS	None
16	4	M	ASD, cataract	C1–2	C1 LMS+C2 left PS and laminar screw	Intraoperative C2 pedicle fracture
17	7	W	Serous otitis media	C1–2	C1 LMS+C2 PS	None
18	8	M	ASD, strabismus, hypermetropia	C1–2	C1 LMS+C2 left PS and laminar screw	None
19	3	W	Aberrant right subclavian artery, hypoacusis	C1–2	C1 LMS+C2 PS	None
20	3	W	ASD, PDA	O–C2	Occipital plate+C2 left PS and laminar screw	Superficial infection

ECD, endocardial cushion defect; ASD, atrial septal defect; PDA, patent ductus arteriosus; VSD, ventricular septal defect; PS, pedicle screw; LMS, lateral mass screw.

tolerate general anesthesia. Hypoacusis or serous otitis media was found in 5; dysopia, 4; and gastrointestinal anomalies in 3 patients. One patient had recurrent pneumonia and bronchitis, although no congenital anomalies were diagnosed in the respiratory system (Table 1).

The operation time was 257.9 ± 55.6 minutes (182–365 minutes) (Fig. 1A), and the EBL was 101.6 ± 77.9 mL (22–330 mL) (Fig. 1B). None of the patients required a transfusion. Postoperative Halo immobilization was applied for 56.1 ± 23.7 days (0–90 days) (Fig. 1C). The postoperative follow-up period was 9.1 ± 4.8 years (2.0–19.8 years).

Complications related to the operation occurred in 6 patients (30.0%) (Table 2). They included one major complication in 1 patient (5.0%): hydrocephalus at 3 months postoperatively, possibly related to an intraoperative dural tear. Other complications included 3 cases of superficial surgical site infections, 1 case of deep infection in the bone graft donor site (iliac crest), 1 case of C2 pedicle fracture, 1 case of Halo ring dislocation at postoperative day 1, 1 case of pseudoarthrosis resulting in a revision surgery, and 1 case of temporary neurological deficit after Halo removal at 2 months postoperatively for an unknown reason. The case with pseudoarthrosis (case 1) had no postoperative complications in the revision surgery, which was not included in this study, and achieved bone union after the second surgery. The other 19 cases obtained bone union within 12 months. The complications that were indirectly related to the operation included 2 cases of respiratory infections and 1 case of implant loosening due to a fall at 9 months postoperatively (Table 3). No permanent or severe neurological complications related to

surgery and perioperative death were observed. During the follow-up, no subaxial malalignment significant adjacent disc degeneration, kyphotic changes, or hardware failure were observed.

To clarify the difference of complication rate between the construct type, we compared 3 cases with rod-wiring/hook constructs and 17 cases with rod-screw constructs. Surgery-related complication was observed in 2 cases with rod-wiring/hook constructs and 4 with rod-screw constructs ($p = 0.20$). Surgery-unrelated complication was found in 1 with rod-wiring/hook constructs and 2 with rod-screw constructs ($p = 0.40$).

1. Illustrative cases

1) Case 8

A 6-year-old girl was diagnosed with AAI by a pediatrician; however, she did not present any symptoms of cervical myelopathy or radiculopathy. She underwent cardiac surgery for ASD and VSD at 5 months of age, and her cardiac function was maintained. Lateral radiography indicated that AAI and the atlas were irreducible even at the extension position (Fig. 2A). We performed C1–2 fusion with C1 lateral mass screws and C2 pedicle screws, transplanting a bone graft from the right iliac crest (Fig. 2B). Because this case had an irreducible atlas, we gently release and loosen C1–2 facet joints followed by gradual reduction with C1 lateral mass screws and C2 pedicle screws. Upon reduction, the assistant surgeon carefully pushes the C2 spinous process, and the primary surgeon tightens the screws and rods. The lateral mass screw successfully reduced the dislocation of C1 and enabled the preservation of the posterior arch of the atlas. The operation time was 296 minutes, and the EBL was 330 mL. No intraoperative and postoperative complications were observed. After the application of the Halo vest for 2 months, followed by a cervical collar for 8 months, bone union was achieved. At the latest follow-up, 6 years postoperatively, no deterioration was found in clinical symptoms and radiographic features (Fig. 2C).

2) Case 9

A 4-year-old girl was diagnosed with AAI by a pediatrician, although she did not have any neurological symptoms. She underwent surgery for ASD at 6 months of age and her cardiac function was assessed to tolerate general anesthesia and cervical surgery. Lateral radiography indicated that AAI and the atlas were overreduced, that is posterior subluxation, at the extension position (Fig. 3A). We performed C1–2 fusion with C1 lateral mass screws and C2 pedicle screws, transplanting a bone graft from the right iliac crest (Fig. 3B). In the cases of os odon-

Table 3. Summary of the complications

Complication	No. of complications
Major complications (1 in 1 patient)	
Hydrocephalus (related to dural tear)	1
Other surgery-related complications (8 in 6 patients)	
Superficial infection	3
Deep infection (bone graft donor site: iliac crest)	1
C2 pedicle fracture	1
Halo ring dislocation	1
Pseudoarthrosis (resulting in revision surgery)	1
Temporary muscle weakness after Halo removal	1
Surgery-unrelated complications (3 in 3 patients)	
Respiratory infection	2
Implant loosening due to a fall	1

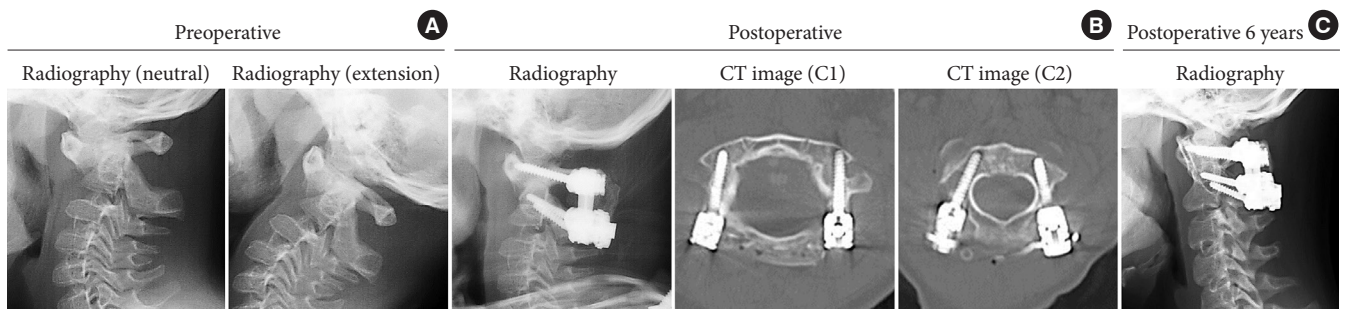


Fig. 2. Case 8. Six-year-old girl. (A) Preoperative lateral radiograph of the cervical spine at neutral and extension positions. C1 was irreducible even at the extension position. (B) Postoperative lateral radiography and computed tomography (CT) reconstruction of C1 and C2. Successful reduction of C1 and appropriate insertion of screws are shown. (C) Lateral radiograph at the latest follow-up at 6 years postoperatively. No instrument-related abnormal findings and subaxial deformity were found.

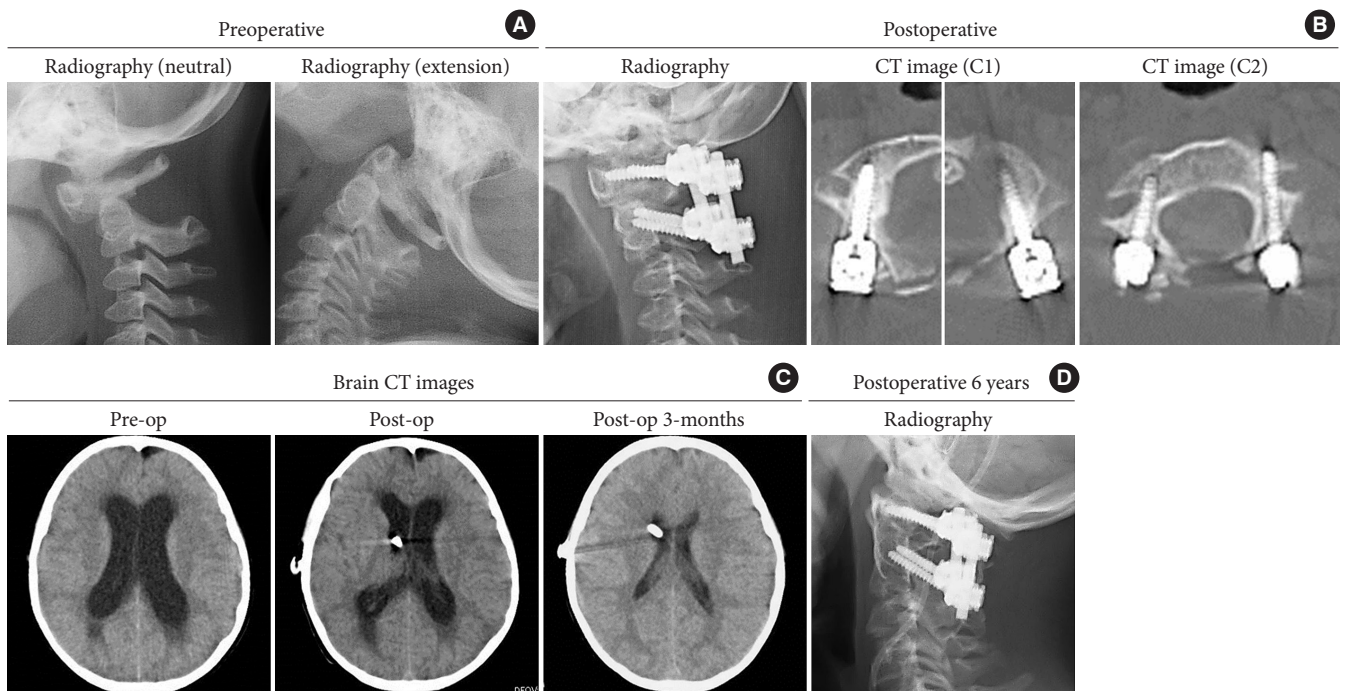


Fig. 3. Case 9. Four-year-old girl. (A) Preoperative lateral radiograph of the cervical spine at neutral and extension positions. C1 was overreduced (posterior subluxation) at the extension position. (B) Postoperative lateral radiography and computed tomography (CT) reconstruction of C1 and C2. Appropriate C1 reduction and screw insertion are shown. (C) Brain CT images after the diagnosis of hydrocephalus. Dilated cerebral ventricles were found, and ventriculoperitoneal shunting was performed. Hydrocephalus resolved after 3 months. (D) Lateral radiograph at the latest follow-up at 6 years postoperatively. No instrument-related abnormal findings and subaxial deformity were found.

toideum with posterior subluxation of atlas, os odontoideum protrudes into the spinal canal. Therefore, overreduction could result in cord compression and we have made a careful and mild reduction of the atlas. Because a dural tear occurred during the surgery, the tear was repaired using Prolene sutures. The operation time was 365 minutes, and the EBL was 120 mL. Although slight superficial infection and protracted wound

healing with subcutaneous accumulation of cerebrospinal fluid (CSF) were observed, no other complications were found until Halo removal at 2 months postoperatively. Four days after Halo removal, she developed a convulsive seizure. Brain CT showed hydrocephalus and ventriculoperitoneal shunting was performed immediately. Hydrocephalus gradually resolved (Fig. 3C). After the application of a cervical collar for 10 months,

bone union was achieved. At the latest follow-up, 6 years postoperatively, no deterioration was found in clinical symptoms and radiographic features (Fig. 3D).

DISCUSSION

The surgery-related complication rate of upper cervical fusion in pediatric patients with Down syndrome remained high at 30.0%. However, the percentage of major complications decreased substantially (5.0%), and no life-threatening or surgery-related severe neurological complications occurred. The overall complication rate in the current study was comparable to that reported in adult patients with rheumatoid arthritis (8.1%–41.8%).^{23–25} A strength of this study was relatively large population treated by a single surgeon, while a review/meta-analysis article has been published including various backgrounds and treatments.²⁶

Neurological complications are occasionally unpredictable; however, they can be minimized by the development of management approaches, such as preoperative imaging, intraoperative fluoroscopic guidance or navigation, and neurophysiological monitoring.²⁶ One patient (case 3) showed temporary muscle weakness in the right upper and lower limbs after Halo removal at 3 months postoperatively. However, the cause of muscle weakness could not be identified, even with image inspection. This late-phase neurological complication can only be recognized and handled by careful postoperative observation. Hydrocephalus, found in case 9, is not a common complication of spinal surgery. Several cases have been reported as late complications: 1 month after a C2 dumbbell tumor resection,²⁷ 10 months after lumbar decompression and fusion,²⁸ and 5 months after a stab injury to the upper cervical spine.²⁹ They do not appear to be specific to Down syndrome but are related to dural tear and repair. In case 9, the detailed cause of hydrocephalus is unclear. However, the patient exhibited dural tear followed by subcutaneous accumulation of CSF without any neurological symptoms under Halo vest immobilization and developed a convulsive seizure after Halo removal at postoperative 2 months. Thus, we estimated that dural tear and CSF leakage could be related to hydrocephalus. Once a dural tear is recognized, careful and long-term postoperative follow-up is warranted for symptoms, such as headache, nausea, and convulsions. In cases 3 and 9, these complications were observed immediately after Halo removal. Complications related to Halo vest immobilization are frequent in children,^{30,31} most of which are pin site infections and loosening. Although neurological complications immediately after

Halo removal has not been reported or elucidated, the sudden change in the axial pressure or alignment could have triggered the complications in our cases. The reason why we apply Halo vest immobilization is the difficulty in rest due to mental retardation and the demand for rigid fixation in the light of systemic joint laxity in Down syndrome. We applied Halo vest for 3 months when only hooks and wiring are available. However, after using lateral mass/pedicle screws, we have shortened the duration; as short as 1 month. We regard Halo vest as a support for bone union in patients with Down syndrome.

Pseudoarthrosis may be a major concern in fusion surgery for Down syndrome. For successful bone union, rigid fixation and substantial bone grafting are required,¹⁰ in which C1 lateral mass screws play a key role. The C1 lateral mass screws not only facilitate improved stabilization but also enable reduction of the dislocated atlas. This results in the preservation of the posterior arch of the atlas, which is a precious bed for bone grafting, as shown in case 8. A recent meta-analysis showed that screw fixation for pediatric AAI in patients with Down syndrome significantly reduced the loss of reduction or pseudoarthrosis.²⁶ Segal et al.⁵ reported that 10 pediatric patients with Down syndrome had cervical or O-C fusion with modified Gallie technique, resulting in 100% surgery-related complications. Among their cases, 7 of 10 patients exhibited graft absorption and/or hardware failure, which could be related to insufficient fixation. Doyle et al.⁶ reported 15 patients with Down syndrome, including 9 pediatric cases. In their study, 10 of 15 patients showed non-union and/or loss of reduction, which could be caused by a lack of rigid fixation. In our cases, especially after adopting C1 lateral mass screw, we consider that rigid fixation has been achieved owing to advance in the cervical instrumentation and the surgical techniques. This may be one reason for lower complication rate. Stabilization with C1 lateral mass screws helps avoid O-C fusion and maintain the O-C motion segment. Initially, we selected C1–2 fusion if the atlas was reducible at extension position of lateral radiography and O-C fusion if it was irreducible. However, after demonstrating that C1 lateral mass screws can reduce the irreducible atlas, we apply O-C fusion only for the cases in which C1 lateral mass screws cannot be inserted. We extended the fusion to C3 when we used hook/wiring or C2 was not available as an anchor due to anatomical reasons. After we started using C1 lateral mass screws for pediatric patients in 2009, no pseudoarthrosis was found in C1–2 fusion cases. However, rigid fixation in children can affect the growth of the C2 vertebral body and fused-disc height, as well as the subaxial alignment.^{22,32,33} Although there were no cases with postopera-

tive subaxial malalignment in our study, radiographic evaluation should be carefully continued.

Another concern is infection. Four surgical site infections, including 3 superficial infections and 1 deep infection, and 3 respiratory infections were found in our patients. Postoperative infection may be related to immunodeficiency in patients with Down syndrome,³⁴ which is not easy to prevent completely. The most optimal efforts should be careful observation and appropriate treatment once the infection is recognized.

A radiographic guideline, suggested in 2005, stated that surgical intervention is required when the ADI is >9.9 mm or the ADI is 4.5–10 mm with neurological deficit and evidence of spinal cord compression on MRI.³⁵ In this guideline, high-risk activities, such as gymnastics and soccer, were restricted when the ADI was higher than 4.5 mm even without neurological abnormalities, which indicated that even low-energy head injury could damage the spinal cord in these patients. While the incidence of symptomatic AAI is 10.0%–17.5% in all pediatric AAI patients with Down syndrome,^{3,8} it is difficult to predict the progressive widening of the ADI and the appearance of neurological deficits due to the lack of evidence in the natural course of AAI. Therefore, careful radiographic follow-up and physical assessment are required. Furthermore, we recommend early surgical intervention even without symptoms; our current surgical indication for AAI in pediatric patients with Down syndrome is an ADI larger than 7.0 mm with symptoms or an ADI larger than 7.0 mm with smaller SAC than 10.0 mm and os odontoideum without symptoms. We regard os odontoideum as a possible indicator of severe AAI. The cases with os odontoideum could have posterior subluxation at extension position as shown in case 9, which is sometimes difficult to point out. Because anterior arch rides on the axis at extension in posterior subluxation, careful interpretation of radiography is warranted. A high complication rate may have been the main reason why patients with Down syndrome are hesitant to undergo surgery. However, our results demonstrated that the rate is no longer extremely high compared to that in patients with other comorbidities such as rheumatoid arthritis.

This study has several limitations. First, the study has a retrospective design. Second, although O-C fusions and C1–2 fusions may differ in terms of their surgical invasion or stress for patients, we included them together. This difference could affect the incidence or severity of the complications. While we did not find specific complications to O-C fusions or C1–2 fusions, this difference could affect the incidence or severity of the complications.

CONCLUSION

While careful preoperative preparation and postoperative observation are undoubtedly needed, improved intra- and perioperative management can facilitate successful surgical intervention for upper cervical instability in pediatric patients with Down syndrome. Although the overall complication rate of upper cervical fusion in Down syndrome remains high, clinicians should not hesitate to select surgical intervention.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Original Article

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Spinal Fractures in Ankylosing Spondylitis: Patterns, Management, and Complications in the United States – Analysis of Latest Nationwide Inpatient Sample Data

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Objective: Ankylosing spondylitis (AS) is a rheumatic inflammatory disease marked by chronic inflammation of the axial skeleton. This condition, particularly when severe, can lead to increased risk of vertebral fractures attributed to decreased ability of the stiffened spinal column to sustain normal loads. However, little focus has been placed on understanding the locations of spinal fractures and associated complications and assessing the correlation between these. In this review, we aim to summarize the complications and treatment patterns in the United States in AS patients with spinal fractures, using the latest Nationwide Inpatient Sample (NIS) database (2016–2018).

Methods: We analyzed the NIS data of years 2016–2018 to compare the fracture patterns and complications.

Results: A total of 5,385 patients were included. The mean age was 71.63 years (standard deviation [SD], 13.21), with male predominance (83.8%). The most common population is Whites (77.4%), followed by Hispanics (7.9%). The most common fracture level was thoracic level (58.3%), followed by cervical level (38%). Multiple fracture levels were found in 13.3% of the patients. Spinal cord injury (SCI) was associated with 15.8% of the patients. The cervical level had a higher proportion of SCI (26.5%), followed by thoracic level (9.2%). The mean Elixhauser comorbidity score was 4.82 (SD, 2.17). A total of 2,365 patients (43.9%) underwent surgical treatment for the fractures. The overall complication rate was 40.8%. Respiratory complications, including pneumonia and respiratory insufficiency, were the predominant complications in the overall cohort. Based on the regression analysis, there was no significant difference ($p = 0.45$) in the complication rates based on the levels. The presence of SCI increased the odds of having a complication by 2.164 times (95% confidence interval, 1.722–2.72; $p \leq 0.001$), and an increase in Elixhauser comorbidity score predicted the complication and in-hospital mortality rate ($p \leq 0.001$).

Conclusion: AS patients with spinal fractures have higher postoperative complications than the general population. The most common fracture location was thoracic in our study, although it differs with few studies, with SCI occurring in 1/6th of the patients.

Keywords: Ankylosing spondylitis, Spinal fractures, Respiratory complications, National Inpatient Sample



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INTRODUCTION

Ankylosing spondylitis (AS) is a rheumatic disorder marked by chronic inflammation of the axial skeleton.¹ It is a relatively rare disease with an incidence of 0.5–14 per 100,000 people per year.² This condition, particularly when severe, can lead to increased risk of vertebral fractures attributed to decreased ability of the stiffened spinal column to sustain normal loads (decreased tensile strength of the spine as a unit).³ A population-based study reported an odds ratio of 7.7 for sustaining a spinal fracture in patients with AS compared to the average population. With each year of increasing age, a 1.3% risk of having a fracture is added.³ The reported prevalence of spinal fractures in AS patients is highly variable (1.4%–58%). Spinal trauma literature details a 6%–11% mortality rate in AS patients who underwent hospitalization for traumatic spinal fracture.⁴ Spinal cord injury (SCI) is a severe complication after traumatic fracture of the ankylosed spine.^{2,5} A Finnish national study reported the incidence of SCI in AS patients 11.4 times more than the average population.⁶

The etiology behind vertebral fractures in AS patients stems from inflamed facet joints and ligaments and stiffened intervertebral spaces, resulting in decreased spinal column flexibility.¹

The classic "bamboo spine" develops with even marginal syndesmophyte formation, contributing to compromised bone integrity (Fig. 1).⁷ Literature advocates comprehensive spinal imaging in AS patients who suffer from even mild trauma to ensure fractures are not overlooked. However, little focus has been placed on understanding the locations of spinal fractures and postfracture complications and the correlation between these. The extra-articular manifestations in AS affect the other systems (cardiovascular, respiratory, and renal, etc.), further complicating the postoperative course. In this review, we aim to summarize the complications and treatment patterns in the United States in AS patients with spinal fractures, using the latest Nationwide Inpatient Sample (NIS) database (2016–2018).

MATERIALS AND METHODS

1. Study Population

Data were extracted from the NIS database for the years 2016–2018 (3 years). NIS data is the largest database providing data of more than 7 million hospitalizations in the United States. The data is coded in the form of diagnostic and procedural International Statistical Classification of Diseases, 10th revision (ICD-10) codes.

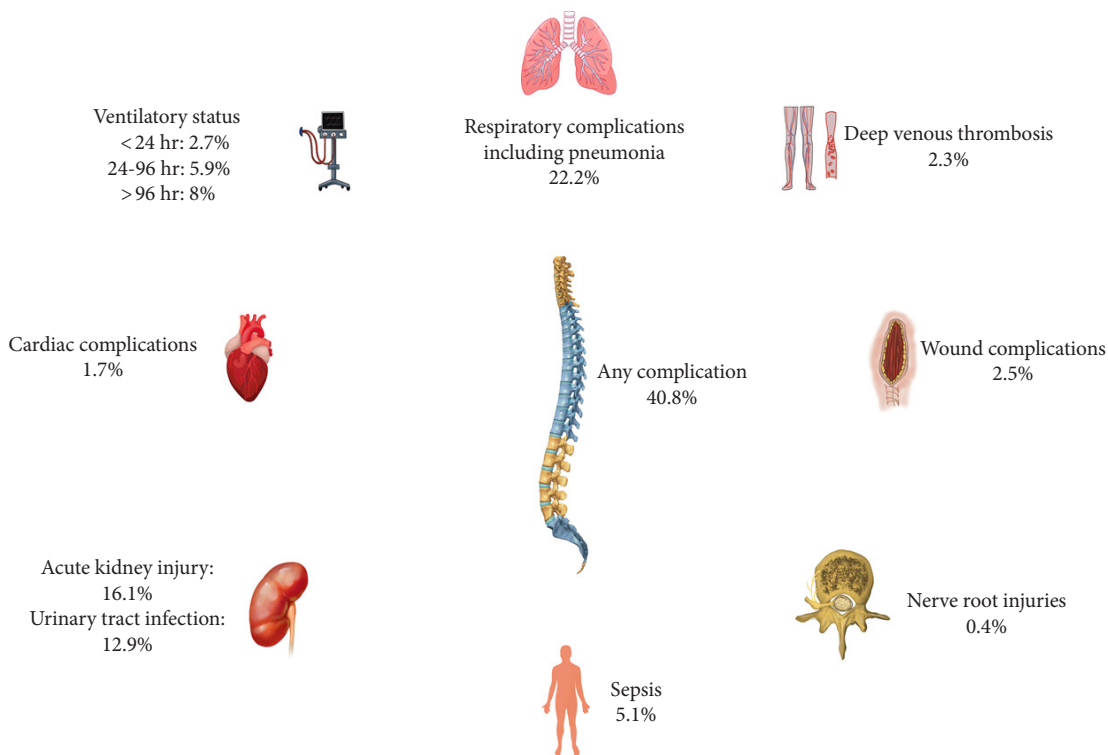


Fig. 1. Pathogenesis involved in ankylosing spondylitis.

Table 1. Details of the ICD-10 codes used for data extraction

Diagnosis	ICD-10 code
Ankylosing spondylitis	M45.(1-9)
Cervical fractures and dislocations	Base codes: S12.0(X), S12.1(X), S12.2X, S12.3(X), S12.4(X), S12.5(X), S12.6(X), S12.8(X), S12.9(X)
Thoracic fractures and dislocations	Base codes: S22.00(x), S22.01(x), S22.02(x), S22.03(x), S22.04(x), S22.05(x), S22.06(x), S22.07(x), S22.08(x)
Lumbar fracture	Base codes: S32.00(x), S32.01(X), S32.02(X), S32.03(X), S32.04(X), S32.05(X)
Sacral level	Base codes: S32.11(X), S32.12(X), S32.13(X), S32.14(X), S32.15(X), S32.16(X), S32.17(X), S32.19(X)
Spinal cord injury	S14(X), S24(X), S34(X)
Fusion	0RG0070,0RG0071,0RG007J,0RG00A0,0RG00AJ,0RG00J0,0RG00J1,0RG00JJ,0RG00K0,0RG00K1,0RG00KJ,0RG0370,0RG0371,0RG037J,0RG03A0,0RG03AJ,0RG03J0,0RG03J1,0RG03JJ,0RG03K0,0RG03K1,0RG03KJ,0RG0470,0RG0471,0RG047J,0RG04A0,0RG04AJ,0RG04J0,0RG04J1,0RG04JJ,0RG04K0,0RG04K1,0RG04KJ,0RG1070,0RG1071,0RG107J,0RG10A0,0RG10AJ,0RG10J0,0RG10J1,0RG10JJ,0RG10K0,0RG10K1,0RG10KJ,0RG1370,0RG1371,0RG137J,0RG13A0,0RG13AJ,0RG13J0,0RG13J1,0RG13JJ,0RG13K0,0RG13K1,0RG13KJ,0RG1470,0RG1471,0RG147J,0RG14A0,0RG14AJ,0RG14J0,0RG14J1,0RG14JJ,0RG14K0,0RG14K1,0RG14KJ,0RG2070,0RG2071,0RG207J,0RG20A0,0RG20AJ,0RG20J0,0RG20J1,0RG20JJ,0RG20K0,0RG20K1,0RG20KJ,0RG2370,0RG2371,0RG237J,0RG23A0,0RG23AJ,0RG23J0,0RG23J1,0RG23JJ,0RG23K0,0RG23K1,0RG23KJ,0RG2470,0RG2471,0RG247J,0RG24A0,0RG24AJ,0RG24J0,0RG24J1,0RG24JJ,0RG24K0,0RG24K1,0RG24KJ,0RG4070,0RG4071,0RG407J,0RG40A0,0RG40AJ,0RG40J0,0RG40J1,0RG40JJ,0RG40K0,0RG40K1,0RG40KJ,0RG4370,0RG4371,0RG437J,0RG43A0,0RG43AJ,0RG43J0,0RG43J1,0RG43JJ,0RG43K0,0RG43K1,0RG43KJ,0RG4470,0RG4471,0RG447J,0RG44A0,0RG44AJ,0RG44J0,0RG44J1,0RG44JJ,0RG44K0,0RG44K1,0RG44KJ,0RG6070,0RG6071,0RG607J,0RG60A0,0RG60AJ,0RG60J0,0RG60J1,0RG60JJ,0RG60K0,0RG60K1,0RG60KJ,0RG6370,0RG6371,0RG637J,0RG63A0,0RG63AJ,0RG63J0,0RG63J1,0RG63JJ,0RG63K0,0RG63K1,0RG63KJ,0RG6470,0RG6471,0RG647J,0RG64A0,0RG64AJ,0RG64J0,0RG64J1,0RG64JJ,0RG64K0,0RG64K1,0RG64KJ,0RG7070,0RG7071,0RG707J,0RG70A0,0RG70AJ,0RG70J0,0RG70J1,0RG70JJ,0RG70K0,0RG70K1,0RG70KJ,0RG7370,0RG7371,0RG737J,0RG73A0,0RG73AJ,0RG73J0,0RG73J1,0RG73JJ,0RG73K0,0RG73K1,0RG73KJ,0RG7470,0RG7471,0RG747J,0RG74A0,0RG74AJ,0RG74J0,0RG74J1,0RG74JJ,0RG74K0,0RG74K1,0RG74KJ,0RG8070,0RG8071,0RG807J,0RG80A0,0RG80AJ,0RG80J0,0RG80J1,0RG80JJ,0RG80K0,0RG80K1,0RG80KJ,0RG8370,0RG8371,0RG837J,0RG83A0,0RG83AJ,0RG83J0,0RG83J1,0RG83JJ,0RG83K0,0RG83K1,0RG83KJ,0RG8470,0RG8471,0RG847J,0RG84A0,0RG84AJ,0RG84J0,0RG84J1,0RG84JJ,0RG84K0,0RG84K1,0RG84KJ,0SG0070,0SG0071,0SG007J,0SG00A0,0SG00AJ,0SG00J0,0SG00J1,0SG00JJ,0SG00K0,0SG00K1,0SG00KJ,0SG0370,0SG0371,0SG037J,0SG03A0,0SG03AJ,0SG03J0,0SG03J1,0SG03JJ,0SG03K0,0SG03K1,0SG03KJ,0SG0470,0SG0471,0SG047J,0SG04A0,0SG04AJ,0SG04J0,0SG04J1,0SG04JJ,0SG04K0,0SG04K1,0SG04KJ,0SG1070,0SG1071,0SG107J,0SG10A0,0SG10AJ,0SG10J0,0SG10J1,0SG10JJ,0SG10K0,0SG10K1,0SG10KJ,0SG1370,0SG1371,0SG137J,0SG13A0,0SG13AJ,0SG13J0,0SG13J1,0SG13JJ,0SG13K0,0SG13K1,0SG13KJ,0SG1470,0SG1471,0SG147J,0SG14A0,0SG14AJ,0SG14J0,0SG14J1,0SG14JJ,0SG14K0,0SG14K1,0SG14KJ,0SG3070,0SG3071,0SG307J,0SG30A0,0SG30AJ,0SG30J0,0SG30J1,0SG30JJ,0SG30K0,0SG30K1,0SG30KJ,0SG3370,0SG3371,0SG337J,0SG33A0,0SG33AJ,0SG33J0,0SG33J1,0SG33JJ,0SG33K0,0SG33K1,0SG33KJ,0SG3470,0SG3471,0SG347J,0SG34A0,0SG34AJ,0SG34J0,0SG34J1,0SG34JJ,0SG34K0,0SG34K1,0SG34KJ,0SG5070,0SG5071,0SG507J,0SG50A0,0SG50AJ,0SG50J0,0SG50J1,0SG50JJ,0SG50K0,0SG50K1,0SG50KJ,0SG5370,0SG5371,0SG537J,0SG53A0,0SG53AJ,0SG53J0,0SG53J1,0SG53JJ,0SG53K0,0SG53K1,0SG53KJ,0SG5470,0SG5471,0SG547J,0SG54A0,0SG54AJ,0SG54J0,0SG54J1,0SG54JJ,0SG54K0,0SG54K1,0SG54KJ,0SG6070,0SG6071,0SG607J,0SG60A0,0SG60AJ,0SG60J0,0SG60J1,0SG60JJ,0SG60K0,0SG60K1,0SG60KJ,0SG6370,0SG6371,0SG637J,0SG63A0,0SG63AJ,0SG63J0,0SG63J1,0SG63JJ,0SG63K0,0SG63K1,0SG63KJ,0SG6470,0SG6471,0SG647J,0SG64A0,0SG64AJ,0SG64J0,0SG64J1,0SG64JJ,0SG64K0,0SG64K1,0SG64KJ
Corpectomy	0P540ZZ,0P840ZZ,0PB40ZX,0PB40ZZ,0PC40ZZ,0PD40ZZ,0PH404Z,0PN40ZZ,0PR407Z,0PR40JZ,0PR40KZ,0PU407Z,0PU40JZ,0PU40KZ,0R560ZZ,0RB60ZX,0RB60ZZ,0RC90ZZ,0RG6070,0RG607J,0RG60A0,0RG60AJ,0RG60Z0,0RG60JJ,0RG60K0,0RG60KJ,0RH604Z,0RH608Z,0RR607Z,0RR60JZ,0RR60KZ,0XRG609Z,0XRG60F3,0XRG709Z,0XRG70F3,0XRG809Z,0XRG80F3,0Q500ZZ,0Q800ZZ,0QB00ZX,0QB00ZZ,0QC00ZZ,0QD00ZZ,0QH004Z,0QH005Z,0QN00ZZ,0QR007Z,0QR00JZ,0QR00KZ,0QS004Z,0QS00ZZ,0QS0XZZ,0QU007Z,0QU00JZ,0QU00KZ,0S500ZZ,0SB00ZX,0SB00ZZ,0SC00ZZ,0SG0070,0SG007J,0SG00A0,0SG00AJ,0SG00J0,0SG00JJ,0SG00K0,0SG00KJ,0SH004J,0SH008Z,0SN00ZZ,0SR007Z,0SR00JZ,0SR00KZ,0SU007Z,0SU00JZ,0SU00KZ,0P530ZZ,0P830ZZ,0PB30ZX,0PB30ZZ,0PC30ZZ,0PD30ZZ,0PH304Z,0PN30ZZ,0PR307Z,0PR30JZ,0PR30KZ,0PU307Z,0PU30JZ,0PU30KZ,0R500ZZ,0RB00ZX,0RB00ZZ,0RB10ZX,0RB10ZZ,0RC00ZZ,0RC10ZZ,0RG0070,0RG0071,0RG007J,0RG00A0,0RG00AJ,0RG00J0,0RG00J1,0RG00JJ,0RG00K0,0RG00KJ,0RG1070,0RG107J,0RG10A0,0RG10AJ,0RG10J0,0RG10J1,0RG10JJ,0RG10K0,0RG10KJ,0RH004Z,0RR007Z,0RR00JZ,0RR00KZ,0RR107Z,0RR10JZ,0RR10KZ,0RU007Z,0RU00JZ,0RU00KZ,0RU107Z,0RU10JZ,0RU10KZ,0XRG009Z,0XRG00F3,0XRG109Z,0XRG10F3

(Continued)

Table 1. Details of the ICD-10 codes used for data extraction (continued)

Diagnosis	ICD-10 code
Wound complications, including CSF leak	T81.3,T81.30,T81.30XA,T81.30XD,T81.30XS,T81.31,T81.31XA,T81.31XD,T81.31XS,T81.32,T81.32XA,T81.32XD,T81.32XS, G97.0
Respiratory complications	J81.0,J80,J96.00,J96.90,J96.91,J96.92,J96.01,J96.02,J95.89,J95.859,T8.182XA,J18,J18.0,J18.1,J18.2,J18.8,J18.9
Acute Kidney Injury	N17.0,N17.1,N17.2,N17.8,N17.9
UTI	N39.0
Cardiac complications	I97.710, I97.790, I97.88, I97.89
Nerve root injuries	S14.2(X), S24.2(X), S34.2(X)
Sepsis and septic shock	A410,A4101,A4102,A411,A412,A413,A414,A415,A4150,A4151,A4152,A4153,A4159,A418,A4181,A4189,A419,T81.12, T81.12XA, T81.12XD, T81.12XS
Ventilation	5A1935Z, 5A1945Z, 5A1955Z
DVT	I82.2(X)

ICD-10, International Statistical Classification of Diseases, 10th revision; CSF, cerebrospinal fluid; UTI, urinary tract infection; DVT, deep venous thrombosis.

2. Inclusion Criteria

(1) All patients with AS and spinal fractures, (2) Spinal fractures as a primary cause of admission, age > 18 years.

3. Exclusion Criteria

Spinal fractures are not a primary cause of admission.

4. Data Extraction

The data was extracted from the NIS data based on the ICD-10 diagnostic and procedural codes. NIS data provides weighted frequencies allowing to extrapolate national estimates. The diagnostic and procedural codes used to extract AS, spinal fractures at various levels, and complications of the surgical treatment were detailed in Table 1. The data were grouped based on the fracture level (i.e., cervical, thoracic, etc.).

The patient-level comorbidities were extracted based on the Elixhauser comorbidity algorithm⁸ provided on the Healthcare Cost and Utilization Project website (<https://www.hcup-us.ahrq.gov/nisoverview.jsp>). Along with these variables, patient-level factors like race, socioeconomic characteristics, location of the patient, and hospital and patient's zip code's median income were also analyzed and described in the descriptive fashion. Complications were calculated for the patients who underwent surgical treatment.

5. Statistical Analysis

All variables were described in a standard descriptive fashion. Continuous variables are described as mean, standard deviation (SD), and median as appropriate and categorical variables as frequencies. Logistic regression analysis was used to calculate

the odds ratios for the mutually exclusive levels and probability of the complications after adjusting for the SCI, Elixhauser comorbidities score and used Wald statistics to test the differences between them. Statistical significance was considered if the p-value (2-tailed) is 0.05. NIS discharge weights were used to extrapolate at the national level. All the analysis was performed using IBM SPSS Statistics ver. 27.0 (IBM Co., Armonk, NY, USA).

RESULTS

1. Clinical Characteristics

1) Overall patient cohort

A total of 5,385 patients were included. The mean age was 71.63 years (SD, 13.21), with male predominance (83.8%). The most common population is Whites (77.4%), followed by Hispanics (7.9%). The most common fracture level was thoracic level (58.3%), followed by cervical level (38%). Multiple fracture levels were found in 13.3% of the patients. SCI was associated with 15.8% of the patients. The cervical level had a higher proportion of SCI (26.5%), followed by thoracic level (9.2%). The mean Elixhauser comorbidity score was 4.82 (SD, 2.17). Complete details are listed in Table 2.

2) Socioeconomic characteristics

Overall Central counties (24.8%) and Fringe counties (24.8%) are the predominant locations of the patients. Twenty-seven percent of the patients fell in the 51st to 75th percentile of the zip codes' median household income. The most common insurance availed was Medicare (70.9%), followed by

Table 2. Demographics and discharge dispositions of the cohorts (weighted frequencies)

Variable	Overall (n = 5,385)	Cervical (n = 2,055)	Thoracic (n = 3,140)	Lumbar (n = 955)	Sacral (n = 120)
Age (yr)	71.63 ± 3.21	69.88 ± 13.58	72.20 ± 12.85	71.30 ± 13.4	69.54 ± 15.75
Sex					
Male	83.8	88.6	83.4	82.2	45.8
Female	16.2	11.4	16.6	17.8	54.2
Race					
White	4,170 (77.4)	1,520 (74)	2,455 (78.2)	740 (77.5)	100 (83.3)
African Americans	265 (4.9)	145 (7.3)	110 (3.5)	65 (6.8)	N/A
Hispanics	265 (7.9)	185 (9.3)	250 (8)	55 (5.8)	10 (8.3)
Asian/Pacific Islander	165 (3.1)	90 (4.4)	75 (2.4)	25 (2.6)	N/A
Native Americans	30 (0.6)	5 (0.2)	25 (0.8)	5 (0.5)	5 (4.2)
Others	110 (2)	40 (1.9)	65 (2.1)	30 (3.1)	N/A
Spinal cord injury	850 (15.8)	545 (26.5)	290 (9.2)	45 (4.7)	N/A
Elixhauser comorbidity score	4.82 ± 2.14	4.45 ± 2.05	5.13 ± 2.14	4.67 ± 2.28	6 ± 0
Insurance					
Medicare	3,820 (70.9)	1,375 (66.9)	2,265 (72.1)	675 (70.7)	70 (58.3)
Medicaid	225 (4.2)	130 (6.3)	80 (2.5)	35 (3.7)	10 (8.3)
Private	970 (18)	380 (18.5)	580 (18.5)	180 (18.8)	35 (29.2)
Self-pay	100 (1.9)	65 (3.2)	35 (1.1)	15 (1.6)	5 (4.2)
No charge	10 (0.2)	10 (0.5)	N/A	N/A	N/A
Others	250 (4.6)	90 (4.4)	175 (5.6)	50 (5.2)	N/A
Patient location					
“Central” counties of metro areas of ≥ 1 million population	1,335 (24.8)	470 (22.9)	785 (25)	270 (28.3)	50 (41.7)
“Fringe” counties of metro areas of ≥ 1 million population	1,335 (24.8)	520 (25.3)	785 (25)	240 (25.1)	30 (25)
Counties in metro areas of 250,000–999,999 population	1,185 (22)	515 (25.1)	635 (20.2)	175 (18.3)	15 (12.5)
Counties in metro areas of 50,000–249,999 population	495 (9.2)	205 (10)	275 (8.8)	80 (8.4)	10 (8.3)
Micropolitan counties	555 (10.3)	210 (10.2)	325 (10.4)	100 (10.5)	15 (12.5)
Not metropolitan or micropolitan counties	465 (8.6)	125 (6.1)	325 (10.4)	90 (9.4)	N/A
Discharge disposition					
Routine	1,040 (19.3)	445 (21.7)	585 (18.6)	165 (17.3)	10 (8.3)
Transfer to short-term hospital	240 (4.5)	110 (5.4)	160 (5.1)	20 (2.1)	N/A
Transfer other: includes skilled nursing facility, intermediate care facility, another type of facility	3,115 (57.8)	1,065 (51.8)	1,860 (59.2)	595 (62.3)	95 (79.2)
Home Health Care	640 (11.9)	235 (11.4)	370 (11.8)	125 (13.1)	15 (12.5)
Against Medical Advice	10 (0.2)	5 (0.2)	5 (0.2)	50 (5.2)	N/A
Died	335 (6.2)	190 (9.2)	160 (5.1)	N/A	N/A
Hospital charges (US dollar)	162,423.63 ± 16,7112	184,558.78 ± 183,818	163,523.38 ± 161,991	150,966.64 ± 136,839	142,685.26 ± 241,209
Median household income					
0–25th percentile	1,180 (21.9)	470 (22.9)	670 (21.3)	225 (23.6)	30 (25.0)
26th–50th percentile (median)	1,400 (26.0)	580 (28.2)	815 (26.0)	260 (27.2)	20 (16.7)
51st–75th percentile	1,490 (27.7)	580 (28.2)	870 (27.7)	220 (23.0)	30 (25.0)
76th–100th percentile	1,215 (22.6)	385 (18.7)	730 (23.2)	220 (23.0)	40 (33.3)

Values are presented as mean ± standard deviation or number (%).

NA, not available.

private insurance (18%) (Table 2).

3) Surgical treatment and complications

A total of 2,365 patients (43.9%) underwent surgical treatment for the fractures. The most common surgery was fusion (71%), followed by corpectomy (29%). Fusion was the predominant surgery in all the groups. In the cervical level, 64.4% of the patients underwent 2 or more levels fusion. In thoracic fractures, 76.1% patients underwent 2 to 7 levels of fusion and 0.4% of the patients underwent more than 8 levels of the fusion. In lumbar fractures, 9.2% of the patients underwent 2 or more levels of fusion. The overall complication rate was 40.8% (Table 3). Respiratory complications, including pneumonia and respiratory insufficiency, were the predominant complications in the overall cohort (22.2%) as well cervical (27.7%), thoracic (21.5%), and lumbar (13%) levels (Fig. 2). Sacral fractures had lesser respiratory complications (13%). Cervical fracture patients (10.9%) required ventilatory support for more than 96 hours. The next common complication was acute kidney injury (AKI) (16.1%). Thoracic levels (18.3%) and lumbar levels (18.2%) had a higher proportion of AKI. Urinary tract infections (UTI) were found

in 12.9% of the patients. Wound complications were found in 2.5% of the patients overall, with the lumbar level having the highest rate (5.2%). The cardiac complication rate was 1.7%, and the deep venous thrombosis rate was 2.3%. Sepsis was found in 5.1% of patients overall. The mean hospital stay was 11.44 days (SD, 12.57) overall. The in-hospital mortality rate was 5.7% overall, with the cervical level (7.9%) being higher than other levels. The mean hospital charges were \$162,423.63 (SD, 167,112), with the cervical level having the highest charges (\$184,558). Overall, the most common discharge disposition was to a skilled nursing facility or another type of facility for rehabilitation (57.8%), followed by discharge to home (19.3%).

Logistic regression analysis was used after adjusting for the Elixhauser comorbidities and SCI, predominantly affecting the complication rate (Table 4). The probability of the complications by the fracture level was computed through the odds ratio with the lumbar level as the reference. Based on the regression analysis, there was no significant difference ($p = 0.45$) in the complication rates based on the levels. The odds ratio of having a complication in the cervical level patients was 1.308 (95% confidence interval [CI], 0.829–2.064; $p = 0.247$), 1.141 (95% CI, 0.722–1.803;

Table 3. Surgical management, complications, length of stay, and mortality (weighted frequencies)

Variable	Overall	Cervical (n = 2,055)	Thoracic (n = 3,140)	Lumbar (n = 955)	Sacral (n = 120)
Surgery	2,365 (43.9)	1,010 (49.1)	1,420 (45.2)	385 (40.3)	20 (16.6)
Fusion	1,680/2,365 (71)	625/1,010 (61.9)	1,100/1,420 (77.5)	225/385 (58.4)	15/20 (75)
Corpectomy	685/2,365 (29)	385/1,010 (38.1)	320/1,420 (22.5)	160/385 (41.6)	5/20 (25)
No. of levels fused	NA	2/more = 64.4%	2 to 7 levels = 76.1% > 8 levels = 0.4%	2/more levels = 9.2%	NA
Any complication	40.8%	435/1,010 (43.1)	590/1,420 (41.5)	145/385 (37.7)	5/20 (25)
Wound complications	2.5%	15/1,010 (1.5)	40/1,420 (2.8)	20/385 (5.2)	5/20 (25)
Respiratory including pneumonia	22.2%	280/1,010 (27.7)	305/1,420 (21.5)	50/385 (13)	0%
Ventilation < 24 hr	2.7%	30/1,010 (3)	40/1,420 (2.8)	10/385 (2.6)	0%
Ventilation 24 hr–96 hr	5.9%	90/1,010 (8.9)	65/1,420 (4.6)	70/385 (7.8)	0%
Ventilation > 96 hr	8%	110/1,010 (10.9)	110/1,420 (7.7)	10/385 (2.6)	0%
Cardiac complications	1.7%	10/1,010 (1)	35/1,420 (2.5)	5/385 (1.3)	0%
Acute kidney injury	16.1%	125/885 (12.4)	260/1,420 (18.3)	70/385 (18.2)	0%
UTI	12.9%	105/1,010 (10.4)	195/1,420 (13.7)	45/385 (11.7)	5/20 (25)
Nerve root injuries	0.4%	5/1,010 (0.5)	5/1,420 (0.4)	0%	0%
DVT	2.3%	20/1,010 (2)	35/1,420 (2.5)	15/385 (3.9)	5/20 (25)
Sepsis	5.1%	30/1,010 (3)	75/1,345 (5.3)	45/385 (5.2)	5/20 (25)
In-hospital mortality	135/2,365 (5.7)	80/1,010 (7.9)	70/1,420 (4.9)	25/385 (6.5)	
Hospital stay (day)	11.44 ± 12.57	12.17 ± 14.9	11.13 ± 11.16	12.65 ± 17.2	41.75 ± 54 (median, 13)

Values are presented as number (%) or mean ± standard deviation unless otherwise indicated.

NA, not available; UTI, urinary tract infection; DVT, deep venous thrombosis.

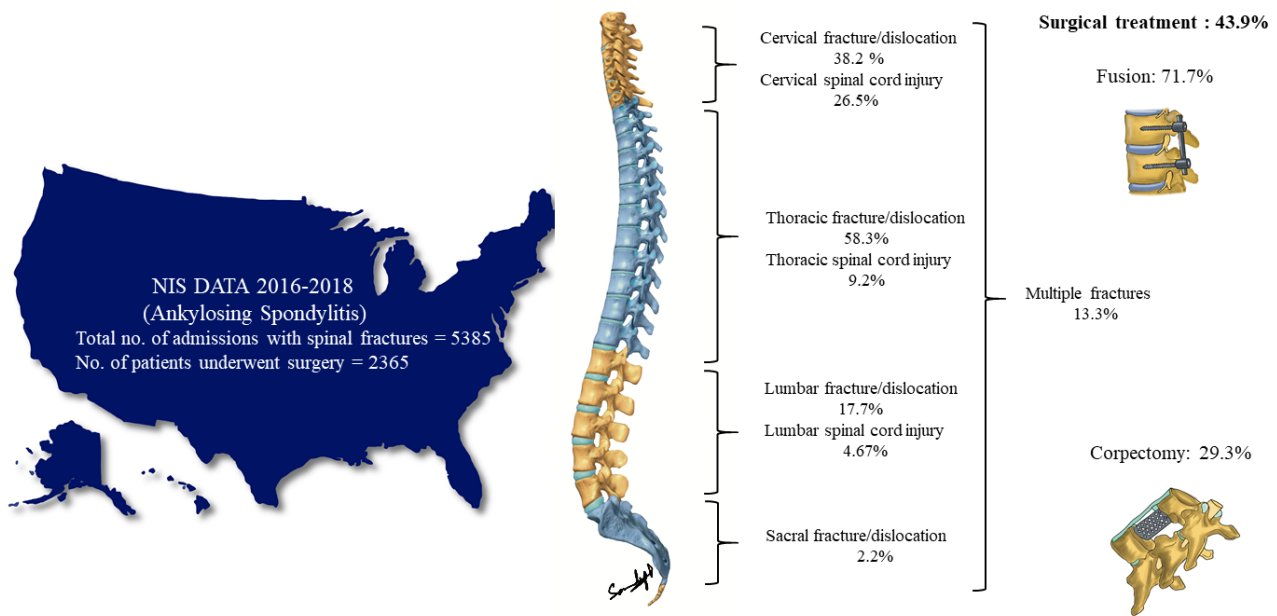


Fig. 2. Distribution of overall cohort, spinal cord injury, and surgical treatments. NIS, Nationwide Inpatient Sample.

Table 4. Logistic regression analysis of factors predicting complications and in-hospital mortality

Variable	Any complication			In-hospital mortality		
	OR	95% CI	p-value	OR	95% CI	p-value
Age	NA	NA	0.0518	NA	NA	0.0518
Elixhauser comorbidity score	NA	NA	<0.001	NA	NA	<0.001
Presence of spinal cord injury	2.164	1.722–2.72	<0.001	Excluded in the model		
Multiple levels	1.073	0.643–1.792	0.7866	2.527	0.913–6.998	0.0743
Cervical level	1.308	0.829–2.064	0.2472	1.761	0.714–4.341	0.2186
Thoracic level	1.141	0.722–1.803	0.5721	0.536	0.211–1.362	0.1894
Lumbar level	1.119	0.698–1.795	0.6395	1.26	0.513–3.098	0.6131

OR, odds ratio; CI, confidence interval; NA, not available.

p=0.5721) in the thoracic level, and 1.119 (95% CI, 0.698–1.795; p=0.6395) in the lumbar level; however, none of them were statistically significant. The presence of SCI increased the odds of having a complication by 2.164 times (95% CI, 1.722–2.72; p≤0.001), and a unit increase in Elixhauser comorbidity score increased the odds of having complications (p≤0.001). Age (p=0.296) and the presence of multiple fracture levels (odds ratio [OR], 1.073; 95% CI, 0.643–1.792; p=0.786) did not predict the complication rate. In-hospital mortality was predicted only by Elixhauser comorbidity score (p≤0.001) (Table 4).

DISCUSSION

Spinal fractures are a relatively rare complication of AS pa-

tients. Since AS is a relatively less common rheumatological disease, the literature describing the patterns of spinal fractures and complications of surgical management is mainly in the form of single-center studies and systematic reviews. Through the NIS database, we aim to review the treatment patterns and complications for traumatic fractures in AS patients at the national level. In our study, the majority of the patients underwent non-operative management (56.1%). Our data is not granular enough to distinguish different types of nonoperative management due to the coding bias. Our study's most common fracture level was thoracic, followed by cervical level, although it differs with a few studies⁹⁻¹³ (Table 5). In the operated patients, 40.8% had at least one complication, with respiratory (22.2%) being the most common complication. The presence of the complications did

Table 5. Literature review of ankylosing spondylitis with spinal fractures

Study	Total no. of patients	Average age (yr)	Patients with fractures	Total fracture incidents	Fracture location	Complications with rates (%)	Median length of stay (day)	Mortality rate (%)
Teunissen et al. ¹⁰ (2017)	2,089	69.3	172	189	C: 104 (60.8) T: 72 (42.1) L: 26 (15.2) S: 3 (1.8)	Pneumonia (50.6), respiratory failure (6.4), altered mental status (6.4), UTI (4.3), wound infection (2.1)	7 (3–15)	24.6
Longo et al. ¹¹ (2015)	110	59.2	86	110	C: 110 (100.0) T: 0 L: 0 S: 0	Epidural (2.0) hematoma, pneumonia (5.0), infection (4.0), ARDS (2.0)	NA	21.0
Rustagi et al. ¹² (2017)	-	63.4	-	-	C: 53.0 T: 41.9 L: 18.2 S: 1.5	Overall 84.0: (pneumonia, respiratory failure)	NA	32
Lukasiewicz et al. ⁹ (2016)	939	68.4	939	1,076	C: 53.0 T: 41.9 L: 18.2 S: 1.5	UTI (9.6), AKI (7), pneumonia (6.3)	NA	6.6
Sedney et al. ¹⁷ (2016)	38	74.0	38	38	T: 87.0 Multilevel: 13.0	Reoperation (13)	NA	13
Moussallem et al. ¹⁸ (2016)	41	75.56	17	17	C: 0 T: 30.0 L: 65.0 S: 2.5	Overall 67.5 (wound infection, DVT, PE, pneumonia)	NA	5.0
Altun et al. ¹³ (2016)	30	70.4	30	42	C: 60.0 T: 33.0 L: 3.0 S: 4.0	Pseudoarthrosis (3.3), wound infection (3.3), pneumonia (3)	NA	3.3
Robinson et al. ¹⁴ (2015)	17,297	65.7	990	1131	C: 53.9 T: 36.5 L: 25.0 S: 6	Pseudoarthrosis, wound infection	NA	17
Lu et al. ¹⁹ (2013)	28	54.2	25	25	C: 7.0 T: 52.0 L: 36.0 S: 5.0	Overall 66.7 (respiratory failure, empyema, osteomyelitis)	NA	0
Kouyoumdjian et al. ²⁰ (2012)	19	60.84	19	19	C: 100.0 T: 0 L: 0 S: 0	Hematoma (5.3)	NA	26
Backhaus et al. ²¹ (2011)	119	67.0	119	129	C: 39.5 T: 42.6 L: 17.8 S: 0	Wound infection (14), Pseudoarthrosis requiring revision (15)	NA	NA
Caron et al. ⁵ (2010)	112	62.4	112	122	C: 55.0 T: 21.0 L: 8.0 S: 0 TL Jxn: 16.0	UTI (35), Wound infection (16), DVT (8)	NA	NA

(Continued)

Table 5. Literature review of ankylosing spondylitis with spinal fractures (continued)

Study	Total no. of patients	Average age (yr)	Patients with fractures	Total fracture incidents	Fracture location	Complications with rates (%)	Median length of stay (day)	Mortality rate (%)
Sapkas et al. ²² (2009)	20	55.4	20	20	C: 35.0 T: 45.0 L: 5.0 S: 0 TL Jxn: 15.0	Wound infection (5), Hardware loosening (10)	NA	NA
Kanter et al. ²³ (2008)	13	60.4	13	13	C: 53.8 T: 46.2 L: 0 S: 0	Hardware failure (15), neurological decline (8)	NA	8
Thumbikat et al. ²⁴ (2007)	18	56.2	18	18	C: 78.0 T: 14.0 L: 5.5 S: 5	Neurologic decline after surgery (17)	63–204	28

C, cervical; T, thoracic; L, lumbar; S, sacral; PE, pulmonary embolism; ARDS, acute respiratory distress syndrome; UTI, urinary tract infections; NA, not available; AKI, acute kidney injury; DVT, deep venous thrombosis.

not depend upon the fracture level rather dependent upon the Elixhauser comorbidities ($p \leq 0.001$) and the presence of the SCI (OR, 2.164; 95% CI, 1.722–2.72; $p \leq 0.001$). In our study, age was not a predictor of complication rate ($p = 0.296$).

1. Age

The mean age in our study was 71.63 years (SD, 13.21) with the range of 23 years to 90 years. Most of the studies reported a mean age of >65 years. Our study is in agreement with these studies.^{9-12,14} As age increases, the severity of the disease increases and the chances of fall, predisposing to spinal fractures in these patients. Few single-center studies reported age as an independent predictor of mortality in AS patients with spinal fractures,⁵ the inherent limitations in the NIS data precludes us from doing a survival analysis. Also, in our study, the in-hospital mortality rate was not affected by age ($p = 0.051$).

2. Sex

Our study showed a male predominance (83.8%), in line with the results of other studies. Interestingly in the sacral fractures, there was a female predominance (54.2%). Evidence shows the HLA-B27 allele (most important allele in AS) being less often positive in women, explaining the male predominance. Another interesting genetic study in AS patients showed 1,522 unique gene expressions in males and 291 genes in women compared to controls in the general population.¹⁵ Hormones play an essential role in modulating the pain mechanisms, inflammation, and syndesmophytes development.¹⁶ Rusman et al.¹⁶ in their re-

view, reported that although men have a higher radiological progression, the disease burden is equal.

3. Spinal Cord Injury

The rate of SCI was 15.8% in our study. SCI was associated with a higher chance of postoperative complications in our study. Westerveld et al.⁴ reported an SCI incidence of 67.2% in 232 AS patients. Another study by Caron et al.⁵ reported an incidence of 58%. In another older NIS database study, the incidence of SCI reported was 21.2%. There are significant discrepancies between the institutional cohorts and NIS data, reflecting the coding patterns and bias in the NIS sample. Also, the chance of having a delayed SCI in AS patients cannot be underestimated. Harboring an unstable fracture that was either missed in the initial evaluation or ignored by the patients as the injury is trivial can progress to a delayed SCI. Teunissen et al.¹⁰ in their study, reported a delay in diagnosis of spinal fracture in 44.2% of the patients. The delay in diagnosis was associated with SCI in 4.1% of the cases. Similarly, Caron et al.⁵ reported an incidence of 36.8% delayed diagnosis in their series. Hence it is recommended to evaluate for a spinal fracture in AS patients with persistent pain after minor fall/trauma even though the pain is not disabling.

4. Complication Rates

Our study showed that at least one complication was present in 40.8% of the patients who underwent surgical treatment. Respiratory complication was the most common (22.2%), followed by AKI (16.1%) and UTI (12.9%). Most of the studies showed

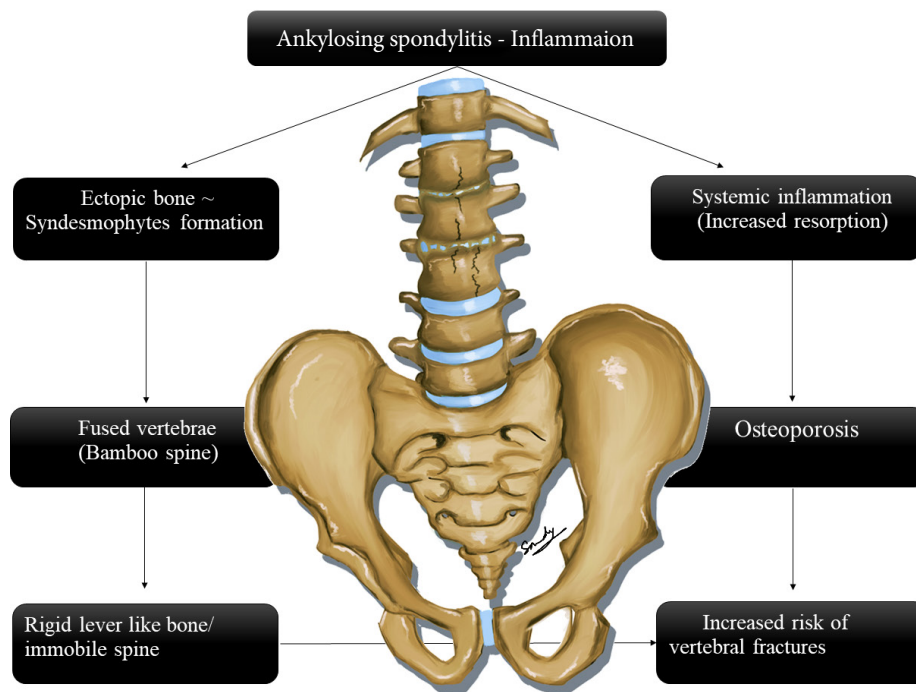


Fig. 3. Showing the distribution of the complications.

significant morbidity and complications in the AS patients irrespective of the treatment.¹⁷⁻²⁴ Based on these studies, the complications might be a manifestation of physiological endpoints of organ modeling in AS rather than the procedures per se (Fig. 3). The majority of people are near 70 years with a mean comorbidity score of 4.82, predisposing them to multiple postoperative complications. Our study showed ventilator dependency of more than 96 hours in 8% of the people, with cervical patients being higher (10.9%) than others. A Danish National registry reported 57.6% of AS patients have at least one or more comorbidities.²⁵ Interestingly they also reported that AS with pneumonia as a cause of admission did not increase the mortality rates. Although intriguing, our study cannot be compared with this registry as they differ in population sets. Westerveld et al. reported higher complications than the control population (85.7% vs. 48.7%) in the AS patients.²⁶ Lukasiewicz et al.⁹ reported that fracture location did not correlate with the adverse events in agreement with our study. However, we included only inpatient complications, which can underreport the delayed complications if post-discharge was also considered.

5. Limitations

Our study has several limitations. The lack of SCI severity grading (pre-and postinjury), mechanism of the injury, readmission data due to complications, and long-term follow-up

were a few, limiting us to discuss only the early complications in the postoperative period. Along with these, the preoperative comorbidities specific to AS which can influence the postoperative outcome were not available. We reduced this bias slightly by adjusting the Elixhauser comorbidities and SCI while calculating the odds of complication by the fracture level. Again, we do not have the information on the location of the fracture in the vertebrae (Denis 3 column-wise). Also, the NIS data comes with inherent selection and sampling bias along with interrater coding bias. The details regarding the nonoperative management in the data were also lacking.

CONCLUSION

AS patients with spinal fractures have higher postoperative complications. The most common fracture location was thoracic in our study, although it differs with few studies, with SCI occurring in 1/6th of the patients. Although with significant limitations, we intend to provide a bird's eye view of patterns, management, and complications in AS patients with spinal fractures.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Original Article

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Cross-Cultural Adaptation and Psychometric Validation of the Dutch Version of the Core Outcome Measures Index for the Neck in Patients Undergoing Surgery for Degenerative Disease of the Cervical Spine

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Objective: To perform the psychometric validation of the Dutch version of the Core Outcome Measures Index (COMI) for the neck.

Methods: A total of 178 patients, who had an indication for surgery due to degenerative cervical spinal disease, were enrolled in the study. They filled in a baseline booklet containing the Dutch version of the COMI-neck, Likert-scales for neck and arm/shoulder pain, the Neck Disability Index (NDI), the EuroQol-5 dimensions (EQ-5D) and the 12-item Short Form health survey (SF-12). Aside from analyzing construct validity using the Spearman correlation test, test-retest reliability, and responsiveness at 3 months were assessed using the intraclass correlation coefficient (ICC) and the receiver-operating characteristic (ROC) curve, respectively.

Results: The COMI-neck showed good acceptability with missing data ranging from 0% to 4.5% and some floor/ceiling effects for 3 of the domains at baseline. The COMI-summary score showed good to very good correlation with the EQ5D ($\rho = -0.43$), the physical component summary of the SF-12 ($\rho = -0.47$) and the NDI ($\rho = 0.73$). Individual domains showed correlations of -0.28 to 0.85 with the reference questionnaires. Test-retest reliability analysis showed an ICC of 0.91 with a minimal detectable change of 1.7. Responsiveness analysis of the COMI-neck showed an area under 0.79 under the ROC-curve. The standardized response mean for a good outcome was 1.24 and for a poor outcome 0.37.

Conclusion: The current study shows that the Dutch version of the COMI-neck is a valid, reliable and responsive Patient-Reported Outcome Measure, among patients undergoing surgery for degenerative cervical spinal disorders.

Keywords: Core outcomes measures index, Dutch, Validation



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INTRODUCTION

Surgery for degenerative cervical spinal disorders is frequently performed by spine surgeons.¹ Similar to the variation of the surgical techniques applied by surgeon, outcomes of these procedures may also vary per surgeon or center. To monitor the quality of the care given and measure the burden of disease, outcomes of patients and procedures are increasingly being collected by clinicians.² Aside from surgical outcomes such as complications and intraoperative blood loss, clinical outcomes of patients, are deemed to be of more importance in tracking outcomes.³

Patient-Reported Outcome Measures (PROMs) are the outcomes of choice when outcome domains as function, quality of life or pain, are assessed in patients undergoing cervical spine surgery.⁴ As assessing these domains through different questionnaires can be time-consuming for both patients and clinicians, there is a necessity for a brief PROM to assess these patient outcomes. With the intention to address this issue, the core outcomes measures index (COMI) was developed as a brief PROM that measures outcome on 5 domains.^{4,5} Separate versions of the COMI exist to assess outcomes for the lower back and neck. Previous studies have extensively studied the psychometric properties of the COMI-back and COMI-neck in different languages and showed that the COMI is a valid and reliable PROM to measure outcomes in patients with spinal disorders.⁶⁻⁹ A validation of the COMI-neck in the Dutch language, however, had yet to be conducted. Therefore, the purpose of the current study was to perform a psychometric validation of the COMI-neck in Dutch language among patients with degenerative cervical spinal disorders.

MATERIALS AND METHODS

1. COMI-Neck and Translation Process

The COMI-neck is a questionnaire containing 7 questions, testing 5 outcome domains.⁸ These domains are pain, function, symptom-specific well-being, quality of life, and disability. Aside from these domains, a summary score can be calculated in which a “0” indicates the “best score” and “10” the “worst score.”

In a previous study, the COMI-back was cross-culturally adapted and validated in Dutch.^{10,11} For the current study, 2 researchers (1 laymen and 1 researcher in spine surgery) made adaptations to the Dutch version of the COMI-back, independently. These adaptations include changing “back” to “neck,” “leg pain/buttock pain” to “arm/shoulder pain” and “back problem” to

“neck problem.” The remaining wording and structure of the COMI-back was retained. Both adapted versions were discussed by both researchers and a neurosurgeon and lead to the final version of the COMI-neck. This study was approved by the Institutional Review Board of Erasmus University Medical Center (approval number: MEC-2016-261) before the involvement of patients.

2. Patients

To validate the Dutch version of the COMI-neck, patients were included at 1 secondary and 1 tertiary referral centers for spine surgery in the Netherlands from January 2016 to January 2018. Patients were informed about the study after their consultation with the neurosurgeon and were subsequently approached by mail to be enrolled. To be included in this study, patients needed to (1) have age above 18 years or above; (2) have an indication for surgery due to cervical radiculopathy or myelopathy caused by degenerative disease; and (3) have adequate knowledge of Dutch language to complete the forms. Patients were excluded if they had (1) psychiatric disorders; (2) would undergo surgery due to infectious or oncological causes and (3) had general exclusion criteria for surgery (e.g., pregnancy, high American Society of Anesthesiologists physical status classification).

3. Study Procedures

After providing written informed consent, patients received a booklet containing the COMI-neck and other, prior validated, questionnaires. Five days after completing the baseline booklet and before undergoing surgery, a random selection of patients was approached to fill in the test-retest questionnaire. Finally, 3 months after surgery, another subset of patients were approached to fill in the responsiveness questionnaires. Besides the COMI-neck, the baseline booklet contained questions regarding demographics, Likert-scales on neck and arm pain, the Neck Disability Index (NDI), the EuroQol-5 dimensions (EQ-5D) and the 12-item Short Form health survey (SF-12). The retest and responsiveness questionnaires also contained a global treatment outcome (GTO) questionnaire in addition to the COMI-neck.

4. Outcomes

1) Demographics

Questions were included regarding baseline demographics. Data was collected on sex, marital status, age, employment, level of education, and intoxications.

2) Likert-scale pain

Two 5-point Likert-scales were added which measured neck and arm/shoulder pain. The Likert- scales for neck pain and arm/shoulder pain were tested for correlation with the corresponding COMI-domains on neck and arm/shoulder pain.

3) Neck Disability Index

The NDI is a PROM that measures functional disability due to neck disorders.¹² The NDI is expressed in a score ranging from “0” indicating “no disability” to “100” indicating “maximal disability.” The NDI was tested for correlation with the COMI-domains function, symptom-specific well-being, disability and the summary score.

4) EuroQol-5 dimensions

The EQ5D is a five-question PROM that measures health-related quality of life.¹³ In addition to these 5 questions, a 0 to 100 visual analogue scale (VAS) is included in which patients can indicate their health status (EQ-5D-VAS). The domains symptom-specific well-being and quality of life were correlated to both EQ-5D-scores. Furthermore, the COMI-summary score was tested for correlation with the EQ-5D.

5) 12-item Short Form health survey

The SF-12 is a 12-question PROM focused on the General Health status.¹⁴ The SF-12 measures outcomes on 8 domains, including General Health, Bodily Pain, and Physical Functioning among others. The scores on the different domains of the SF-12 can be transformed into physical component summary (PCS) and mental component summary (MCS) scores. The domain General Health was tested for correlation with the COMI-domain quality of life, while the domain Bodily Pain was tested for correlation with the domains neck and arm/shoulder pain. The PCS was tested for correlation with the domains function, disability, and the summary score.

6) Global Treatment Outcome

The GTO was a 5-point Likert-scale in which patients could indicate recovery. The 2 items indicating “full recovery” and “almost full recovery” were dichotomized as “recovered.” The other 3 options were categorized as “not recovered.”

5. Statistical Analysis

Descriptive statistics were used to demonstrate demographics. Missing data were handled as per instructions of the respective PROMs, with no missing data allowed for the COMI-neck.

To validate the Dutch version of the COMI-neck, it was tested for (1) acceptability, (2) floor/ceiling effects, (3) construct validity, (4) test-retest stability, and (5) responsiveness. Acceptability was measured by depicting the percentages of missing data. Floor/ceiling effects were indicated if > 15% of the answers were the worst (floor) or best (ceiling) scores on the COMI-summary score or any of the COMI-domains. A floor/ceiling effect > 75% was considered to be detrimental. Construct validity was calculated using the Spearman ρ correlation test. A ρ lower than 0.21 indicated no correlation, a ρ between 0.21–0.40 indicated poor correlation, a ρ between 0.41–0.61 indicated a good correlation, a ρ between 0.61–0.81 indicated a very good correlation and a $\rho \geq 0.81$ indicated an excellent correlation.¹⁵

Test-retest stability was measured by calculating the intraclass correlation coefficient (ICC) of the COMI score at baseline and approximately 5 days later. An ICC > 0.7 in a sample of at least 50 patients, indicated acceptable reproducibility.¹¹ In addition to the ICC, the standard error of measurement agreement (SEM) and minimum detectable change (MDC) were calculated. Responsiveness was tested by using a t-test comparing baseline and 3-month scores on the COMI-neck, calculating the standardized response mean (SRM) and by constructing a receiver-operating characteristic (ROC) curve anchored on the GTO. An area under the curve (AUC) of at least 0.70 on the ROC-curve was considered acceptable.¹¹

All analyses were conducted using IBM SPSS Statistics ver. 25.0 (IBM Co., Armonk, NY, USA) with a p-value of < 0.05 indicating statistical significance.

RESULTS

The Dutch version of the COMI-neck is shown in the Supplementary Material. During the study's enrollment period, 178 patients filled in a baseline booklet. Of these patients 134 returned the COMI-neck approximately 5 days after inclusion and 86 returned the questionnaire 3-months after surgery (Fig. 1).

1. Demographics

Table 1 gives an overview of the baseline demographics of the enrolled patients. Patients had a mean age of 57.2 ± 13.4 years, a mean body mass index of 26.8 ± 5.2 , and 52.8% was male. In general, majority of the patients were in a relationship (77.1%), had no (paid) job (55.6%) and followed middle education (50.2%). Furthermore, most used pain medication (59.6%), while cigarettes/tobacco, antidepressants, and muscle relaxants were used by 33.7%, 10.1%, and 8.4%, respectively. Baseline scores on the

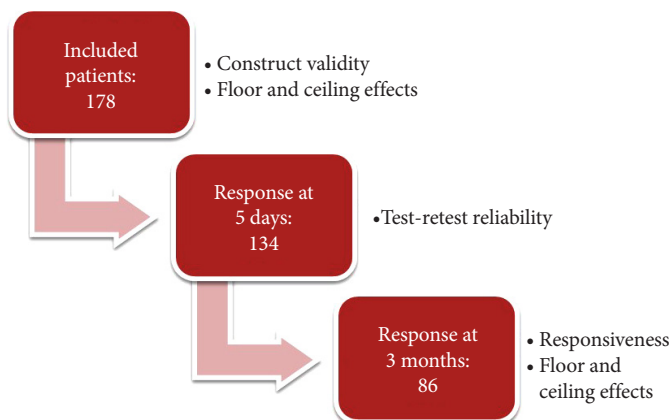


Fig. 1. Flowchart of study procedures.

PROMS are also shown in Table 1. Of the 178 included patients, 175 underwent surgery because 3 patients with cervical radiculopathy recovered spontaneously while awaiting surgery. Of the remaining patients, 110 (62.9%) underwent posterior decompression due to cervical myelopathy, while 65 (37.1%) underwent anterior cervical discectomy with or without fusion due to cervical radiculopathy.

2. Acceptability and Floor/Ceiling Effects

Table 2 gives an overview of the missing data at baseline and the floor/ceiling effects at baseline and 3-month follow-up. Missing data ranged from 0% to 4.5%, with 4.5% missing data for the COMI-summary score. At baseline, the COMI-domains symptom-specific well-being (70.1%), social disability (45.7%), and work disability (37.6%) had floor effects while the domain work disability showed ceiling effects (29.5%). At 3-month follow-up, floor effects were visible in the domains symptom-specific well-being (26.7%), social (24.7%) and work (27.3%) disability. Ceiling effects at 3-month follow-up were visible at all domains, except for quality of life, ranging from 17.8% to 42%. The COMI-summary score had no floor or ceiling effects at baseline or 3-month follow-up.

3. Construct Validity

The results of the correlation tests to assess construct validity are shown in Table 3. Excellent correlation was shown for the COMI-domain neck pain and the Likert-scale for neck pain ($\rho = 0.85$), while the item arm/shoulder pain showed a very good correlation with the Likert-scale for arm/shoulder pain ($\rho = 0.80$). The COMI-domain function showed good correlations with the NDI ($\rho = 0.58$) and PCS ($\rho = -0.41$), while the domain symptom-specific well-being showed a good correlation

Table 1. Baseline demographics of the included patients

Characteristic	Value
Age (yr)	57.2 ± 13.4
Sex	n = 178
Female	84 (47.2)
Male	94 (52.8)
Body mass index (kg/m ²)	26.8 ± 5.2
Marital status	n = 175
Married/in a relationship	135 (77.1)
Single	40 (22.9)
Job status	n = 176
Paid job	78 (44.4)
No (paid) job	98 (55.6)
Educational level	n = 175
Lower education	82 (46.9)
Middle education	88 (50.2)
Higher education	5 (2.9)
Use of the following	n = 199
Cigarettes/tobacco	60 (33.7)
Antidepressants	18 (10.1)
Muscle relaxants	15 (8.4)
Pain medication	106 (59.6)
Patient-Reported Outcome Measure	
Neck Disability Index	41.2 ± 18.1
Physical component summary	31.8 ± 7.1
Mental component summary	38.5 ± 9.9
EQ-5D	0.736 ± 0.087
COMI-summary score	6.6 ± 2.1
Procedure undergone	n = 178
Anterior cervical discectomy with or without fusion	65 (36.5)
Posterior decompression	110 (61.7)
None (due to spontaneous recovery)	3 (1.7)

Values are presented as mean ± standard deviation or number (%). EQ-5D, EuroQol-5 dimension; COMI, Core Outcome Measures Index.

with the NDI ($\rho = 0.41$), but a poor correlation with the EQ-5D ($\rho = -0.28$). Furthermore, the domain quality of life showed a poor correlation with the EQ-5D ($\rho = -0.40$) and a good correlation with the NDI ($\rho = 0.51$). The domains social and work disability both showed a poor correlation with the PCS ($\rho = -0.39$ and $\rho = -0.33$, respectively) and a good correlation with the NDI ($\rho = 0.48$ and $\rho = 0.53$, respectively). The overall, COMI-summary score showed a very good correlation with the NDI ($\rho = 0.73$) and a good correlation with the EQ-5D ($\rho = -0.43$) and PCS

Table 2. Floor and ceiling effects at baseline and at 3 months of follow-up

COMI-domain	Range	Missing at baseline	Baseline		3-Month follow-up	
			Floor effects	Ceiling effects	Floor effects	Ceiling effects
Neck pain	0–10	3 (1.7)	3 (1.7)	21 (12.0)	0 (0)	24 (27.3)
Arm/shoulder pain	0–10	4 (2.2)	4 (2.3)	13 (7.5)	0 (0)	27 (31.4)
Function	0–10	0 (0)	25 (14.0)	12 (6.7)	7 (7.8)	16 (17.8)
Symptom-specific well-being	0–10	1(0.6)	124 (70.1)	5 (2.8)	24 (26.7)	18 (20.0)
Quality of life	0–10	1 (0.6)	16 (9.0)	4 (2.3)	1 (1.1)	8 (8.9)
Social disability	0–10	3 (1.7)	80 (45.7)	21 (12.0)	22 (24.7)	24 (27.0)
Work disability	0–10	5 (2.8)	65 (37.6)	51 (29.5)	24 (27.3)	37 (42.0)
Summary score	0–10	8 (4.5)	1 (0.6)	0 (0)	0 (0)	4 (4.7)

Values are presented as number (%).
COMI, Core Outcome Measures Index.

Table 3. Construct validity

COMI-domain	Reference questionnaire	Spearman ρ
Neck pain	Likert neck pain	0.85*
Arm/shoulder pain	Likert arm/shoulder pain	0.80*
Function	NDI	0.58*
	PCS	-0.41*
Symptom-specific well-being	EQ5D	-0.28*
	NDI	0.41*
Quality of life	EQ5D	-0.40*
	NDI	0.51*
Social disability	NDI	0.48*
	PCS	-0.39*
Work disability	NDI	0.53*
	PCS	-0.33*
Summary score	EQ5D	-0.43*
	NDI	0.73*
	PCS	-0.47*

COMI, Core Outcome Measures Index; NDI, Neck Disability Index; PCS, physical component summary; EQ-5D, EuroQol-5 dimension.
* $p < 0.05$, statistical significance.

($\rho = -0.47$).

4. Test-Retest Reliability

The results of the test-retest reliability are shown in Table 4. All COMI-domains, except for symptom-specific well-being and quality of life, showed acceptable reproducibility with ICCs ranging from 0.78 to 0.90. The domains symptom-specific well-being and quality of life had an ICC of 0.66 and 0.65, respectively. The COMI-summary score had an ICC of 0.91 (95% confidence interval [CI], 0.86–0.94). Furthermore, the summa-

ry score had a SEM of 0.63 which leads to MDC 95% of 1.7.

5. Responsiveness

Three months after surgery, 58.3% of the patients were fully recovered according to the dichotomized GTO. Mean COMI-summary score at baseline (6.6 ± 2.1) decreased to 4.2 ± 2.7 at 3-month follow-up, leading to a mean difference of 2.29 with a standard deviation of 2.8 and thus a SRM of 0.81. The SRM for a good outcome was 1.24, while the SRM for a poor outcome was 0.37. The ROC-curve (shown in Fig. 2) had an AUC of 0.79 (95% CI, 0.69–0.89). The optimal cutoff point at the ROC-curve yielded a sensitivity of 100% and a specificity of 42%.

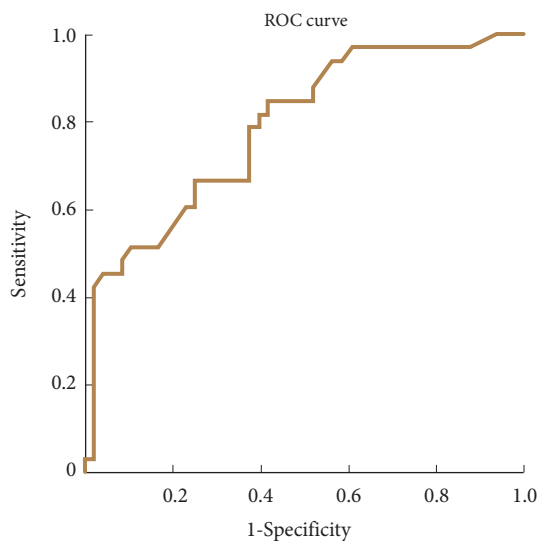
DISCUSSION

The current study is the first to construct a Dutch version of the COMI-neck and assess its' psychometric properties. The Dutch version of the COMI-neck showed good acceptability with missing data for the individual domains ranging from 0% to 2.8%. As no missing data is accepted from the individual domains to produce the summary score, 4.5% was missing for the overall score. Three domains showed floor/ceiling effects at baseline, while 6 showed floor/ceiling effects at 3-month follow-up. However, no domains had detrimental floor/ceiling effects and the COMI-summary score had negligible floor/ceiling effect. Individual domains showed poor to excellent correlations with the reference questionnaires. In contrast, the COMI-summary score showed good to very good correlation with the EQ-5D, the PCS of the SF-12 and the NDI. Test-retest reliability analysis showed acceptable reliability for the COMI-summary score and all but 2 domains (symptom-specific well-being and quality of life). Responsiveness analysis of the COMI-neck

Table 4. Test-retest reliability

COMI-domain	Mean \pm SD		ICC (95% CI)	SEM	MDC 95%
	1st measurement	2nd measurement			
Neck pain	4.6 \pm 2.9	4.9 \pm 2.7	0.89 (0.83–0.93)	0.96	2.7
Arm/shoulder pain	5.6 \pm 2.7	6.1 \pm 6.5	0.90 (0.84–0.94)	0.85	2.4
Function	6.2 \pm 2.8	6.0 \pm 2.8	0.78 (0.67–0.86)	1.31	3.6
Symptom-specific well-being	8.6 \pm 2.5	8.4 \pm 2.5	0.66 (0.50–0.77)	1.46	4.0
Quality of life	6.0 \pm 2.2	5.6 \pm 2.0	0.65 (0.49–0.76)	1.30	3.6
Social disability	7.0 \pm 3.5	6.5 \pm 3.7	0.84 (0.76–0.90)	1.40	3.9
Work disability	5.5 \pm 4.3	5.8 \pm 4.1	0.88 (0.82–0.93)	1.49	4.1
Summary score	6.6 \pm 2.1	6.6 \pm 2.5	0.91 (0.86–0.94)	0.63	1.7

COMI, Core Outcome Measures Index; SD, standard deviation; ICC, intraclass correlation coefficient; CI, confidence interval; SEM, standard errors of measurement agreement; MDC, minimum detectable change.

**Fig. 2.** Receiver-operating characteristic (ROC) curve.

showed an acceptable ability to discriminate between a good and a poor outcome.

Previously, translations and validations of the German, Italian, Polish, Turkish and Japanese versions of the COM-neck have been published (Table 5).^{6,8,9,16,17} These validations were conducted in both surgical and conservatively treated patients. All of these studies assessed floor/ceiling effects and construct validity. Test-retest reliability was previously researched in 4 versions while responsiveness was assessed in 3 previous validations.

Overall, floor/ceiling effects of the COMI-summary score were negligible at baseline and follow-up moments. Floor/ceiling effects of the domain symptom-specific well-being, is known to be present in the COMI-neck, but also at the COMI-back.^{7,8,10,17,18} The findings of the present study are in line with

this. Furthermore, construct validity and test-retest reliability of the present study was also comparable to those reported in previous validations. Responsiveness analyses showed that the current study had an AUC of 0.79 and a SRM of 1.4 for a good outcome at 3-month follow-up, which is comparable to the Japanese validation which was conducted among a similar study population but at 12-month follow-up.⁶ The discriminative ability of these studies, however, was somewhat lower than in the German validation which assessed responsiveness at 3-month follow-up. The difference in study population might partially explain this difference as Fankhauser et al.⁸ studied patients who were candidates for disc replacement surgery and had a mean age of 46 years, while the study population of the current and the study of Oshima et al.⁶ was 11 to 18 years older and underwent surgery for mixed indications such as radiculopathy and/or myelopathy. Nevertheless, all these studies showed more than acceptable (AUC > 0.70) discriminatory abilities of the COMI-neck.

Some study limitations have to be acknowledged. Firstly, this version of the COMI-neck was formulated based on the Dutch version of the COMI-back, rather than the English version of the COMI-neck for pragmatic reasons.^{8,10} This was decided because it would be less-time consuming and would lead to a version the COMI-neck which would be more conform the Dutch version of the COMI-back. Furthermore, the modifications from the Dutch version of the COMI-back would only be minor and previous studies have shown that this method would also lead to valid translations.^{9,17} Another limitation might be that this version of the COMI-neck was only validated in a surgical population and might have other psychometric populations in conservatively treated patients. However, based on the literature and other studies validating the COMI-neck in conservatively

Table 5. Comparison with psychometric properties in other validated versions of the COMI-neck

Study	Language	Studied population	Floor/ceiling effects summary score	Construct validity summary score	Test-retest reliability	MDC 95% summary score	Responsiveness
Fankhauser et al., ⁸ 2012	German	Patients with degenerative disease of the cervical spine with an indication for surgery (n = 89)	1.1% and 0 at baseline, 0 and 13.3% at follow-up	-0.60 (EQ-5D) 0.7 (NASS-cervical disability)	NR	NR	AUC (ROC) = 0.95 (0.88–0.99)
Monticone et al., ⁹ 2014	Italian	Patients with chronic neck pain undergoing rehabilitation (n = 103)	0 at baseline and 0 at follow-up	NR	0.87 (0.81–0.91)	NR	AUC (ROC) = 0.73 (0.62–0.85)
Miekisiak et al., ¹⁷ 2014	Polish	Patients with neck pain, with or without radiating arm/shoulder pain, with or without an indication for surgery (n = 123)	0.8% and 0.8% at baseline	0.65 (NDI)	0.88 (0.82–0.92)	1.97	NR
Karabicak et al., ¹⁶ 2020	Turkish	Patients with chronic neck pain from outpatient physiotherapy and rehabilitation clinics (n = 106)	0 at baseline	0.70 (NDI) 0.65 (NPDS) 0.62 (VAS/NRS)	0.96 (0.94–0.97)	NR	NR
Oshima et al., ⁶ 2021	Japanese	Patients with an indication for surgery due to cervical spinal disorders (n = 177) and volunteers with chronic neck pain (n = 59)	1.2% and 0.6% at baseline, 0.1% and 5.3% at follow-up	-0.62 (EQ-5D) 0.78 (NDI)	0.97 (0.96–0.98)	0.77	AUC (ROC) = 0.78 MCID 2.1
Gadjradj et al., ¹⁰ 2021	Dutch	Patients with degenerative disease of the cervical spine with an indication for surgery (n = 178)	0.6% and 0 at baseline, 0 and 4.7% at follow-up	-0.43 (EQ-5D) 0.73 (NDI) -0.47 (PCS)	0.91 (0.86–0.94)	1.7	AUC (ROC) = 0.79 (0.69–0.89)

COMI, Core Outcome Measures Index; MDC, minimum detectable change; EQ-5D, EuroQol-5 dimension; NR, not reported; MCID, minimal clinically important difference; NPDS, Neck Pain and Disability Scale; AUC, area under the curve; ROC, receiver-operating characteristic; NASS, North American Spine Society; VAS, visual analogue scale; NRS, Numeric Rating Scale; NDI, Neck Disability Index; PCS, physical component summary.

treated patients (Table 5), the psychometric properties seem to be comparable. Another limitation might be that no selection based on GTO was applied, when test-retest reliability was tested. In the validation of the Dutch version of the COMI-back this 'no change' filter was applied when the retest questionnaire was distributed approximately 2 weeks after completing the baseline booklet. By shortening the retest period to 5 days, the filter expected to be unnecessary. *Post hoc* analyses confirmed this, as ICCs did not change significantly when this filter was applied. Finally, the GTO-question was based on a 5-point Likert-scale, whereas a 7-point Likert-scale may have been more appropriate. However, since the COMI-neck as used in the Spine Tango also contains a 5-point Likert-scale to assess GTO, the inclusion of a 5-point scale seemed more appropriate.

The current study shows that the Dutch version of the COMI-neck is a valid, reliable and responsive PROM. As the COMI-neck is a brief questionnaire and has appropriate psychometric properties, it can be recommended as a PROM among Dutch patients undergoing surgery for the degenerative cervical spine.

CONFLICT OF INTEREST

The authors have nothing to disclose.

SUPPLEMENTARY MATERIAL

Supplementary Material can be found via <https://doi.org/10.14245/ns.2142682.341>

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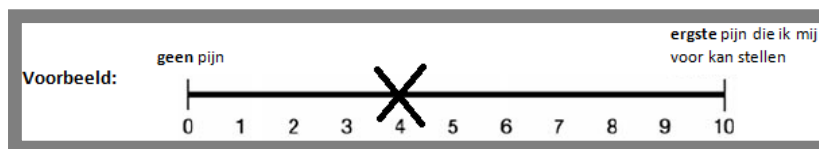
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Nekproblemen kunnen leiden tot nekpijn en/of pijn in de arm/schouder regio. Daarnaast kunnen er ook gevoelsstoornissen zoals tintelingen, een prikkend of een doof gevoel in deze gebieden ontstaan

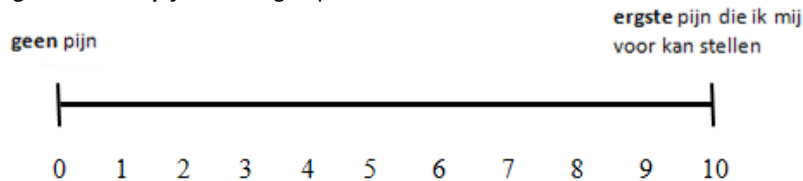
- 1 Van welk van de volgende problemen heeft u **het meeste** last? Kruis **één optie** aan.
- ₁ nekpijn
 - ₂ arm/schouderpijn
 - ₃ gevoelsstoornissen in de nek/arm/schouder zoals een tintelend of doof gevoel, of een prikkend gevoel.
 - ₄ geen van bovenstaande opties

2 Voor de volgende 2 vragen (vraag 2a en vraag 2b) zouden we u willen vragen de ernst van uw pijn aan te geven door een kruisje te zetten op de schaal van 0-10 (waarbij "0"= geen pijn, "10"=de ergste pijn die u zich kunt voorstellen).

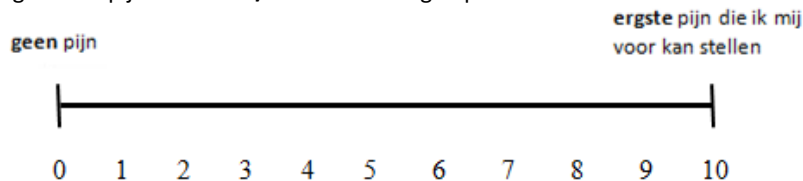
Er zijn aparte vragen voor nekpijn en voor pijn in de arm/schouder.



2a Hoe erg was uw **nekpijn** in de afgelopen week?



2b Hoe erg was de pijn in uw **arm/schouder** de afgelopen week?




- 3 Gedurende de **afgelopen week**, in welke mate stond uw nekprobleem uw **normale activiteiten** (zowel werk buitenshuis als in het huishouden) in de weg ?
- ₁ helemaal niet
 - ₂ een klein beetje
 - ₃ matig
 - ₄ best wel
 - ₅ uiterst

- 4 Als u **de rest van uw leven** zou moeten leven **met de klachten die u nu heeft**, hoe zou u zich daar dan bij voelen?
- ₁ erg tevreden
₂ enigszins tevreden
₃ noch tevreden noch ontevreden
₄ enigszins ontevreden
₅ erg ontevreden
- 5 Terugkijkend op de **afgelopen week**, hoe zou u uw kwaliteit van leven beoordelen?
- ₁ erg goed
₂ goed
₃ gematigd
₄ slecht
₅ erg slecht
- 6 **Gedurende de afgelopen 4 weken**, hoeveel dagen heeft u moeten minderen met **de activiteiten die u doorgaans onderneemt** (uw werk, het huishouden, school, ontspannende activiteiten) vanwege uw nekprobleem?
- ₁ geen
₂ tussen de 1 en 7 dagen
₃ tussen de 8 en 14 dagen
₄ tussen de 15 en 21 dagen
₅ meer dan 21 dagen
- 7 **Gedurende de afgelopen 4 weken**, hoeveel dagen heeft uw nekprobleem u **ervan weerhouden om te gaan werken** (uw werk, school, het huishouden)?
- ₁ geen
₂ tussen de 1 en 7 dagen
₃ tussen de 8 en 14 dagen
₄ tussen de 15 en 21 dagen
₅ meer dan 21 dagen

Original Article

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INTRODUCTION

Since Galibert and Deramond first described the use of percutaneous vertebroplasty (PVP) for the treatment of symptomatic vertebral hemangioma in 1984,¹ cement augmentation with polymethylmethacrylate (PMMA) has been widely used in the treatment of painful vertebral fractures and osteoporosis-related

Risk Factors for Pulmonary Cement Embolism (PCE) After Polymethylmethacrylate Augmentation: Analysis of 32 PCE Cases

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Objective: Pulmonary cement embolism (PCE) is an underestimated but potentially fatal complication after cement augmentation. Although the treatment and follow-up of PCE have been reported in the literature, the risk factors for PCE are so far less investigated. This study aims to identify the preoperative and intraoperative risk factors for the development of PCE.

Methods: A total of 1,373 patients treated with the polymethylmethacrylate (PMMA) augmentation technique were retrospectively included. Patients with PCE were divided into vertebral augmentation group and screw augmentation group. Possible risk factors were collected as follows: age, sex, bone mineral density, body mass index, diagnosis, comorbidity, surgical procedure, type of screw, augmented level, number of augmented vertebrae, fracture severity, presence of intravertebral cleft, cement volume, marked leakage in the paravertebral venous plexus, and periods of surgery. Binary logistic regression analyses were used to analyze independent risk factors for PCE.

Results: PCE was identified in 32 patients, with an incidence rate of 2.33% (32 of 1,373). For patients who had undergone vertebral augmentation, marked leakage in the paravertebral venous plexus (odds ratio [OR], 1.2; 95% confidence interval [CI], 0.1–10.3; $p = 0.000$) and previous surgery (OR, 16.1; 95% CI, 4.2–61.0; $p = 0.007$) were independent risk factors for PCE. Regarding patients who had undergone screw augmentation, the marked leakage in the paravertebral venous plexus (OR, 4.2; 95% CI, 0.5–37.3; $p = 0.004$) was the main risk factor.

Conclusion: Marked leakage in the paravertebral venous plexus and previous surgery were significant risk factors related to PCE. Paravertebral leakage and operator experience should be concerned when performing PMMA augmentation.

Keywords: Pulmonary embolism, Polymethylmethacrylate, Augmentation, Risk factors

ed degenerative spine disorders.² PMMA bone cement is heavily used in PVP, percutaneous kyphoplasty (PKP), and cement-augmented pedicle screw instrumentation (CAPSI) owing to the rapid and durable stability improvements of the fracture area and bone-screw interface.^{3,4} However, these surgical procedures also bear a high risk of cement leakage into the vertebral venous system and fracture gaps.⁵ The incidence of cement

leakage is as high as 38.3%–93.6% in PVP/PKP⁶⁻⁸ and 12.5%–82.4% in CAPSI.^{5,6,9-11} Similarly, the same high incidence of cement leakage after CAPSI (81.68%) was also found in our inpatients.⁵ Cement leakage may lead to serious complications such as nerve root injury,⁸ spinal cord compression,⁵ pulmonary cement embolism (PCE),^{12,13} cardioembolism,^{14,15} anaphylactic shock,¹⁶ and even death.^{16,17} Among the abovementioned complications, PCE is one of the most severe complications.

PCE is caused by cement leakage into the vertebral venous plexus and reaches the pulmonary arteries through the azygous/hemiazygos system and cava vein. According to previous reports in the literature, PCE was detected in 1.0%–28.6% of patients by postoperative chest radiographs and/or computed tomography (CT).¹⁸⁻²¹ Although most PCE patients are asymptomatic or present mild pulmonary symptoms,²² a portion of PCE cases may develop aggravated hemodynamic repercussions or result in death.^{16,17} Therefore, it is important to identify the risk factors for the development of PCE.

Whereas several case reports and case series have investigated the treatment and follow-up of PCE,^{5,18,23-25} studies on the risk factors for PCE are lacking. To our knowledge, only 3 studies have investigated the risk factors for PCE after cement augmentation.^{20,26,27} This study aims to explore the risk factors for PCE and has collected the largest sample size to date.

MATERIAL AND METHODS

1. Patient Population

The study involving human participants were reviewed and approved by the Ethics Committee of The First Affiliated Hospital of Guangzhou University of Chinese Medicine (No. ZYY-ECK[2019]186). This study has been performed following the ethical standards in an appropriate version of the 1964 Declaration of Helsinki. Informed consent was waived by the Ethics Committee. Patients who underwent PVP, PKP, or CAPSI between January 2006 and December 2019 were reviewed. A total of 1,838 patients with osteoporotic vertebral fractures, spinal tumors, and degenerative spine diseases were initially retrieved from the hospital database. Patients without postoperative chest radiographs or chest CT were excluded. Finally, a total of 1,373 patients were included for further analyses.

The demographic and clinical information of patients was collected, including sex, age at operation, spinal bone mineral density (BMD), diagnosis, body mass index (BMI), comorbidities, date of surgery, surgical procedure, augmented level, type of screw, cement volume per level, and viscosity of bone cement.

Patients with PCE were divided into vertebral augmentation group and screw augmentation group to conduct a subgroup analysis. For no obvious cement leakage occurred in vertebral augmentation level, patients who had undergone CAPSI+PVP were classified as screw augmentation group.

PMMA-based cement materials were used for all patients. Low-viscosity PMMA (Tecres S.P.A., Sommacampagna, Italy) was used in most patients. In contrast, part of patients who received vertebral augmentation was used high-viscosity PMMA (Confidence spinal cement system, Medtronic, Minneapolis, MN, USA) at the discretion of the attending surgery. In general, we injected PMMA with every 0.1-mL increment when it had a toothpaste-like viscosity (Mixing the low-viscosity bone cement for 30 seconds and waiting for 390 seconds, then the consistency of cement will change from liquid to toothpaste-like). The cement volume in the thoracic and lumbar vertebrae was about 2.5–6 mL and 3–8 mL. All vertebral augmentation procedures were performed bilaterally. According to different screw augmentation techniques, cement-augmented pedicle screws were divided into fenestrated and solid screws. The periods of surgery were classified equally into 2 periods. Because vertebral augmentation technique and screw augmentation technique were successively carried out in our department, time division of surgical periods between vertebral augmentation group (2006–2012 and 2013–2019) and screw augmentation group (2008–2013 and 2014–2019) was a little different.

2. Radiographic Analysis

Generally, the chest x-ray was reviewed routinely after the operation. If the patients complain of pulmonary problems, they will receive additional thoracic CT. To distinguish vascular calcification or calcified granuloma from PCE, a comparison between preoperative and postoperative chest radiographs (or chest CT scans, if possible) was performed. PCE was defined as postoperative emerging, solitary, or multiple branching linear density along the pulmonary vessel. If the distinction between vascular calcification and PCE was sometimes difficult in x-ray, a high-density branching with an attenuation greater than 500 HU in CT was judged as PCE.¹⁹ Cement embolism sites were categorized as right lung, left lung, or bilateral lungs according to the location of the PCE in postoperative imaging (x-ray or CT scan). The length of PCE was measured in anterior-posterior or lateral chest x-rays by the Picture Archiving and Communication System. According to the semiquantitative classification of Genant et al.²⁸ fracture severity was classified as mild-moderate (20%–40%) or severe (>40%). The presence of an

intravertebral cleft was identified by a linear-like or irregular shape of very low density within a compressed vertebral body on CT and/or x-rays of the spine.²⁹ Evaluation of fracture severity and the presence of intravertebral cleft was only performed for cases with vertebral fractures. A significant leakage in the paravertebral venous plexus was defined as a linear-shaped, high-density leakage with a minimum length of 1 cm in the anterior or lateral region of the vertebral body. All radiographic analyses were performed by 2 experienced observers independently.

3. Selection of the Control Group

In general, PCE and non-PCE cases were matched in a 1:4 ratio to provide sufficient statistical power.³⁰ Non-PCE patients were selected by random sampling. The sampling strategy consisted of the following: Randomization was performed with computer-generated random numbers on the website www.randomizer.org. Depending on the sample size of vertebral augmentation group and screw augmentation group, a certain number of numbers were randomly generated to constitute the control group. This selection method made the control group consistent with non-PCE patients to the greatest possible degree.

4. Statistical Methods

Statistical analyses were performed using IBM SPSS Statistics ver. 19.0 (IBM Co., Armonk, NY, USA). Measurement data were compared by using independent-sample t-tests. For counting data, Fisher exact probability tests were used. Multivariate logistic regression analysis was further analyzed risk factors with a significant difference for multivariate analysis. A $p < 0.05$ was regarded to be significantly different.

RESULTS

1. Characteristics of PCE Patients

Thirty-two patients (3 males, 29 females) with PCE were identified. The overall incidence rate of PCE was 2.33% (32 of 1,373). The PCE sample had an average age of 71.52 years (range, 53–92) and an average T score of -3.75 SD (range, -6.6 to -1.3). The demographics of the PCE and non-PCE patients are shown in Table 1.

All emboli were found in subsegment pulmonary arteries classified as peripheral PCE. There were no perioperative deaths due to PCE. Most embolisms appeared in the right lung (68.75%, $n = 22$), with some appearing bilaterally in the lungs (31.25%,

Table 1. Baseline characteristics of total sample and patients who developed pulmonary cement embolism

Characteristic	PCE	Non-PCE
No. of patients	32 (2.33)	1,341 (97.67)
Age (yr)	71.52 ± 11.22 (53–92)	71.63 ± 10.17 (41–110)
Sex		
Male	3 (9.38)	252 (18.79)
Female	29 (90.63)	1,089 (81.21)
Diagnosis		
OVCF	25 (78.13)	1,068 (79.64)
ST	0 (0)	31 (2.31)
LDD	7 (21.88)	242 (18.05)
Surgical procedure		
PVP	18 (56.25)	851 (63.46)
PKP	4 (12.5)	204 (15.21)
CAPSI	9 (28.13)	269 (20.06)
CAPSI+PVP	1 (3.13)	17 (1.27)

Values are presented as number (%) or mean ± standard deviation (range).

PCE, pulmonary cement embolism; OVCF, osteoporotic vertebral compression fractures; ST, spinal tumors; LDD, lumbar degenerative disease; PVP, percutaneous vertebroplasty; PKP, percutaneous kyphoplasty, CAPSI, cement-augmented pedicle screw instrumentation.

$n = 10$). Of the 32 patients with PCE, 5 patients (15.63%) experienced transient symptoms or hemodynamic repercussions and received symptomatic or anticoagulation therapy, and the remaining 27 patients (84.38%) did not demonstrate clinical syndromes during the perioperative period. No patient required further surgery to remove the cement emboli. After discharge, 3 patients still took aspirin or warfarin due to cardiovascular disease, while the remaining patients did not receive long-term anticoagulation therapy. Demographic and clinical information of PCE patients is presented in Table 2.

2. Risk Factor Analysis

From non-PCE patients, 88 patients who had undergone vertebral augmentation (PVP or PKP) and 40 patients who had undergone screw augmentation were randomly selected as the control group 1 and 2. For patients who had undergone vertebral augmentation, the incidence of PCE was significantly more frequent in cases with a larger number of augmented vertebrae ($p < 0.05$), marked leakage in the paravertebral venous plexus ($p < 0.001$), and previous surgery ($p < 0.05$) (Table 3). For patients who had undergone screw augmentation, marked leakage in the paravertebral venous plexus ($p < 0.05$) is a significant

Table 2. Characteristics of patients who developed pulmonary cement embolisms

Case No.	Sex/age (yr)	BMD	Diagnosis	Surgical procedure	Type of screws	Augmented level	Location of PCE	Symptoms
1	F/56	-3.6	OVCF	PVP	-	L1	Bilateral lungs	None
2	F/60	-3.0	OVCF	PVP	-	T12, L3, L4	Right lung	None
3	F/78	-3.5	OVCF	PKP	-	L3	Bilateral lungs	None
4	F/71	-3.1	OVCF	PKP	-	T6, T8	Right lung	None
5	F/80	-4.9	OVCF	PVP	-	T7, T10	Bilateral lungs	None
6	F/85	-4.1	OVCF	PKP	-	L1	Right lung	None
7	F/73	-4.2	OVCF	PKP	-	T12	Bilateral lungs	None
8	F/58	-2.8	OVCF	PVP	-	L4	Right lung	None
9	F/81	-6.6	OVCF	PVP	-	T11	Right lung	None
10	F/77	-3.7	OVCF	PVP	-	T10, T11	Right lung	None
11	F/76	-2.2	OVCF	PVP	-	L4	Bilateral lungs	Chest tightness, chest pain
12	F/67	-2.8	OVCF	PVP	-	L4	Bilateral lungs	None
13	F/72	-3.3	OVCF	PVP	-	T4, T5, T7	Bilateral lungs	None
14	F/88	-4.0	OVCF	PVP	-	L2	Right lung	None
15	F/78	-4.7	OVCF	PVP	-	T4	Right lung	None
16	F/92	-4.0	OVCF	PVP	-	T12, L1, L5	Right lung	None
17	F/56	-5.3	OVCF	PVP	-	T8, T11, L1	Bilateral lungs	None
18	M/87	-4.2	OVCF	PVP	-	L2	Right lung	None
19	F/62	-4.9	OVCF	PVP	-	T10, T11, L1	Right lung	None
20	M/83	-3.9	OVCF	PVP	-	T10	Right lung	None
21	F/83	-4.7	OVCF	PVP	-	T7	Right lung	None
22	M/62	-1.3	OVCF	PVP	-	T12	Bilateral lungs	Hypoxemia
23	F/84	-2.6	OVCF+KD	CAPSI+PVP	Solid	T11- L1	Bilateral lungs	Blood pressure fluctuations
24	F/84	-4.1	LS+LSS	CAPSI	Solid	L4, L5	Right lung	Fever, dyspnea, expectoration
25	F/67	-4.1	LSS	CAPSI	Fenestrated	L4-S1	Right lung	None
26	F/62	-4.0	LS+LSS	CAPSI	Fenestrated	L4	Right lung	None
27	F/78	-3.5	LSS	CAPSI	Fenestrated	L3-L5	Right lung	Dyspnea, hypoxemia
28	F/73	-4.3	OVCF	CAPSI	Fenestrated	L2-L5	Right lung	None
29	F/53	-3.1	OVCF+KD	CAPSI	Fenestrated	T10, T11, L1, L2	Right lung	None
30	F/54	-3.2	LSS	CAPSI	Fenestrated	L4, L5	Right lung	None
31	F/65	-3.5	LS+LSS	CAPSI	Solid	L4, L5	Right lung	None
32	F/65	-2.9	DS+LSS	CAPSI	Solid	L1-5	Right lung	None

BMD, bone mineral density; PCE, pulmonary cement embolism; OVCF, osteoporotic vertebral compression fractures; PVP, percutaneous vertebroplasty; PKP, percutaneous kyphoplasty; KD, kyphotic deformity; CAPSI, cement-augmented pedicle screw instrumentation; LS, lumbar spondylolisthesis; LSS, lumbar spinal stenosis; DS, degenerative scoliosis.

risk factor for the occurrence of PCE (Table 4). These risk factors with significant differences were further compared by a multivariate logistic regression model. For patients who had undergone vertebral augmentation, the regression analysis revealed that marked leakage in the paravertebral venous plexus

(OR, 1.2; 95% CI, 0.1–10.3; p = 0.000) and previous surgery (OR, 16.1; 95% CI, 4.2–61.00; p = 0.007) were independent risk factors for PCE. Regarding patients who had undergone screw augmentation, the marked leakage in the paravertebral venous plexus (OR, 4.2; 95% CI, 0.5–37.3; p = 0.004) was the main risk

Table 3. Comparison of risk factors for the occurrence of PCE in vertebral augmentation group

Factor	Vertebral augmentation group (n = 22)	Control group 1 (n = 88)	p-value
Age (yr)	73.86 ± 11.03 (56–92)	73.39 ± 9.80 (53–90)	0.846
Female sex	19 (86.36)	67 (76.14)	0.394
BMI (kg/m ²)	21.43 ± 3.15 (14.95–27.27)	21.78 ± 4.06 (14.69–37.11)	0.641
BMD	-3.85 ± 1.13 (-6.6 to -1.3)	-3.71 ± 1.33 (-6.2 to -0.2)	0.709
Diagnosis			> 0.99
OVCF	22 (100)	86 (97.27)	
ST	0 (0)	2 (2.27)	
Comorbidity			
Diabetes	3 (13.64)	10 (11.36)	0.721
Hypertension	9 (40.91)	30 (34.09)	0.621
Chronic pulmonary disease	2 (9.09)	3 (3.41)	0.261
Coronary heart disease	3 (13.64)	8 (9.09)	0.458
Surgical procedure			0.755
PVP	18 (81.82)	74 (84.09)	
PKP	4 (18.18)	14 (15.91)	
No. of augmented vertebrae			0.041*
1 or 2	17 (77.27)	82 (93.18)	
3	5 (22.73)	6 (6.82)	
Augmented level			0.256
Thoracic vertebra	21 (60.00)	58 (48.74)	
Lumbar vertebra	14 (40.00)	61 (51.26)	
Fracture severity			0.327
Mild-moderate	24 (65.79)	69 (57.98)	
Severe	11 (34.21)	50 (42.02)	
Presence of intravertebral cleft			0.068
Yes	1 (4.55)	20 (22.73)	
No	21 (95.45)	68 (77.27)	
Viscosity of bone cement			0.261
Low	20 (90.91)	85 (96.59)	
High	2 (9.09)	3 (3.41)	
Cement volume per level (mL)			
PVP	4.56 ± 1.81	5.04 ± 1.60	0.376
PKP	4.10 ± 0.98	5.28 ± 1.69	0.199
Marked leakage in the paravertebral venous plexus			0.000**
Yes	21 (95.45)	19 (21.59)	
No	1 (4.55)	69 (78.41)	
Periods of surgery			0.003**
2006–2012	16 (72.73)	32 (36.36)	
2013–2019	6 (27.27)	56 (63.64)	

Values are presented as number (%) or mean ± standard deviation (range).

PCE, pulmonary cement embolism; BMI, body mass index; BMD, bone mineral density; OVCF, osteoporotic vertebral compression fractures; ST, spinal tumors; PVP, percutaneous vertebroplasty; PKP, percutaneous kyphoplasty.

*p < 0.05. **p < 0.01.

Table 4. Comparison of risk factors for the occurrence of PCE in screw augmentation group

Factor	Screw augmentation group (n = 10)	Control group 2 (n = 40)	p-value
Age (yr)	68.50 ± 11.11 (53–84)	68.10 ± 7.44 (53–90)	0.892
Female	10 (100)	35 (80.00)	0.569
BMI (kg/m ²)	22.20 ± 5.35 (14.67–30.70)	23.11 ± 4.22 (15.94–33.05)	0.531
BMD	-3.53 ± 0.58 (-4.3 to -2.6)	-3.30 ± 1.11 (-5.9 to 0)	0.566
Diagnosis			
OVCF+KD	3 (30.00)	10 (25.00)	0.707
LSS	3 (30.00)	18 (45.00)	0.148
LS+LSS	3 (30.00)	7 (17.50)	0.397
DS+LSS	1 (10.00)	5 (12.50)	> 0.99
Comorbidity			
Diabetes	3 (30.00)	8 (20.00)	0.671
Hypertension	3 (30.00)	13 (32.50)	> 0.99
Chronic pulmonary disease	0 (0.00)	3 (7.50)	> 0.99
Coronary heart disease	1 (10.00)	1 (2.50)	0.363
Number of augmented vertebrae			0.474
< 3	5 (50.00)	26 (65.00)	
≥ 3	5 (50.00)	14 (35.00)	
Augmented level			0.174
Thoracolumbar spine	2 (20.00)	2 (5.00)	
Lumbosacral spine	8 (80.00)	38 (95.00)	
Type of screw			> 0.99
Fenestrated screws	6 (60.00)	23 (57.50)	
Solid screws	4 (40.00)	17 (42.50)	
Cement volume per level (mL)	3.73 ± 1.68 (1–6.3)	3.87 ± 1.36 (2–8)	0.775
Marked leakage in the paravertebral venous plexus			0.001**
Yes	9 (90.00)	11 (27.50)	
No	1 (10.00)	29 (72.50)	
Periods of surgery			0.150
2008–2013	6 (60.00)	13 (17.50)	
2014–2019	4 (40.00)	27 (82.50)	

Values are presented as number (%) or mean ± standard deviation (range).

PCE, pulmonary cement embolism; BMI, body mass index; BMD, bone mineral density; OVCF, osteoporotic vertebral compression fractures; KD, kyphotic deformity; LSS, Lumbar spinal stenosis; LS, lumbar spondylolisthesis; DS, degenerative scoliosis.

*p < 0.05. **p < 0.01.

factor (Table 5). Representative cases of PCE patients undergoing PVP and CAPSI are shown in Figs. 1 and 2, respectively.

DISCUSSION

PCE after vertebral cement augmentation procedures was first reported in 1999 by Padovani et al.³¹ In 2011, Luetmer et al.²⁶ described the largest PCE case series (n = 23) thus far. Sub-

sequently, El Saman et al.²¹ reported the highest incidence of PCE (28.6%, 12 of 42) through routine postoperative chest imaging in 2013. The clinical importance of PCE is underestimated since previous studies showed that most cases were asymptomatic or had slight discomfort. However, a growing number of severe cases have been reported involving acute respiratory distress syndrome^{16,32-34} and even death.^{16,17} Therefore, surgeons must be aware of this potentially fatal complication following

Table 5. Multivariate logistic regression analysis of the risk factors for pulmonary cement embolism

Factor	OR	95% CI	p-value
Vertebral augmentation group			
Number of augmented vertebrae	68.7	13.4–351.4	0.652
Marked leakage in paravertebral venous plexus	1.2	0.1–10.3	0.000**
Periods of surgery	16.1	4.2–61.0	0.007**
Screw augmentation group			
Marked leakage in paravertebral venous plexus	4.2	0.5–37.3	0.004**

OR, odds ratio; CI, confidence interval.

** $p < 0.01$.

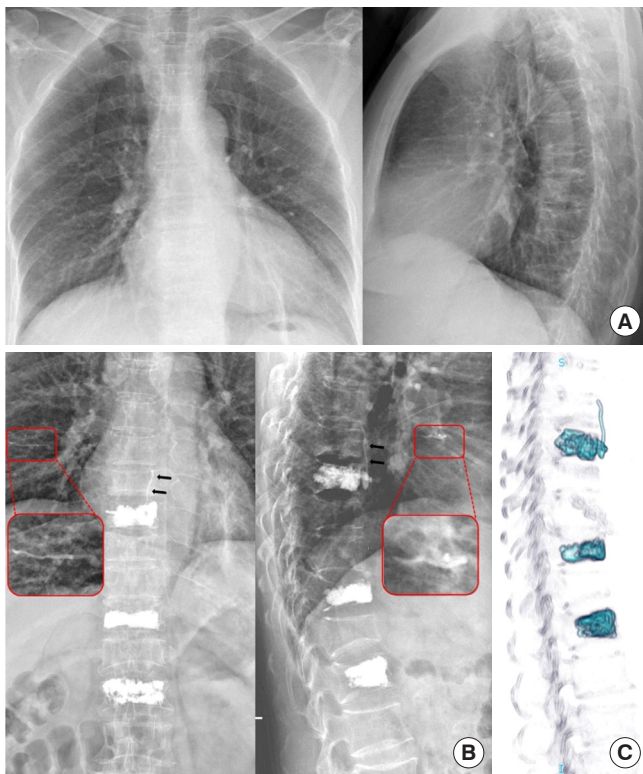


Fig. 1. A 56-year-old female developed postoperative pulmonary cement embolism after vertebroplasty at the T8, T11, and L1 levels (case No. 17). (A) Chest radiography findings were normal before surgery. (B) Postoperative x-ray showed significant leakage of the paravertebral venous plexus (black arrow) at the T8 level and a tubular-shaped, high-density embolism in the right lung (red box: zoomed region). (C) The 3-dimensional computed tomography reconstruction provided more accurate and clearer views of cement leaks.

PMMA augmentation. Identifying risk factors for PCE can help surgeons improve preoperative planning and reduce the incidence.

This study revealed that marked leakage in the paravertebral venous plexus and previous surgery had a statistically signifi-

cant relationship with the development of PCE. Anatomically, the vertebral venous plexus consists of 3 interconnected veins: the internal vertebral venous plexuses, the external vertebral venous plexuses, and the basivertebral veins.³⁵ The external vertebral venous plexuses were connected with the superior and inferior vena cava through intercommunication with the azygos venous system and the lumbar veins, respectively.³⁵ When the vertebral venous plexus was injured by vertebral compression fracture, paracentesis procedures, or screw insertion, liquid PMMA bone cement can easily escape into the ruptured venous system. Then, through the valveless vertebral venous plexus and vena cava, the leaked cement can drain into the pulmonary circulation.³⁶ Thus, paravertebral venous leakage can be recognized as an early sign of PCE. When significant leakage in the paravertebral venous plexus occurs intraoperatively, the surgeon should alert the high risk of developing PCE and stop the injection immediately.

Factors related to paravertebral venous plexus leakage have been reported in the literature,^{3-7,21,37} including large-volume injection of bone cement, multilevel cement augmentation, the low viscosity of cement, early injection when bone cement is in dilute viscosity, high application pressure, the tip of screw/puncture needle adjacent to the mid-part of the vertebral body, less experienced surgeons, and inadequate fluoroscopic confirmation. Knowing these risk factors could be useful to develop preventive strategies for paravertebral venous plexus leakage and therefore decrease the incidence of PCE.

Although the period of surgery was not an independent risk factor in screw augmentation group (probably due to the small sample size), previous surgery bears a significantly higher risk of PCE than subsequent surgery. This result suggests that surgical experience and awareness about PCE have important implications for the occurrence of this complication. With the improvement of surgical techniques and the understanding of PCE, surgeons have been more careful in filling the vertebral

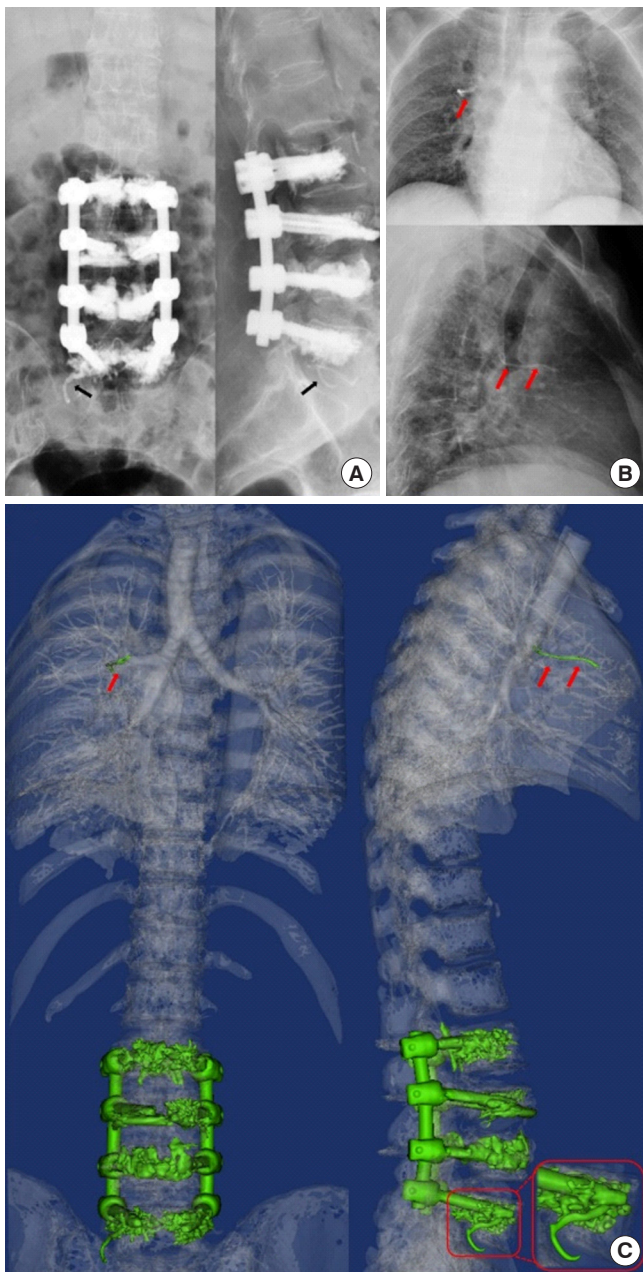


Fig. 2. A 73-year-old female developed postoperative pulmonary cement embolism after cement-augmented pedicle screw instrumentation at the L2–5 level (case No. 28). (A) Anteroposterior and lateral digital radiographs showed curvilinear cement in the paravertebral venous plexus (black arrow). (B) Postoperative chest x-rays showed a linear-like, hyperdense cement embolism in the right lung (red arrow). (C) The zoomed region of the red box shows cement leakage into the paravertebral venous plexus at the L5 level. In addition, a cement embolism was found in the right pulmonary vascular tree (red arrows).

body and have paid more attention to paravertebral cement leakage.³⁸ Based on the above risk factors and our experience, we recommend injecting cement with a toothpaste-like viscosity in small doses multiple times (0.1 mL–0.2 mL for each injection) and under continuous fluoroscopic monitoring.^{2,39,40} Some measures, including keeping the tip of screw/puncture needle away from the midline of the vertebral body,⁵ reduce the volume of cement,¹³ and limit the number of augmented vertebral body,⁴⁰ could also be useful to prevent cement leakage and to contribute to reductions in the incidence of PCE.

Additional risk factors for PCE have also been reported in the literature. Kim et al.²⁰ found that cement leakage into the inferior vena cava is a significant risk factor for PCE, which agrees with the present study. According to Luetmer et al.²⁶ and Hsieh et al.²⁷ those with PCE were significantly younger, treated with more total levels, and injected with a larger volume of cement. The author did not have a definitive explanation for age differences. Concerning more augmented levels and larger volumes of cement, it is more likely to invade the basivertebral system.^{37,41} Although not statistically significant, our study also reveals that more augmented vertebrae may be a risk factor for PCE. Besides, a lower frequency of PCE was noted for the presence of intravertebral clefts ($p=0.068$), which may be related to the low injection pressure and avascular necrosis of the vertebral body.

The primary limitation is that some patients did not undergo postoperative chest radiography or chest CT, which may underestimate asymptomatic patients. A secondary limitation is that although operator variability and their manipulation may play a pivotal role in the development of PCE, we did not analyze the different operators or their operative habits. A final limitation is that some patients underwent PVP twice or more, so these patients were included multiple times.

CONCLUSION

PCE was not a very rare complication after PMMA augmentation. Significant leakage in paravertebral venous plexus and previous surgery were significant risk factors related to PCE. Paravertebral leakage and operator experience should be concerned when performing PMMA augmentation technique.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Original Article

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Multiple-Rod Constructs Do Not Reduce Pseudarthrosis and Rod Fracture After Pedicle Subtraction Osteotomy for Adult Spinal Deformity Correction but Improve Quality of Life

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Objective: To compare the radiological and functional outcomes and complications of adult spinal deformity patients who underwent a pedicle subtraction osteotomy (PSO) below L2 but categorized according to their construct where either 2-rod or multiple-rod construct is applied.

Methods: Sixty-seven patients met the inclusion criteria, and were categorized into 3 groups: 2 rods (2R), multiple rods around the PSO (MRP), multiple rods around the PSO and lumbosacral junction (MRL). Demographic data, operative parameters, spinopelvic parameters, functional outcomes, and complications were collected.

Results: Health-related quality of life scores showed a better outcome at 6 months and last follow-up visits in the MRP and MRL groups which were noted on different domains of Scoliosis Research Society-22 questionnaire, 36-item Short Form Health Surve, and Oswestry Disability Index scores ($p < 0.05$). The 3 groups showed similar rates of rod-related complications with no significant difference ($p = 0.95$). And inside each group, distribution of complications between pseudarthrosis with revision and rod fracture without revision was also similar ($p = 0.99$).

Conclusion: The use of multiple rods across the PSO did not show a better outcome when compared to single rods in terms of incidence and types of mechanical complications. However, better postoperative coronal alignment and health-related quality of life scores in the multiple rods group could be seen demonstrating an improved functional outcome.

Keywords: Adult spine deformity, Pedicle subtraction osteotomy, Multiple-rod construct, Rod fracture, Pseudarthrosis, Revision



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INTRODUCTION

Three-column osteotomies such as pedicle subtraction osteotomy (PSO) and vertebral column resection are commonly

used for the management of severe spinal deformities. The classical treatment typically used a standard 2-rod construct in order to correct the deformity and stabilize the osteotomy site, however, the important correction potential has been associat-

ed to a high instability at the level of the PSO explaining why high rates of pseudarthrosis or implant failure (rod fracture) reaching up to 30% have been previously reported in the literature.^{1,2} In addition to spinal osteotomy, other risk factors may be associated with rod fracture such as advanced age, elevated body mass index (BMI), level of the PSO, use of pelvic fixation, more severe sagittal malalignment, and large correction of sagittal parameters³ in addition to rod extreme contouring that may produce metal fatigue.⁴ To palliate such complications, alternatives to the classical Titanium Alloy rod material have been proposed such as the use of cobalt chrome,⁵ but most importantly multiple-rod construct consisting of placing supportive rods across the PSO site to enhance the stiffness and stability have been advocated.⁶

The objective of the current study was to compare the radiological and functional outcomes and complications between adult spinal deformity patients who underwent a PSO but categorized according to their construct where either a standard 2-rod or a multiple-rod construct is applied.

MATERIALS AND METHODS

This is a retrospective review of a prospective adult spinal deformity database collected from 5 centers. Data from consecutive cases involving patients who underwent thoracic or lumbar PSO with a minimum follow-up of 2 years were obtained, and all patients were enrolled into and Institutional Review Board-approved protocol by the respective sites. Inclusion criteria are: age of at least 18 years, presence of a spinal deformity defined by at least one of the following parameters: Cobb angle $\geq 20^\circ$, pelvic tilt (PT) $\geq 25^\circ$, sagittal vertical axis (SVA) ≥ 5 cm, or thoracic kyphosis (TK) $\geq 60^\circ$.

Mobility around the PSO site was systematically checked preoperatively (dynamic flexion and extension views, computed tomography scan) in order to ensure fusion in that area postoperatively, therefore patients had either a previously ankylosed spine due to a previous surgery, or in case of mobile levels above or below, anterior support by cages at the aforementioned levels would be systematically done or a modified PSO including the disc above would be performed.

Patients who presented a proximal junctional failure (20 from the initial cohort of 104 patients) were excluded in order to focus on the rods specifically related complications.

Multiple rods technique was defined as using in addition to the classical 2 rods, at least one accessory or satellite rod systematically spanning the PSO area or the PSO and lumbosacral junction

(cobalt chrome or titanium).

Demographic data, operative parameters, spinopelvic parameters, functional outcomes, and complications were collected. And complications were distributed into 3 categories: no complications, rod fracture without revision, pseudarthrosis with revision.

Full spine standing anteroposterior and lateral radiographs were made and the different radiological parameters that were assessed preoperatively, at 6 months, and at the last follow-up after the index surgery included: SVA (distance between the C7-plumb line and posterior superior margin of S1), global tilt (GT: angle formed by the intersection of 2 lines, the 1st line is drawn from the center of C7 to the center of the sacral endplate and the 2nd line is drawn from the center of the femoral heads to the center of the sacral endplate), pelvic incidence (PI), PT, lumbar lordosis (LL), TK, and the coronal C7 plumb line (in relation to the center sacral vertical line [CSVL]). Angles were considered negative if lordotic and positive if kyphotic.

Univariate and multivariate analysis was performed on the relationship between the different rod constructs and the radiological parameters and functional scores using IBM SPSS Statistics ver. 25.0 (IBM Co., Armonk, NY, USA). Student t-test and the Mann-Whitney U-test were used to compare continuous variables. Chi-square and Fisher exact tests were performed for categorical variables. Continuous variables are expressed as mean \pm standard deviation, and frequency data are expressed as counts and percentages. All p-values were 2-tailed, and $p < 0.05$ was considered statistically significant. Multiple regression analysis was performed to identify risk factors for rods fracture.

For the subjects number, and based on statistical calculations with the use of the following formula:

$$N = \frac{2 X \bar{p}(1 - \bar{p}) \left(\frac{Z_\alpha}{2} + Z_\beta \right)^2}{(p1 - p2)^2}$$

It was found that when taking into account the initial sample of patients (single rods group) with the known incidence of mechanical complications (around 23%), looking into the number of patients required to see a decrease in the complications rate in the multirods group gave the following results:

- reaching a 3% decrease with a mechanical complications rate of 20% would require 44 patients.
- reaching an 8% decrease with a mechanical complications rate of 15% would require 91 patients.
- reaching a 13% decrease with a mechanical complications rate of 10% would require 231 patients.

RESULTS

Initial data included all PSOs performed in the thoracic and lumbar area (84 patients), however, data analysis showed no complications at all for PSOs above T9 with 85% of single rods being used in this category, in addition, PSOs performed between T10 and L2 included only 2 patients out of 10 with rod fractures with no revision at all. Therefore, and in order to properly compare single rods and multiple rods in a homogeneous sample of patients and avoid any bias, only the PSOs below L2 were included.

A total of 67 patients met the final inclusion criteria and were categorized into 3 groups: 2 rods (2R), multiple rods around the PSO (MRP), multiple rods around the PSO and lumbosacral junction (MRL).

Demographic and surgical data are presented in Table 1. Fifty-three had a prior spinal surgery and mean age at the index surgery was 60 years, with a mean follow-up period of 30 months. The mean number of fused segments was 9. Mean operative

time and surgical bleeding were 307 minutes and 1,800 mL, respectively.

The different groups showed a comparable preoperative sagittal malalignment with no significant difference in the different values of GT ($p=0.69$). From preoperatively to the final follow-up, significant improvements occurred in LL, TK, SVA, PT, GT, and C7-CSVL for coronal alignment (all, $p<0.05$). Table 2 details the aforementioned radiological data for the whole population. Coronal alignment parameter showed a better value on the last follow-up visit for both MRP and MRL groups when compared to the 2R group with a significant difference ($p=0.03$) testifying a better long-term coronal alignment. Between 6 months and 2 years, there was no significant difference in the radiological data of the 2 main groups (2R vs. MRP/MRL), however the loss of correction was less in the multiple rods group when compared to the single rod with a LL decreasing from 55.45° to 54.41° and from 53.56 to 50.15° respectively, a GT increasing from 24.57° to 25.84° and from 25.98° to 31.16° respectively and a SVA increasing from 35.71° to 37.13° and from 32.97° to 39.16°

Table 1. Demographic and surgical data of the 3 main groups

Variable	2R (n=26)	MRP (n=20)	MRL (n=21)	p-value
Age (yr)	58.9±13	59.8±14	61.5±9	0.778
Female sex	19 (73)	17 (85)	15 (71)	0.534
Body mass index (kg/m ²)	26.4±4	28.1±5	26.6±4	0.403
Smoking history (%)	15 (57.6)	5 (25)	8 (38)	0.162
Prior lumbar fusion	20 (76.9)	16 (80)	17 (81)	0.936
Level of PSO				
L3	4 (15.4)	2 (10)	3 (14.2)	
L4	16 (61.5)	15 (75)	12 (57.1)	
L5	6 (23.1)	3 (15)	6 (28.5)	0.232
Interbody cage placement at PSO site	17 (65.3)	12 (60)	13 (62)	0.792
No. of instrumented vertebra	9.3±2.1	10.1±3.4	10.5±3.8	0.632
Iliac fixation	21 (80.7)	16 (80)	18 (85.7)	0.834
No. of rods				0.413
2	26 (100)	-	-	
3	-	5 (25)	6 (28.5)	
4	-	12 (60)	13 (62)	
5	-	3 (15)	2 (9.5)	
Estimated blood loss (L)	1.8±1.2	2.0±1.5	2.3±1.2	0.723
Operation duration (min)	305±64	322±86	350±43	0.526
Follow-up period (mo)	30±6	31±6	33±7	0.651

Values are presented as mean ± standard deviation or number (%).

2R, 2 rods; PSO, pedicle subtraction osteotomy; MRP, multiple rods around the PSO; MRL, multiple rods around the PSO and lumbosacral junction.

respectively.

Health-related quality of life (HRQoL) scores showed a better outcome at 6 months and last follow-up visits in the MRP and MRL groups with globally similar values when compared to the single rods group, and this outcome was noted on different domains of SRS-22, SF-36, and ODI scores (Table 3). This finding was also noted when merging both MRP and MRL groups into a single one and comparing it to the 2R group (Table 4).

Multivariate analysis did not identify specific risk factors for rods complications when comparing the different parameters in the groups. However, a higher tendency for mechanical com-

plications when iliac fixation was performed could be seen.

The 3 groups showed similar rates (between 20% and 23%) of rod-related complications with no significant difference ($p = 0.95$). And inside each group, the distribution of complications between pseudarthrosis with revision and rod fracture without revision was also similar ($p = 0.99$). In fact, around 50% of patients with a rod fracture did not require to be revised (Table 5).

Table 2. Pre- and postoperative radiological data of total population

Parameter	Preoperative	Postoperative		p-value (preop/postop)
		6 Months	2 Years	
LL (°)	-29.22 ± 17.3	-54.89 ± 13.5	-52.31 ± 14.7	< 0.001
TK (°)	27.78 ± 10.6	44.22 ± 10.9	46.38 ± 9.2	< 0.001
PI (°)	61.27 ± 14.5	59.98 ± 13.9	60.80 ± 13.8	0.97
PT (°)	32.02 ± 10	20.91 ± 8.5	23.91 ± 8.4	< 0.001
GT (°)	45.55 ± 14	23.19 ± 9	29.12 ± 10.33	< 0.001
SVA (mm)	113.86 ± 65	43.28 ± 32	47.10 ± 37	< 0.001
C7-CSVL (mm)	34.68 ± 65	18.55 ± 14	16.02 ± 13	< 0.001

Values are presented as mean ± standard deviation. LL, lumbar lordosis; TK, thoracic kyphosis; PI, pelvic incidence; PT, pelvic tilt; GT, global tilt; SVA, sagittal vertical axis; CSVL, center sacral vertical line.

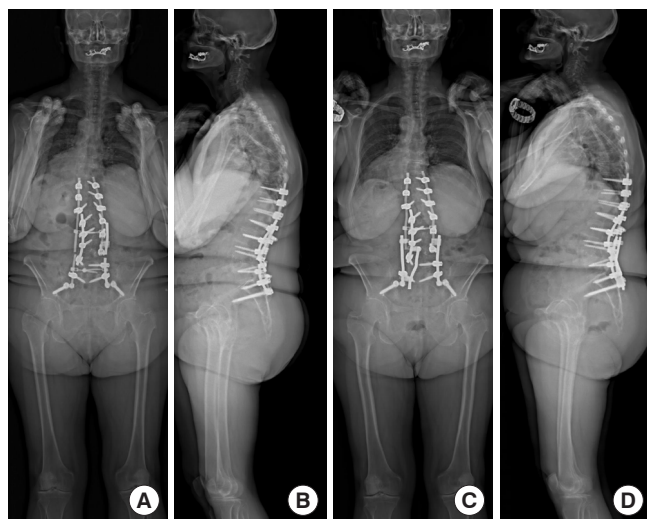


Fig. 1. (A, B) Clinical case depicting pseudarthrosis at the level of the pedicle subtraction osteotomy with 2 rods fractures. (C, D) Postoperative x-rays after revision.

Table 3. Health-related quality of life scores showing significant difference between the rods groups in favor of the multiple rods (2R, MRP, MRL) at 6 months and 2 years after surgery

Rods	No.	Mean ± SD	p-value
6M SRS-22 (function/activity)			
2R	20	2.48 ± 0.64	0.008
MRP	20	3.19 ± 0.72	
MRL	20	3.09 ± 0.87	
6M SRS-22 (subtotal score)			
2R	20	2.94 ± 0.62	0.04
MRP	20	3.38 ± 0.63	
MRL	20	3.4 ± 0.67	
6M SF-36 (role-physical)			
2R	19	28.2 ± 6.65	0.005
MRP	19	38.76 ± 11	
MRL	20	36.5 ± 11.44	
6M SF-36 (body pain)			
2R	19	36.77 ± 7.45	0.044
MRP	20	44.68 ± 9.72	
MRL	20	40.93 ± 11.15	
6M SF-36 (general health)			
2R	19	41.07 ± 9.87	0.021
MRP	20	46.26 ± 11.8	
MRL	20	50.69 ± 9.34	
2Y SRS-22 (subtotal score)			
2R	18	2.99 ± 0.77	0.044
MRP	19	3.55 ± 0.67	
MRL	21	3.5 ± 0.73	
2Y SRS-22 (total score)			
2R	18	3.1 ± 0.75	0.05
MRP	19	3.63 ± 0.61	
MRL	21	3.57 ± 0.73	

2R, 2 rods; PSO, pedicle subtraction osteotomy; MRP, multiple rods around the PSO; MRL, multiple rods around the PSO and lumbosacral junction; SD, standard deviation; 6M, 6 months; 2Y, 2 years; SRS-22, Scoliosis Research Society-22 questionnaire; SF-36, 36-item Short Form Health Survey.

Table 4. Health-related quality of life scores showing significant difference between the rods groups in favor of the multiple rods (after merging the 2 multiple rods groups together) at 6 months and 2 years after surgery

Rods	No.	Mean ± SD	p-value
6M ODI score (%)			0.019
Single rods	20	43.6 ± 16.37	
Multirods	40	31.73 ± 18.79	
6M SRS-22 (function/activity)			0.002
Single rods	20	2.48 ± 0.64	
Multirods	40	3.14 ± 0.79	
6M SRS-22 (subtotal score)			0.012
Single rods	20	2.94 ± 0.62	
Multirods	40	3.39 ± 0.64	
6M SRS-22 (total score)			0.014
Single rods	20	3.05 ± 0.59	
Multirods	40	3.48 ± 0.64	
6M SF-36 (role-physical)			0.001
Single rods	19	28.2 ± 6.65	
Multirods	39	37.6 ± 11.14	
6M SF-36 (body pain)			0.028
Single rods	19	36.77 ± 7.45	
Multirods	40	42.81 ± 10.5	
6M SF-36 (general health)			0.014
Single rods	19	41.07 ± 9.87	
Multirods	40	48.47 ± 10.74	
2Y SRS-22 (self-image)			0.022
Single rods	25	2.93 ± 0.79	
Multirods	38	3.41 ± 0.78	
2Y SRS-22 (mental health)			0.037
Single rods	25	3.06 ± 0.95	
Multirods	38	3.54 ± 0.83	
2Y SRS-22 (subtotal score)			0.023
Single rods	26	2.87 ± 0.96	
Multirods	38	3.36 ± 0.72	
2Y SRS-22 (total score)			0.021
Single rods	26	2.94 ± 0.95	
Multirods	38	3.43 ± 0.69	

SD, standard deviation; 6M, 6 months; 2Y, 2 years; ODI, Oswestry Disability Index; SRS-22, Scoliosis Research Society-22 questionnaire; SF-36, 36-item Short Form Health Survey.

When regrouping the patients and comparing them to the no complication group, higher BMI as a risk factor is identified (p = 0.04).

Figs. 1 and 2 illustrate cases of pseudarthrosis with revision.

Table 5. Complications of the series (2R, MRP, MRL)

Rods	No compli- cations	Complications		Total
		Pseudarthrosis with revision	Rod fracture without revision	
2R	20 (76.9)	3 (11.5)	3 (11.5)	26 (100.0)
MRP	16 (80.0)	2 (10.0)	2 (10.0)	20 (100.0)
MRL	16 (76.2)	2 (9.5)	3 (14.3)	21 (100.0)
Total	52 (77.6)	7 (10.4)	8 (11.9)	67 (100.0)

Values are presented as number (%).

2R, 2 rods: PSO, pedicle subtraction osteotomy; MRP, multiple rods around the PSO; MRL, multiple rods around the PSO and lumbosacral junction.

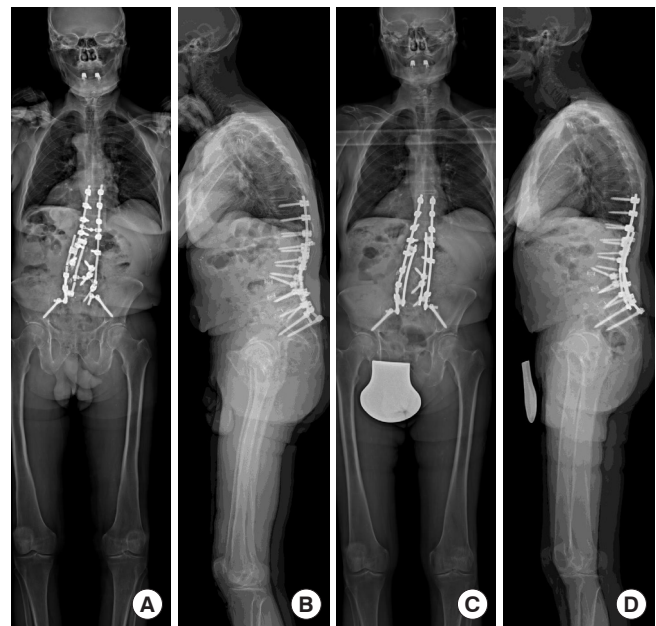


Fig. 2. (A, B) Case showing pseudarthrosis at the level of the pedicle subtraction osteotomy and lumbosacral junction with 3 rods fractures. (C, D) Postoperative x-rays after revision.

DISCUSSION

Fixed sagittal or coronal malalignment often requires complex spinal procedures involving the use of 3-column osteotomies such as PSO. PSO technique enables satisfactory correction but at the cost of creating a high iatrogenic instability at the osteotomy site, leading to a high rate of mechanical complications such as pseudarthrosis and rod fractures.⁷ Rod fracture is the most frequent mode of hardware failure in long segment spinal fusion surgery, and it can negatively impact the clinical outcome by producing spinal pain, functional compromise, instability, and deformity correction.⁸

In order to palliate such disadvantage, the technique evolved over the course of time and the use of multiple rods has been proposed.⁹ Initially, a 3-rod configuration was proposed consisting of the classical 2 rods in addition to a central satellite rod independently anchored with laminar hooks to serve as a guide for PSO closure.¹⁰ This was followed by a 4-rod instrumentation based on accessory rod connected by side-by-side domino connectors.³

The first clinical study that compared a 2-rod construct to a multiple-rod construct showed 17% of rod breakage in the 2-rod group with more than half of the concerned patients requiring revision because of symptomatic pseudarthrosis, whereas only 3% of the multiple-rod group showed partial implant failure without symptomatic pseudarthrosis avoiding the need for any revision in this group.⁶

A biomechanical cadaveric study investigated the effect of PSO stabilization with increasing rod numbers and implantation of adjacent cages on range of motion and primary rod strains. It showed that the supplementation of 2 rods with lateral accessory rods¹¹ coupled to adjacent cages implantation was the most effective strategy in minimizing primary rods strains and even without cages, the strains were significantly reduced.¹²

In a study by Shen et al.,¹³ the dual rods construct consisting of 4 distinct and mechanically independent rods was defended in order to decrease the complications when compared to the use of satellite rods. Their series of 36 adult spinal deformity patients showed 8.3% of rod fractures, and none of them required revision surgery. They advocated the fact that, contrary to the dual construct where all 4 rods are directly on their own pedicle screws, the satellite rods are not, which biomechanically transfers the stress of the reconstruction either proximally or distally resulting in rod fracture above or below the satellite rods.

Another study by Gupta et al.¹¹ provided a comparison between 2 techniques for rod placement across a PSO and suggested that their described novel 4-rod technique may help to reduce the rates of pseudarthrosis and rod failure.

In a finite element study, the effect of delta-rod configuration on the stiffness and primary rod stress reduction in multiple-rod constructs after PSO was analyzed. Avoiding to bend the third and fourth accessory rods with exact matching of the sagittal shape of the main rod enabled more better biomechanical performance in comparison to other multirods configuration minimizing the loss of fixation after initial rod breakage occurred.¹⁴ Another finite element analysis showed how adding satellite rods increases the rigidity of a construct across the PSO level reducing the stress on the primary rods, with a significant ben-

efit in supplementing medial over lateral satellite rods.¹⁵

The current study eliminated patients who presented a proximal junctional failure from the inclusion criteria in order to focus specifically on the rods' complications. In fact, proximal junctional kyphosis/proximal junctional failure (PJK/PJF) definitely affects HRQoL, however, it was decided to exclude such complications in order to avoid any bias and specifically study rods related complications and not global complications as PJK/PJF are proximal complications to the construct that may occur with either 2 or multiple rods and are mostly related to sagittal malalignment but are not directly related to the number of rods inside the instrumentation. The current study suggests an acceptable rate of mechanical rod-related complications of 22.4% with a revision rate of 10.4% in the whole population. However, and contrary to the previous papers of the literature, the use of multiple rods across the osteotomy did not prevent pseudarthrosis and fatigue rod fracture when compared to single rods, subsequently showing a similar rate of complications between the 2 techniques.

This finding may probably be related to the fact that the majority of the patients (68%) were operated before with a previously fused spine, and also the systematic supporting of the anterior column, as suggested in the literature, either through interbody cages around the PSO or at the lumbosacral junction, or by performing a modified or extended PSO including the disc above,^{16,17} which probably decreased rod strains even in the 2R group. The better functional outcome is most probably due to a lesser loss of correction in the multiple rods group; deformity correction seems to be better maintained when multiple rods are used. It has been previously reported that coronal improvement is directly related to better HRQoL outcomes.¹⁸

It should be reminded that with the increased space occupation by the instrumentation, there is proportionally less space available for the placement of bone graft, which may compromise the fusion bed and arthrodesis process.

The addition of extra rods came with a lot of variations in the literature with a significant heterogeneity and lack of convention in describing the constructs as satellite, supportive, delta, outrigger, or accessory rods. This is why a new classification system has been proposed to define the different configurations of multiple rods constructs allowing for standardized communication and research or clinical practice.¹⁹ In our study, surgical technique regarding the use of multiple rods corresponded to the precited definition of using in addition to the classical 2 rods, at least one accessory or satellite rod systematically spanning the PSO area or the PSO and lumbosacral junction which

consists of connecting the accessory or satellite rod to the main rod with one proximal connector and one distal connector placed just below the S1 screw in order to protect the adjacent area. An additional detail is to avoid overloading the proximal part of the construct with multiple rods to avoid proximal overload and PJK. In the classification system for multirod constructs,¹⁹ satellite rods are defined as additional rods attached to anchors with or without an attachment to the main rod construct, therefore, bridging screws heads that went out of line is considered a satellite rod. Accessory rods are not attached to any anchors but to the main rod via connectors.

In a recent study by Lee et al.,²⁰ 2 groups of adult spinal deformity patients were analyzed according to the occurrence or not of a rod fracture during following-up. They showed that 42% of patients who underwent a PSO presented a rod fracture, while patients characteristics did not have an impact on the occurrence of rod fractures. Use of cobalt chrome rod, accessory rod technique, or lateral lumbar interbody fusion was shown to be effective for reducing the rate of rod fractures. In our study, it was clearly demonstrated that a higher BMI is a risk factor for rod fractures.

A recent study by Dinizo et al.²¹ evaluated specifically revision cases that were managed with 2 different posterior techniques. Comparing 2 groups of adult spinal deformity patients, their data demonstrated no difference in fusion grade, or rates of rod fracture and revisions at 2 years, after utilizing a 2 rod versus multiple-rod construct in revision surgery for pseudarthrosis. Such finding goes in pair with our results and clearly demonstrates that the optimal instrumentation configuration is still not identified. Nevertheless, our study showed that despite a similar rate of complications between the different groups, significantly better postoperative coronal alignment and HRQoL scores were noted in the multiple rods groups. This may suggest a more stable construct in the multiple rods group that is preventing secondary loss of correction in the coronal plane and improving the global function of the patient. Such findings will need further research studies in the future in order to be confirmed.

Some limitations of the current study should be acknowledged such as the limited number of patients, the limited number of complications such as pseudarthrosis which may have limited the possibility of comparing the parameters inside the complications group itself. The different types of multiples rods constructs (accessory, satellite) were not analyzed as different subtypes to identify eventual differences as it would have required a bigger number of patients.

CONCLUSION

The use of multiple rods across the PSO site did not show a better outcome when compared to single rods in terms of incidence and types of mechanical complications. However, a better postoperative coronal alignment and HRQoL scores in the multiple rods group could be seen demonstrating an improved functional outcome.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Original Article

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Utility of the MISDEF2 Algorithm and Extent of Fusion in Open Adult Spinal Deformity Surgery With Minimum 2-Year Follow-up

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Objective: Long-segment fusion in adult spinal deformity (ASD) is often needed, but more focal surgeries may provide significant relief with less morbidity. The minimally invasive spinal deformity surgery (MISDEF2) algorithm guides minimally invasive ASD surgery, but it may be useful in open ASD surgery. We classified ASD patients undergoing focal decompression, limited decompression and fusion, and full correction according to MISDEF2 and correlated outcomes.

Methods: A retrospective study of ASD patients treated by 2 surgeons at our hospital was performed. Inclusion criteria were: age > 50, minimum 2-year follow-up, and open ASD surgery. Tumor, trauma, and infections were excluded. Patients had open surgery including focal decompression, short segment fusion, or full scoliosis correction. All patients were categorized by MISDEF2 into 4 classes based upon spinopelvic parameters. Perioperative metrics were assessed. Radiographic correction, complications and reoperation were recorded.

Results: A total of 136 patients met inclusion criteria. Mean follow-up was 46 ± 15.8 months (range, 24–118 months). Forty-seven underwent full deformity correction, 71 underwent short segment fusion, and 18 underwent decompression alone. There were 24 cases of class I, 66 cases of class II, 23 cases of class III, and 23 cases of class IV patients. Patients in class I and II had perioperative complication rates of 0% and 16.7% and revision rates of 8% and 21.2% when undergoing focal decompression or limited fusion. However, class II patients undergoing full correction had higher perioperative complications rate ($p = 0.03$) and revision surgery rates ($p = 0.047$). This difference was not seen in class III patients ($p > 0.05$). All class IV patients underwent full correction, but they had higher perioperative complication rates ($p < 0.019$), comparable revision surgery rates ($p = 0.27$), and better radiographic realignment ($p < 0.001$). In addition, full deformity correction was associated with longer length of stay, increased blood loss, and longer operative time ($p < 0.001$).

Conclusion: The MISDEF2 algorithm may help guide ASD surgical decision making even in open surgery, with focal treatment used in class I and II patients as a viable alternative and full correction implemented in class IV patients because of severe malalignment. However, class II patients with ASD undergoing full deformity correction do have higher complication rates.

Keywords: MISDEF2, Adult spinal deformity, Adult spinal deformity, Minimally invasive surgery, Complications, Outcomes



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INTRODUCTION

Adult spinal deformity (ASD) surgery usually requires long-segment fusion to address the entire pathology, but the morbidity is not trivial. Foraminal up-down compression causing radiculopathy may prompt the patient to seek surgical care because of disabling pain. Such disabling symptoms may manifest from the focal pathology (radiculopathy or listhesis), not from the chronic scoliosis. In such patients, one option may be to treat the focal pathology, especially in frail patients or in patients who do not want a multilevel fusion.¹

There is a concern that a decompression only in spinal deformity may simply worsen the deformity and result in symptom recurrence or progression.² There is also the concern that short-segment fusion fails to correct the deformity and that the remainder of the unfused curve may continue to cause symptoms.³ Both the limitations of focal surgeries and the morbidity of complete scoliosis correction capitulate the need for guidance with regard to choosing the right type of surgery for each patient.³⁻⁶ Silva and Lenke⁷ published a scheme that presented 7 types of treatment for ASD, but there was no patient cohort to validate this scheme as to its efficacy, durability, or surgical appropriateness. However, with the advent modern minimally invasive surgery (MIS), the feasibility and advantages of MIS ASD surgery began to emerge.⁸ To specifically address the role of focal surgery using MIS techniques, the minimally invasive spinal deformity (MISDEF) algorithm was published, later updated to MISDEF2 to incorporate such advanced MIS techniques as the mini-open pedicle subtraction osteotomy (PSO) and anterior column re-alignment/release (ACR).⁹⁻¹² Because the diagnosis of ASD is the same regardless of MIS or open treatment and because many surgeons now treat ASD with both open and MIS

surgery, we wished to examine the applicability of the MISDEF2 algorithm in open ASD surgery.

MATERIALS AND METHODS

1. Patient Population

A retrospective study of ASD patients who underwent open surgical correction by 2 attending spine surgeons at our hospital from 2006 to 2016 was undertaken. Inclusion criteria were: minimum 2-year follow-up, age > 50 years, degenerative scoliosis (Cobb angle > 10°) with or without kyphosis, and open ASD surgical treatment with either decompression alone, decompression with fusion ≤ 3 levels, full ASD correction encompassing entire scoliosis Cobb angle or correction of sagittal imbalance. Patients who underwent decompression or decompression with fusion did not undergo deformity correction. Infection, tumor, and trauma were excluded. Patient demographics, perioperative variables, complications, and revision surgery rates were collected.

2. The MISDEF Algorithm

Mummaneni et al.⁹ proposed the MISDEF algorithm and revised version¹⁰ to provide a guideline for surgeons to choose an MIS approach for ASD surgery. The revised algorithm is based on the radiographic parameters: sagittal vertical axis (SVA), pelvic tilt (PT), pelvic incidence (PI) minus lumbar lordosis (LL) (PI-LL) mismatch, and coronal Cobb angle. Additionally, the algorithm considers whether the spine is rigid, the extent of fusion needed, and pre-existing instrumentation (Table 1). We retrospectively classified patients undergoing surgery for ASD according to MISDEF2 and correlated outcomes.

Table 1. The MISDEF2 algorithm

	Class I	Class II	Class III	Class VI
Sagittal and coronal parameters	SVA < 6 cm PT < 25 PI-LL mismatch < 10° Coronal Cobb < 20°	PI-LL mismatch > 10°, but < 30° SVA > 6 cm or PT > 25 or coronal Cobb > 20°, but thoracic kyphosis < 60° or thoracolumbar kyphosis < 10°	PI-LL mismatch > 30° SVA > 6 cm or PT > 25 or coronal Cobb > 20°, thoracic kyphosis > 60° or thoracolumbar kyphosis < 10°	Fused or rigid spine and > 5 level fusion including L5-S1 or > 10 segments needing treatment or pre-existing multilevel instrumentation
Surgery	MIS surgery with decompression only or fusion of a listhetic level	Multilevel MIS surgery without decompression and interbody fusion	Circumferential MIS with ACR, mini-open PSO, expandable cage technology, and/or hybrid-open approaches	Open surgery with osteotomies +/- extension of fusion to the thoracic spine

SVA, sagittal vertical axis; PT, pelvic tilt; PI-LL, pelvic incidence minus lumbar lordosis; MIS, minimally invasive spinal; ACR, anterior column release; PSO, pedicle subtraction osteotomy.

3. Radiographic Measurements

Full-length 36-inch anteroposterior and lateral radiographs were obtained preoperatively and at last clinic follow-up. Radiographic analyses included measurements of SVA, LL, thoracic kyphosis (TK), thoracolumbar kyphosis (TLK), PI, sacral

slope, PT, PI-LL, and pre- and postoperative Cobb angles. All patients were classified by MISDEF2 into 4 classes (class I: SVA < 6 cm, PT < 25°, PI-LL < 10°, Cobb < 20°; class II: SVA > 6 cm, PT > 25°, PI-LL > 10° < 30°, Cobb > 20°; class III: LL-PI > 30°, TK > 60°, TLK > 10°; and class IV: >5-level fusion including

Table 2. Comparisons of demographic, clinical and radiological parameters

Variable	Open operation			p-value
	Decompression	Limited fusion	Full correction	
Age at surgery (yr)	71.3 ± 5.5	66.5 ± 11	63.5 ± 11.0	0.025
Sex, male:female	12:6	35:35	18:29	0.111
Body mass index (kg/m ²)	29.6 ± 5.71	27.9 ± 6.4	28.6 ± 5.8	0.536
Follow-up (mo)	43.3 ± 14.4	45.2 ± 18.6	47.6 ± 25.7	0.717
Surgical duration (min)	169.1 ± 93	279.6 ± 123.9	423 ± 164.6	< 0.001
Estimated blood loss (mL)	108.3 ± 67	301.8 ± 253.1	1,368.1 ± 810.0	< 0.001
Length of hospital stay (day)	3.1 ± 1.8	4.7 ± 2.5	8.8 ± 3.5	< 0.001
Surgical levels	1.6 ± 0.7	2.0 ± 1.1	8.1 ± 3	< 0.001
Preoperative Cobb angle (°)	12.4 ± 4.1	12.4 ± 6.9	18.9 ± 8.9	< 0.001
Postoperative Cobb angle (°)	8.6 ± 5.6	10.3 ± 7.6	11.6 ± 6.5	0.675
Cobb angle changes	3.8 ± 4.6	2.1 ± 4.5	8.5 ± 8.3	< 0.001

Values are presented as mean ± standard deviation.



Fig. 1. MISDEF2 algorithm class I patient with compression alone. Preoperative coronal and sagittal parameters: sagittal vertical axis, 23 mm; Cobb angle, 14°; pelvic incidence (PI), 61°; pelvic tilt, 18°; sacral slope, 43°; lumbar lordosis (LL), -64°; PI-LL, 3°. (A) Preoperative anteroposterior (AP) radiograph. (B) Preoperative lateral radiograph. (C) Postoperative AP radiograph at 2-year follow-up. (D) Postoperative lateral radiograph at 2-year follow-up.

L5–S1 or > 10 levels) (Table 1).

4. Surgical Technique

In the decompression only group, patients underwent bilateral hemi-laminotomies with preservation of the spinous processes and interspinous ligaments. In the decompression with limited fusion, the patients underwent laminectomy and instrumented fusion at the levels of decompression. Patients who

underwent full correction had multilevel instrumentation to span the entire Cobb angle.

5. Statistical Analysis

All data collection and radiographic analysis was performed either a spine fellow or an attending spine surgeon. Analysis of variance was used to detect if there was a difference among the 3 groups. The chi-square test was used to compare the differ-

Table 3. Revision surgery rates

Class	Decompression	Limited fusion	Full correction	Total	p-value
I	0/4 (0)	2/20 (10)	-	2/24 (8)	-
II	2/12 (16.7)	4/38 (10.5)	8/16 (50)	14/66 (21.2)	0.047
III	0/2 (0)	1/13 (7.7)	2/8 (25)	3/23 (13)	0.541
IV	-	-	8/23 (34.8)	8/23 (34.8)	-
Total	2/18 (11)	7/71 (9.9)	18/47 (38)	27/136 (19.9)	<0.008
p-value	0.621	0.964	0.694	0.27	

Values are presented as revision cases/total cases (%).



Fig. 2. MISDEF2 algorithm class II patient with limited fusion. This was planned as a minimally invasive spinal (MIS) procedure, but converted to open. Because the MIS equipment was ready, the MIS rods were used even though the procedure was open. Preoperative coronal and sagittal parameters: sagittal vertical axis, 20 mm; Cobb angle, 22°; pelvic incidence (PI), 44°; pelvic tilt, 15°; sacral slope, 29°; lumbar lordosis (LL), -40°; PI-LL, 4°. (A) Preoperative anteroposterior (AP) radiograph. (B) Preoperative lateral radiograph. (C) Postoperative AP radiograph at 1-year follow-up. (D) Postoperative lateral radiograph at 1-year follow-up. (E) Postoperative AP radiograph at 3-year follow-up. (F) Postoperative lateral radiograph at 3-year follow-up.

ences in complication and revision rates among the 4 MISDEF2 classes. A $p < 0.05$ was regarded as statistically significant. IBM SPSS Statistics version 20.0 (IBM Corporation, Armonk, NY, USA) was used.

RESULTS

1. Comparisons of Demographic, Clinical, and Radiological Parameters

One hundred thirty-six patients met inclusion criteria, with 71 females and 65 males (Table 2). There were 24 cases of class I, 66 cases of class II, 23 cases of class III, and 23 cases of class IV patients. Forty-seven underwent full deformity correction, 71 underwent limited decompression and fusion, and 18 underwent decompression alone. The mean age was 71.3 ± 5.5 years (range, 55–86 years). The mean body mass index was 28.4 kg/m^2 . The mean follow-up was 46 ± 15.8 months (range, 24–118 months). The average number of surgical levels was 1.6 for decompression alone, 2.0 for limited fusion, and 8.1 for full correction. The mean operative time was 169 minutes for decompression alone, 279.6 for limited fusion, and 423 for full correction. The mean estimated blood loss was 108.3 mL for decompression alone, 301.8 mL for limited fusion, and 1,368.1 mL for full cor-

rection. The average length of stay was 5.9 ± 2.8 days (Table 2).

Focal decompression had 4 class I, 12 class II, 2 class III, and 0 class IV; limited fusion had 20 class I, 38 class II, 13 class III, and 0 class IV; and full correction had 0 class I, 16 class II, 8 class III, and 23 class IV. The mean preoperative coronal Cobb angle was $12.4^\circ \pm 4.1^\circ$ for decompression alone, $12.4^\circ \pm 6.9^\circ$ for limited fusion, and $18.2^\circ \pm 9.8^\circ$ for full correction. The mean postoperative coronal Cobb angle was $8.6^\circ \pm 5.6^\circ$ for decompression alone, $10.3^\circ \pm 7.6^\circ$ for limited fusion, and $11.6^\circ \pm 6.5^\circ$ for full correction. There was a statistically significant difference in the coronal Cobb angle correction among the 3 types of surgeries ($p < 0.001$) (Table 2).

2. Perioperative Complication and Revision Surgery

When analyzing by MISDEF2, patients in classes I and II had peri-operative complication rates of 0/20 and 4/50 (8%) and revision rates of 2/24 (8%), and 6/50 (12%) when they underwent focal decompression or limited fusion ($p = 0.5$, $p = 0.74$) (Figs. 1, 2). No class I patient underwent full correction. Class II patients undergoing full correction had higher revision surgery rates (50%, 8 of 16) and complication rates (43.7%, 7 of 16) than patients undergoing focal decompression or limited fusion ($p = 0.047$, $p = 0.030$) (Tables 3, 4; Fig. 3). There was no differ-

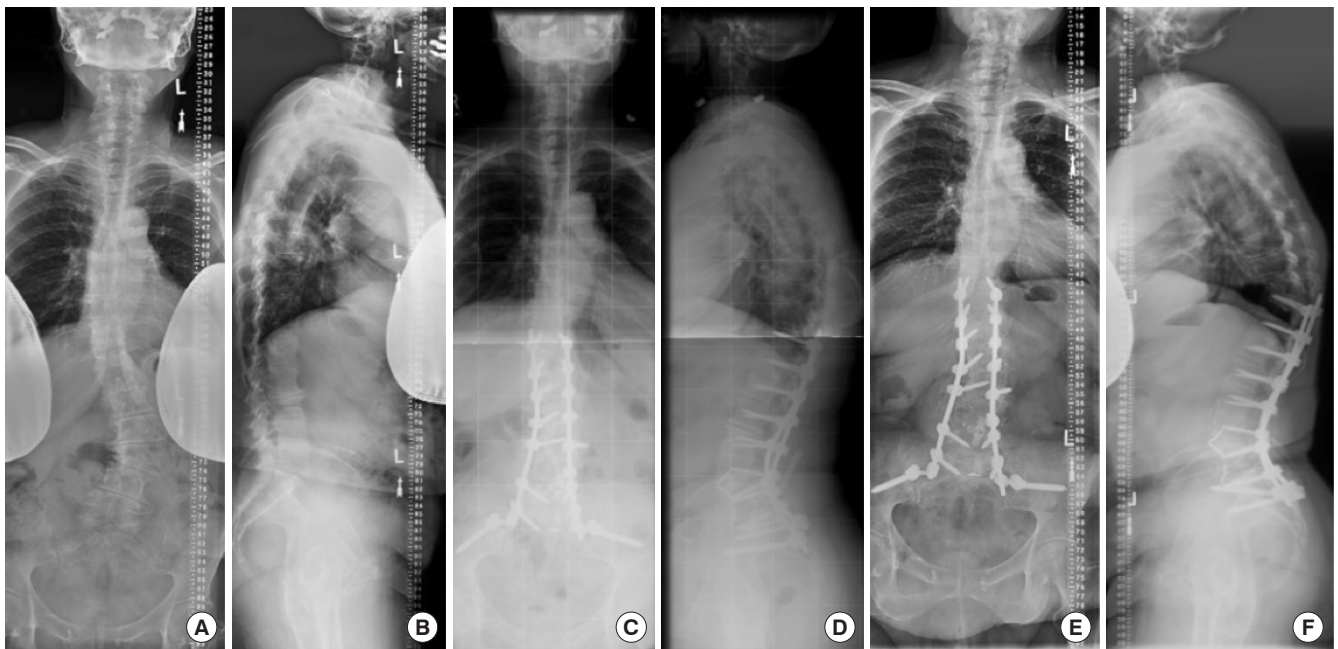


Fig. 3. MISDEF algorithm class II patient with full correction. Preoperative coronal and sagittal parameters: sagittal vertical axis, 68 mm; Cobb angle, 31° ; pelvic incidence (PI), 45° ; pelvic tilt, 24° ; sacral slope, 21° ; lumbar lordosis (LL), -25° ; PI-LL, 20° . (A) Preoperative anteroposterior (AP) radiograph. (B) Preoperative lateral radiograph. (C) Postoperative AP radiograph at 3-month follow-up. (D) Postoperative lateral radiograph at 3-month follow-up. (E) Postoperative AP radiograph at 1-year follow-up. (F) Postoperative lateral radiograph at 1-year follow-up proximal Junctional Kyphosis.

ence in perioperative complication and revision rates for class III patients regardless if they underwent limited fusion or full correction ($p=0.541$, $p=0.431$) (Tables 3, 4). All class IV patients underwent full correction (Fig. 4), and they had higher perioperative complication rates (43.5%, 10 of 23) than class I patients (0 of 24), class II patients (16.7%, 11 of 66), and class III patients (17.4%, 4 of 23) ($p<0.019$) (Table 4). The revision rate of class IV patients 8 of 23 (34.8%) was not statistically different compared to class I (8%, 2 of 24), class II (21.2%, 14 of 66), and class III (13%, 3 of 23) ($p=0.27$) (Table 3). Compared to focal decompression and limited fusion, full correction re-

sulted in better coronal radiographic realignment (Cobb angle correction was $3.8^\circ \pm 4.6^\circ$, $2.1^\circ \pm 4.5^\circ$, and $8.5^\circ \pm 8.3^\circ$ respectively for decompression, limited fusion and full correction) ($p<0.001$) (Table 2). Full deformity correction was also associated with longer length of stay (3.1 ± 1.8 , 4.7 ± 2.5 , and 8.8 ± 3.5 days), more blood loss (108.3 ± 67 , 301.8 ± 253.1 , and $1,368.1 \pm 810$ mL), and longer operative times (169.1 ± 93 , 279.63 ± 123.9 , and 423 ± 164.6 minutes), respectively for decompression, limited fusion and full correction (all $p<0.001$) (Table 2). The reasons for revision surgery and perioperative complications are listed in Tables 5 and 6.

Table 4. Perioperative complication rates

Class	Decompression	Limited fusion	Full correction	Total	p-value
I	0/4 (0)	0/20 (0)	-	0/24 (0)	-
II	1/12 (8.3)	3/38 (7.9)	7/16 (43.7)	11/66 (16.7)	0.030
III	1/2 (50)	1/13 (7.7)	2/8 (25)	4/23 (17.4)	0.431
IV	-	-	10/23 (43.5)	10/23 (43.5)	-
Total	2/18 (11)	4/71 (5.6)	14/47 (29.8)	25/136 (18.4)	<0.009
p-value	0.311	0.464	0.80	<0.019	

Values are presented as revision cases/total cases (%).

Table 5. Revision surgery

Reasons for revision	Decompression	Limited fusion	Full correction
Adjacent segment degeneration	1	1	-
Pseudarthrosis or implant failure	-	2	6
Proximal junctional kyphosis/failure	-	-	8
Persistent cerebrospinal fluid leak requiring exploration	-	1	-
Iliac screw loosening/painful iliac screw	-	-	2
Failure of decompression	1	1	-
Screw malposition	-	-	2
Flat back syndrome/sagittal imbalance	-	2	-

Table 6. Perioperative complications

Perioperative complications	Decompression	Limited fusion	Full correction
Dural tears	-	1	4
Wound Infections	-	1	6
Ileus	-	1	2
Epidural hematoma	-	1	-
Urinary retention	-	-	2
Altered mental status	-	-	2
Renal insufficiency	-	-	1
Post-operative arrhythmia	-	-	2
Worsened lower extremity pain or weakness	-	-	2

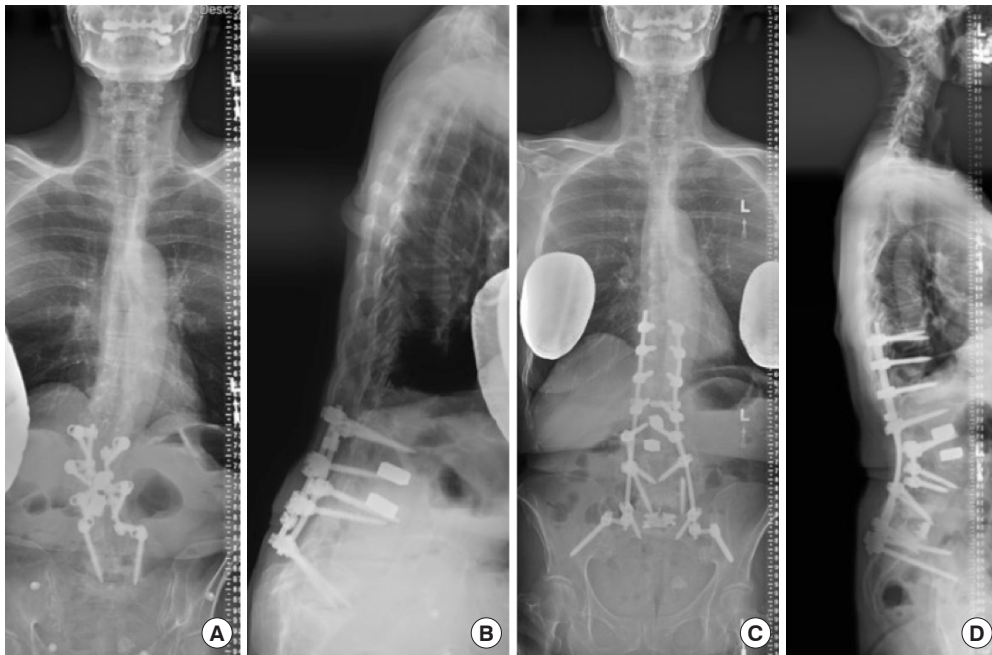


Fig. 4. MISDEF algorithm class IV patient with full correction. Preoperative coronal and sagittal parameters: sagittal vertical axis, 145 mm; Cobb angle, 20°; pelvic incidence (PI), 64°; pelvic tilt, 39°; sacral slope, 25°; lumbar lordosis (LL), -15°; PI-LL, 49°. (A) Preoperative anteroposterior (AP) radiograph. (B) Preoperative lateral radiograph. (C) Postoperative AP radiograph at 2-year follow-up. (D) Postoperative lateral radiograph at 2-year follow-up.

DISCUSSION

The treatment of adult scoliosis can be challenging with high complication rates, complex treatment planning, and an aging, osteoporotic population. Patients with long-standing scoliosis for decades may not have disabling back pain that leads to surgery, but lateral listhesis, spondylolisthesis, or severe stenosis may drive the patient towards surgical treatment. Such patients may simply want their neurogenic and radicular symptoms eliminated with a focal fusion of the listhetic levels and not an entire scoliosis fusion. However, treating a limited portion of the scoliotic curve leaves the rest of the curve untreated and the potential for further degeneration because of partial fusion. Further, there are cases of severe sagittal or coronal imbalance, and complete realignment of the spine is really the only solution to alleviate disability. Finally, there are cases in which the scoliosis itself can be extremely painful because of a high Cobb angle that can no longer properly support the weight of the torso. In our study, we found that the treatment algorithm of MISDEF2 to open spinal deformity has potential to be relevant and applicable.

The first consideration is to ensure that surgery has a high chance of alleviating the patient's symptoms. Performing a he-

mi-laminotomy or adding another fusion level on in a patient with iatrogenically fused flatback and back pain because of a forward stooped posture will most likely be a failure, leading to disappointment for both the surgeon and patient. Performing the proper operation for the patient should still be the goal of the surgery. The second consideration is to weigh the morbidity and the patient's medical comorbidities with the risks and benefits of surgery.

Guidelines for the appropriate treatment options in adult scoliosis are few but studies have reported on the variable surgical strategies for adult scoliosis. Lee et al.¹³ reported that short fusion may be a reasonable option in patients with *de novo* adult degenerative lumbar scoliosis without sagittal imbalance. However, this report was a meta-analysis, not a direct comparison between the two groups. Nonetheless, their review indicated that limited fusion in balanced spines was associated with less morbidity than full fusion with similar decrease in disability in both groups. Weidenbaum⁶ reported success with decompression without fusion in adult scoliosis patients when the primary complaint was not the curve itself. However, this was a limited series without any direct comparison group. Given the very powerful methods of indirect decompression with modern interbody fusion, Chou et al.¹⁴ and Amara et al.¹⁵ have reported

that limited fusion of the fractional curve in adult scoliosis can achieve comparable reduction of leg pain. Although there were comparable immediate results with regard to pain reduction, longer term revision surgery rates appeared to be higher in fusion of the fractional curve only. Lee et al.¹⁶ evaluated scoliosis curve progression in limited fusion cases compared to the natural history of scoliosis progression, and they found no difference in curve progression between the 2 groups. However, their study focused on surgery for degenerative lumbar stenosis who happened to have some component of scoliosis, not scoliosis patients per se.

The MISDEF2 algorithm guides minimally invasive ASD surgery, but it conceptually makes sense to also guide open ASD surgery since the pathology is the same, regardless of treated MIS or open. Using a modified Delphi approach, the MISDEF2 algorithm and recommends 4 treatment classes that incorporate such newer MIS approaches as the ACR¹⁷ and minimally invasive PSO.¹¹ MISDEF2 takes into account spinopelvic parameters and Cobb angle magnitude, and it also accounts for whether the spine is rigid. Although initially designed for MIS deformity surgery, we retrospectively classified our cohort of deformity patients undergoing focal decompression, limited decompression and fusion, and full correction by the MISDEF2 algorithm to evaluate the feasibility of using the algorithm in open surgery. Consistent with the decision tree of MISDEF2, class I and II patients who underwent limited and focal surgery did not have higher revision rates than full correction patients, indicating that in fairly well-balanced spines, patients who present with isolated stenosis or listhesis may consider a focal operation instead of correction of their entire scoliosis. This may be secondary to larger surgeries in class II having higher complication rates, but focal surgeries being fairly effective, precluding revision surgery complications. In class III, however, many of these patients may have needed full correction, yet more focal surgeries resulted in complications because of inadequate correction. These findings are consistent with previous studies. Simmons¹⁸ and Chen et al.¹⁹ have reported that decompression with limited fusion without deformity correction is reasonable in patients who have moderate to severe stenosis affecting 3 or more levels, smaller curves ($< 30^\circ$), no progression of deformity, and no sagittal malalignment.^{18,19} Glassman et al.²⁰ also reported similar findings. In general, small curves (10° – 20°) with limited rotation and normal sagittal balance were identified as potential candidates for decompression alone. Moderate curves (15° – 40°) with segmental instability, significant rotation, or severe concave compression, may be candidates for decompression

and fusion with only limited deformity correction. Larger curves ($> 40^\circ$) or patients with significant coronal or sagittal imbalance generally undergo decompression, fusion, and full deformity correction.²⁰ However, consistent with previously published reports, full correction surgery was associated with more length of stay, more blood loss, and more operative time ($p < 0.001$) (Table 2). In addition, full correction had higher perioperative complication rates than focal decompression or limited fusion ($p < 0.009$). However, full correction also resulted in better radiographic correction ($p < 0.001$).

There are limitations for this paper. First, it is a retrospective, single center study. Second, the MISDEF2 algorithm was designed for MIS deformity surgery, not open deformity surgery. Applying this algorithm to open surgery is a novel and uncharted concept. However, our application of the MISDEF2 algorithm to open cases yielded results that are consistent with the underlying principles of the MISDEF2 and consistent with previously published literature regarding focal surgeries compared to full corrective surgeries for adult scoliosis. Third, the actual surgeries that were carried out had selection bias; older, more frail patients may have undergone smaller surgeries because they simply could not have tolerated larger reconstructive procedures. This selection bias should be considered when interpreting the data. Fourth, the selection of surgery types and the MISDEF2 were retrospectively compiled; the actual selection of surgery was implemented well before the development of MISDEF2. Thus, the surgical selection was based upon surgeon judgement and patient frailty, but the application of the MISDEF2 was retrospectively applied. This could have resulted in selection bias and confounding error. However, the classification of the scoliosis itself was performed via MISDEF2, and the surgeries were analyzed only after classification. Thus, “appropriateness” of surgery was categorized after application of MISDEF2 classification, not as an actual choice of surgical technique. The strengths of this manuscript are minimum 2-year follow-up, complete evaluation of all scoliosis patients with 36-inch standing films, and data analyzing revision surgery and complication rates.

CONCLUSION

In patients who have deformities within class I and II by MISDEF2, open surgeries with decompression only and focal fusions may be viable options for surgical treatment. However, class II patients with ASD appear to have higher complication rates with full correction. Class III patients may be candidates

for limited surgery, but this should be individualized with each patient. Generally, class IV deformities should undergo full correction and realignment of the spine. The MISDEF2 algorithm—although designed for MIS deformity surgery—may also be useful for surgical decision making in open ASD surgery.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Original Article

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INTRODUCTION

In the surgical treatment of degenerative lumbar disease, correction of lumbar lordosis is an important factor in maintaining sagittal balance and for a better postoperative clinical course.¹⁻⁴ In particular, the segmental angle of L5-S1 plays an important role in lumbar lordosis,⁵⁻⁷ and there are various types of fusion operations at L5-S1, including anterior lumbar interbody fusion (ALIF), transforaminal lumbar interbody fusion (TLIF), posterior lumbar interbody fusion (PLIF), and oblique lateral interbody fusion (OLIF). Among them, ALIF and OLIF allow an interbody cage with a larger size and angle to be inserted

An Anatomical Clue for Minimizing Iliac Vein Injury During the Anterolateral Approach at L5-S1 Level: A Cadaveric Study

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Objective: The injury to the common iliac vein (CIV) seems to be the most important concern during the anterior approach to the spine at L5-S1 level. We investigated the anatomy of the L5-S1 vertebral structures related to the CIV through a cadaveric study to find an anatomical clue for safe dissection of CIV.

Methods: Ten cadavers were prepared for this study. After removing the peritoneum and the presacral fascia, the section from the lower part of the L5 to the upper part of the S1 vertebral body was removed with the CIV attached. After decalcification, 2 sections in the vertical and horizontal directions were made for histological study.

Results: An adipose tissue layer was present between the intervertebral disc and CIV. The adipose tissue layer in 6 cadavers was thin, and in 3 of these cadavers, the CIV was attached to the vertebral body and the disc. In the other 4 cadavers, the CIV was clearly separated from the vertebral body and the disc by the intervening adipose tissue layer (IATL). Under the microscope, a thin layer surrounding the anterior longitudinal ligament, periosteum, and disc was observed, and we named this structure the 'perivertebral membrane'. The perivertebral membrane was attached to the CIV when there was no IATL, but a potential space was detected under the membrane.

Conclusion: There was a thin membrane, perivertebral membrane, between the CIV and L5-S1 disc. In cases with CIV adhesion to the disc due to the absence of IATL, the CIV may be mobilized indirectly through the perivertebral membrane.

Keywords: Lumbosacral region, Iliac Vein, Anatomy, Spine, Anterior approach

than do the TLIF and PLIF thus ALIF and OLIF are more effective in lower lumbar lordosis correction.⁸⁻¹⁰ ALIF and OLIF require mobilization of the common iliac vein (CIV) to access the disc space, and injury to the CIV is one of the major fatal complications of these surgical procedures.

Several studies have reported the occurrence of vascular complications in ALIF and OLIF (3.3% vs. 4.3%, respectively),¹¹⁻¹⁴ and other papers on preoperative radiological evaluation have tried to find clues so that such vascular complications can be minimized.¹⁵⁻¹⁷ However, no studies suggest how to prevent complications by using the anatomical structures related to the CIV at the anterior surface of the L5-S1 disc as markers, from a spe-

cific viewpoint of the spinal surgeon.

In this study, we investigated the anatomical relationship of the structures in front of the L5–S1 disc through a cadaveric study and tried to find an anatomical clue to reduce CIV injury during the anterior interbody fusion surgery at the L5–S1 level.

MATERIALS AND METHODS

Ten cadavers (6 males and 4 females) were prepared for this

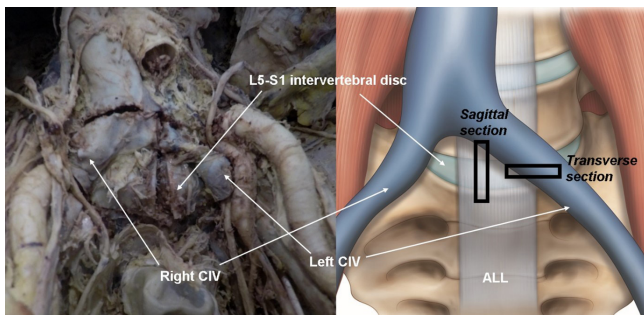


Fig. 1. A cadaver specimen and its schematic diagram. After removing the peritoneum and presacral fascia, the section from the lower part of the L5 to the upper part of the S1 vertebra was removed with the common iliac vein (CIV) attached. After decalcification, 2 sections were created to evaluate the relationship among the structures. The sagittal section included the vertebral bodies of L5 and S1, L5–S1 disc, periosteum, and the anterior longitudinal ligament (ALL); the transverse section included the ALL and left CIV on the middle to left side of the L5–S1 disc.



Fig. 2. A sagittal section showing ‘perivertebral membrane.’ (A) Entire longitudinal view of perivertebral membrane (PM). This figure was composed of 15 separate but continuous photographs in a specimen. The PM was observed anterior to the L5 and S1 vertebrae and the anterior longitudinal ligament (ALL) consistently. Inset: The PM was clearly distinguished from the ALL by potential empty space (hematoxylin and eosin [H&E] stain, $\times 200$). (B) The periosteum (PO) was located between the L5 vertebra and the ALL. It was clearly distinguished from the ALL by a narrow empty space (H&E stain, $\times 200$). AF, annulus fibrosus; CB, cancellous bone.

study. All cadavers were donated to the department of anatomy for educational and research purposes. All the cadavers were Korean, with no history of spinal or abdominal surgery.

1. Preparation of Cadaveric Specimens

After removing the peritoneum and the presacral fascia, a specimen containing the L5 and S1 vertebral bodies and the L5–S1 disc with the left CIV attached to the L5–S1 disc surface was obtained from each cadaver (Fig. 1). The specimens were fixed for 72 hours in 10% neutral buffered formalin and then decalcified in Kristensen’s solution for approximately 2 weeks. After decalcification, we cut the specimens into 2 different sections for the microstructural study.

1) Sagittal section

A section including the vertebral bodies of L5 and S1, L5–S1 disc, periosteum, and the anterior longitudinal ligament (ALL) to study the structural relationship of the bone, disc, and the periosteum at the transitional area between the vertebral bone and the disc.

2) Transverse section

A section including the ALL and left CIV on the left side of the L5–S1 disc to examine the relationship between the prevertebral structures and CIV.

The 2 sections were embedded in paraffin blocks and stained with hematoxylin and eosin.

RESULTS

Gross examination of the structures showed that the CIV bifurcation in each cadaver had a wide angle and the surface of the L5–S1 disc was exposed. An intervening adipose tissue layer (IATL) was present between the vertebrae and CIV and between the disc and CIV. In the 4 cadavers, the CIV was clearly separated from the vertebrae and the disc surfaces by the IATL. In 3 cadavers, the IATL was thin and in the other 3, there was almost no IATL, therefore the CIV is attached to the vertebrae and the disc surface.

Under the microscope, a thin membranous layer covering the ALL, periosteum, and disc was observed. The thickness of the membranous layer was about 0.2 mm (range, 0.1–0.25 mm), which was 8 to 10 times thinner than the ALL, and it was composed of fibrous tissue. We named this structure as ‘perivertebral membrane’.

1. Sagittal Section

The perivertebral membrane was observed in front of the L5 and S1 vertebrae and the disc consistently (Fig. 2). The perivertebral membrane was anterior to ALL and was clearly distinguished from it by a narrow space. The fibers of the perivertebral membrane, periosteum, and ALL were arranged vertically. ALL extended over the anterior surface of the L5 vertebra and L5–S1 disc. The periosteum was located between the L5 vertebra and ALL and was separated from it by a narrow empty space. Thus, as we moved anteriorly from the body of the vertebra, the arrangement of the structures was as follows: bone,

periosteum, ALL, and the perivertebral membrane. The annulus fibrosus (AF) was located behind the ALL outside of the nucleus pulposus. The AF could be distinguished from the ALL due to the different direction of its fibers.

2. Transverse Section

The perivertebral membrane was present in the outermost layer under the CIV, which covered the ALL and AF (Fig. 3). The left CIV was located above the perivertebral membrane,

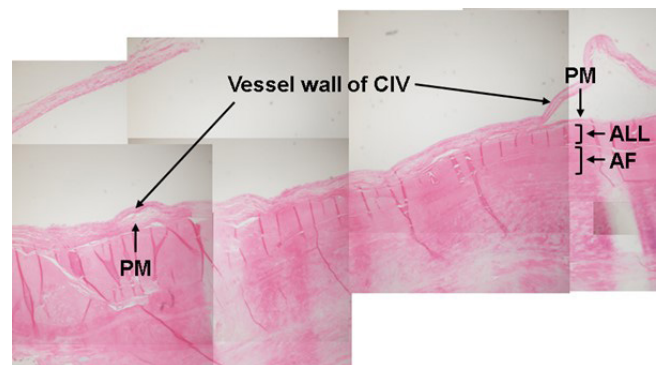


Fig. 3. A transverse section at the level of L5–S1 disc. The perivertebral membrane (PM) was present in the outermost layer, followed by the anterior longitudinal ligament (ALL) and the annulus fibrosus (AF). On the right side of the photograph, the vessel wall and the PM were well separated by the intervening adipose tissue layer (IATL), but the IATL became thin as it went to the left side and there was adhesion between the 2 structures. This figure was composed of 4 separate but continuous photographs in a specimen (hematoxylin & eosin stain, $\times 200$). CIV, common iliac vein.

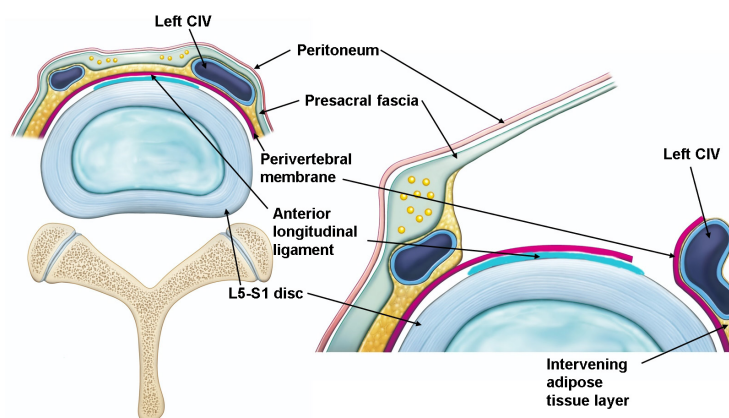


Fig. 4. A schematic diagram of the perivertebral membrane. In case where the intervening adipose tissue layer between the left common iliac vein (CIV) and L5–S1 disc was absent, the perivertebral membrane was cut with a knife, and blunt dissection was performed to open the potential space underneath it. As such, CIV mobilization with the perivertebral membrane attached to the CIV was performed to minimize CIV injury.

and IATL was present between the CIV and the perivertebral membrane. Fig. 4 shows a schematic representation of these structures. However, in the three specimens, the CIV was attached to the perivertebral membrane when there was no IATL.

DISCUSSION

The L5–S1 segment contributes the most in the development of lumbar lordosis.⁵⁻⁷ Among the surgical procedures at the L5–S1 level, ALIF and OLIF are more effective in correcting lordosis than the posterior approaches (TLIF and PLIF).⁸⁻¹⁰ However, ALIF and OLIF require the mobilization of CIV during surgery, and vascular injury occurring during this procedure is one of the most devastating complications.¹¹ In particular, because the left CIV is located in front of the disc and is in contact with the disc surface, it is essential to dissect and retract the left CIV when removing the disc.¹⁵

Several studies report methods for the preoperative evaluation of CIV before surgery at the L5–S1 level.¹⁵⁻¹⁷ Chung et al.¹⁵

reported that CIV mobilization is easier when the perivascular adipose tissue is present under CIV. The IATL observed in our study is probably the same structure as the perivascular adipose tissue reported in this paper. According to our study, it is located between the CIV and the anterior surfaces of the vertebral body and disc rather than wrapped around the vessels; thus, it would be considered appropriate to call it IATL.

Three of the 10 cadavers had no adipose tissue layer, with adhesion between the CIV and perivertebral membrane. Chung et al.¹⁵ reported that the incidence rate of major left CIV injury was as high as 26.7% in the patients with iliac veins without perivascular adipose tissue. This is similar to the absence of IATL observed in our study, which may increase the risk of vascular injury during CIV mobilization. Therefore, in the patients with no adipose tissue layer, other methods of iliac vein mobilization should be devised to reduce iliac vein injury when performing ALIF or OLIF.

In particular, the recently introduced OLIF for L5–S1 is a minimally invasive technique that has an advantage similar to that

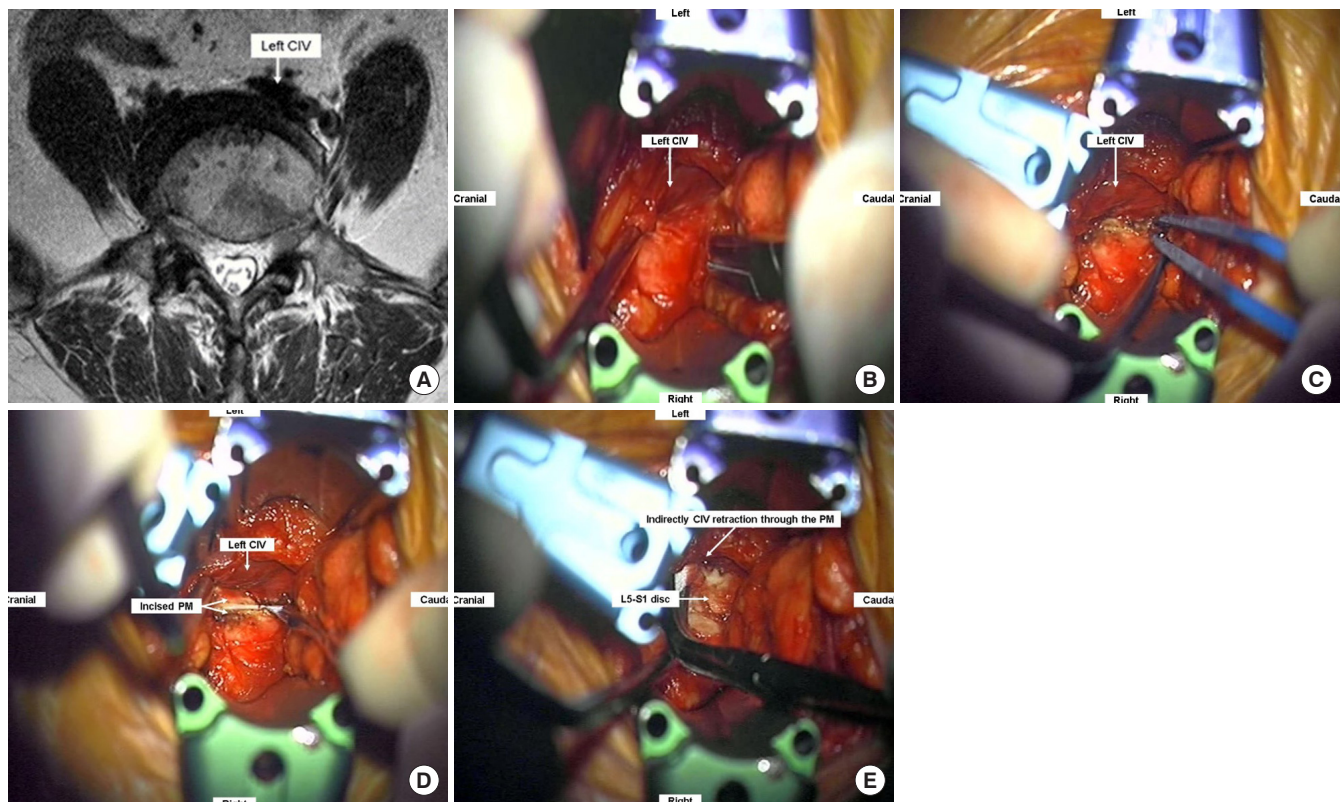


Fig. 5. Intraoperative illustrations of dissection underneath the perivertebral membrane. (A) A case without intervening adipose tissue layer between the left common iliac vein (CIV) and L5–S1 disc on preoperative magnetic resonance imaging. (B) The CIV manipulation was difficult. After cauterizing the perivertebral membrane (PM) near the left CIV (C), it was opened with a scalpel (D). (E) Then the left CIV retraction was performed indirectly through the incised PM.

of ALIF as it allows a cage to be inserted with a larger lordotic angle. It also has the advantage of being performed in the same posture as OLIF for L1–5.¹⁴ The most dangerous step during OLIF at the L5–S1 level is dissecting and retracting the left CIV laterally to the left side, and if there is adhesion between the CIV and the disc surface, a fatal vascular injury may occur.^{15,18} Therefore, the surgeon needs to carefully evaluate the left CIV preoperatively to determine whether there is IATL under the left CIV before performing the surgery.

According to previous studies evaluating the anterior anatomy of the lumbosacral spine, the presacral fascia is located dorsal to the peritoneum, the superior hypogastric plexus is embedded in the presacral fascia, the right and left CIV are present in the dorsal part of the presacral fascia, and there is no special structure between the CIV and the L5–S1 disc except for ALL.^{19,20} However, according to our study, a perivertebral membrane existed between the CIV and L5–S1 disc; based on these results, a schematic diagram was illustrated in Fig. 4.

The perivertebral membrane observed in our study might be helpful in protecting the CIV. It encircled the periphery of the ALL, periosteum, and disc, and it was separated from their surfaces by a potential space. Therefore, the perivertebral membrane could be cut and dissected from the ALL, periosteum, and disc by opening the potential space underneath this membrane. Moreover, CIV injury occurs during CIV mobilization.¹¹ When the CIV was adhered to the adjacent structures (intervertebral disc, ALL, or periosteum), because of the absence of IATL, the perivertebral membrane was cut with a scalpel and blunt dissection was performed to open the potential space under the membrane. If CIV mobilization is performed indirectly through the perivertebral membrane attached to the CIV, CIV injury could be minimized. Based on these points, we had applied it to patients as well, in particular, in cases with no IATL between the CIV and disc, this method was helpful for the safe mobilization of the CIV (Fig. 5).

Most of the anatomical studies performed for the lower lumbar region have focused on the vascular structures or autonomic nerves,^{21–25} but there has been no study mentioning the perivertebral membrane that was observed in our study. We could not determine how far the perivertebral membrane extends to the lateral side, and the results of this study were obtained using a small number of cadavers. Therefore, further anatomic evaluation through additional large-scale studies is needed, and complementary clinical studies on whether the perivertebral membrane can be used during L5–S1 approaches should be conducted as well.

CONCLUSION

A thin membrane, the perivertebral membrane, between the CIV and disc at the L5–S1 level of the cadaveric specimens was observed. In cases with CIV adhesion to the disc surface due to the absence of IATL, we may be able to mobilize CIV safely by sharp dissection and retraction of the perivertebral membrane.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Original Article

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INTRODUCTION

Pedicle screw fixation has been widely used in the surgical treatment of spinal diseases. It provides strong support for the stability of the spine immediately after surgery.^{1,2} The accurate placement of pedicle screws is critical to the success rate of lumbar fusion. The unsatisfactory rate of traditional free-hand pedicle screw placement is up to 40%.³⁻⁵

In the past 2 decades, intraoperative navigation systems have been used in spine surgery to provide higher screw accuracy. With the development and application of robotics in spine surgery, some studies have reported the advantages of robot-assist-

Risk Factors of Unsatisfactory Robot-Assisted Pedicle Screw Placement: A Case-Control Study

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Objective: To identify potential risk factors of unsatisfactory screw position during robot-assisted pedicle screw fixation.

Methods: A retrospective analysis of robot-assisted pedicle screw fixation performed in Beijing Jishuitan Hospital from March 2018 to March 2019 was conducted. Research data was collected from the medical record and imaging systems. Univariate tests were performed on the potential risk factors (patient's characteristics and surgical factors) of unsatisfactory screw position during robot-assisted pedicle screw fixation. For statistically significant variables in univariate tests, a logistic regression test was used to identify independent risk factors for unsatisfactory screw position.

Results: A total of 780 pedicle screws placed in 163 robot-assisted surgeries were analyzed. The rate of perfect screw positions was 93.08%, and the unsatisfactory rate was 6.92%. In patients with severe obesity (body mass index ≥ 30 kg/m²) (odds ratio [OR], 2.459; 95% confidence interval [CI], 1.199–5.044; $p = 0.014$), osteoporosis ($T \leq -2.5$) (OR, 1.857; 95% CI, 1.046–3.295; $p = 0.034$), and the segments 3 levels away from the tracker (OR, 2.216; 95% CI, 1.119–4.387; $p = 0.022$), robot-assisted pedicle screw placement has a higher risk of screw malposition.

Conclusion: During robot-assisted pedicle screw placement for patients with severe obesity, osteoporosis, and segments 3 levels away from the tracker, vigilance should be maintained during surgery to avoid postoperative complications due to unsatisfactory screw position.

Keywords: Robot-assisted surgery, Pedicle screw, Accuracy, Risk factor

ed pedicle screw placement, including higher accuracy and safety. The research focus of robot-assisted pedicle screw fixation is to evaluate the accuracy of the screw. According to reports in the literature, the accuracy of robot-assisted pedicle screw placement is 91% to 100%.⁶⁻¹⁰ However, in most of the previous studies, robot-assisted pedicle screw fixation still could not achieve a 100% rate of perfect position. Few studies have paid attention to the factors affecting the accuracy of robot-assisted pedicle screw fixation. We need to identify some risk factors that may affect the clinical accuracy of robot-assisted pedicle screw placement.

The purpose of the study was to explore the potential risk

factors of unsatisfactory screw position during robot-assisted pedicle screw fixation, including the patient's characteristics and surgical factors.

MATERIALS AND METHODS

1. Study Design

This study is a retrospective study of clinical data. The data was collected from the medical record and imaging system of our hospital. A total of 163 robot-assisted thoracolumbar pedicle screw fixation procedures were performed from March 2018 to March 2019. The study was approved by the Institutional Review Board of Beijing Jishuitan Hospital (20190913).

The inclusion criteria were as follows: (1) diagnosis of lumbar disc herniation, lumbar spinal stenosis, lumbar spondylolisthesis, or thoracolumbar fracture; (2) completion of preoperative and postoperative computed tomography (CT) examinations; (3) surgery was performed using the TiRobot orthopaedic robot (TINAVI Medical Technologies, Beijing, China).

The exclusion criteria were as follows: (1) revision surgery; (2) diagnosis of scoliosis, spinal tumor, or spinal tuberculosis; (3) severe sagittal or coronal spinal deformity.

2. Surgical Methods

Robot-assisted procedures were performed according to the guideline for thoracolumbar pedicle screw placement assisted by orthopaedic surgical robot.¹¹ The patient tracker was placed in the spinal process one segment cranial to the surgical site. Intraoperative CT images were acquired for screw trajectory planning. K-wire was inserted through the cannula on the robotic arm under real-time adjustment. The deviation of TiRobot between the planned and real trajectories was less than 1 mm.¹² It was up to the surgeon to choose percutaneous or open screw placement.

3. Group Allocation

Screw positions were evaluated in the postoperative CT multiplanar reconstruction images. One spine surgeon and 1 radiologist who were blind to this study independently assessed the accuracy of the pedicle screws. A third senior doctor was involved for adjudication in case of disagreement (7.3%).

Pedicle screw accuracy was evaluated according to the Gertzbein and Robbins scale.¹³ Grade A, completely within the pedicle; grade B, pedicle cortical breach < 2 mm; grade C, pedicle cortical breach \geq 2 mm and < 4 mm; grade D, pedicle cortical breach \geq 4 mm and < 6 mm; grade E, pedicle cortical breach

\geq 6 mm.

According to the accuracy of the screw position, the screws were divided into groups. Group A was a group with perfect screw positions (grade A). Group B was a group with unsatisfactory screw positions (grades B, C, D, and E).

4. Risk Factors

Potential risk factors of unsatisfactory screw position were assessed, including (1) Age: \geq 60 years old, < 60 years old. (2) Sex: male; female. (3) Body mass index (BMI): BMI < 25 kg/m² is defined as nonobese; 25 kg/m² \leq BMI < 30 kg/m² is defined as obesity; BMI \geq 30 kg/m² is defined as severe obesity. (4) Bone density (quantitative CT of lumbar vertebral cancellous bone): T value > -2.5 is defined as nonosteoporosis; T value \leq -2.5 is defined as osteoporosis. (5) Preoperative diagnosis: lumbar spondylolisthesis; lumbar disc herniation; lumbar spinal stenosis; thoracolumbar fracture. (6) Instrumented segment: thoracolumbar region (T10–L2); lumbo-sacral region (L3–S1). (7) Screw side: left; right. (8) Distance between the instrumented level and the tracker (gap distance): 1 level; 2 levels; 3 levels or more. (9) Surgical approach: percutaneous; open. (10) Surgeons: 1st group; 2nd group; 3rd group; 4th group (every group included 1 senior doctor, 2 associate senior doctors, and 2 attending doctors).

5. Data Collection and Quality Control

Patient information and surgical information were collected from the medical record management system. Patient's imaging data were collected from the PACS (picture archiving and communication system) imaging system. Two doctors independently recorded and proofread the data using the EpiData software (EpiData Association, Odense, Denmark). Blinding was applied to the measurer to ensure the objectivity of the screw accuracy evaluation.

6. Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics ver. 24.0 (IBM Co., Armonk, NY, USA). Normally distributed continuous variables are represented by mean \pm standard deviation. Nonnormally distributed continuous variables are represented by median (quartile). Categorical variables are represented by quantity (percentage). The chi-square test and Fisher exact test were used to evaluate the difference between categorical variables. Univariate tests were carried out on the potential risk factors of unsatisfactory screw position. A logistic regression test was used to identify the independent risk factors. Cal-

culate the odds ratio (OR) and its 95% confidence interval (CI). A p-value of <0.05 was considered statistically significant.

RESULTS

1. Demographic Data

A total of 163 robot-assisted thoracolumbar pedicle screw placement procedures were included in this study, and a total of 780 pedicle screws were placed. Four groups of spine surgeons performed all procedures. Among the patients, 70 were male, and 85 were female. The average age was 56.74 ± 13.40 years (range, 14–86 years), and the average BMI was 25.77 ± 3.74 kg/m². The preoperative diagnosis included 44 cases of lumbar disc herniation (26.99%), 38 cases of lumbar spinal stenosis (23.31%), 53 cases of lumbar spondylolisthesis (32.52%), and 28 cases of thoracolumbar fractures (17.18%). 135 cases underwent decompression and interbody fusion.

2. Pedicle Screw Accuracy

Of the 780 pedicle screws placed, 726 screws were grade A, 43 screws were grade B, and 11 screws were grade C. The perfect rate of robot-assisted pedicle screw placement was 93.08%, and the unsatisfactory rate (grades B-D) of robot-assisted pedicle screw placement was 6.92%.

3. Univariate Analysis

Univariate analysis of potential risk factors showed that gender ($p=0.672$), age ($p=0.316$), preoperative diagnosis ($p=0.899$), and instrumented segment ($p=0.929$), screw side ($p=0.573$), and surgeons ($p=0.634$) between group A and group B were not statistically significant. Differences in BMI ($p=0.020$), bone density ($p=0.041$), gap distance ($p=0.006$), and surgical approach ($p=0.030$) between group A and group B were statistically significant (Table 1).

In patients with severe obesity (BMI ≥ 30 kg/m²), the unsatisfactory rate (13.21%, 14 of 106) was higher than other patients (5.93%, 40 of 674) ($p=0.020$). The unsatisfactory rate in patients with osteoporosis (8.94%, 32 of 358) was higher than that in other patients (5.21%, 22 of 422) ($p=0.041$). When the gap distance is more than 3 levels (including 3 levels), the unsatisfactory rate was 13.28% (17 of 128), which is significantly higher than 6.44% (21 of 326) at a gap distance of 1 level and 4.91% (16 of 326) at a gap distance of 2 levels ($p=0.006$). The unsatisfactory rate of percutaneously inserted screws (5.26%, 24 of 456) was lower than that of open inserted screws (9.26%, 30 of 324) ($p=0.030$).

Table 1. Univariate analysis for potential risk factors of unsatisfactory screw position

Potential risk factor	Group A (n = 726)	Group B (n = 54)	p-value
Sex			0.672
Male	328 (42.05)	26 (3.33)	
Female	398 (51.03)	28 (3.59)	
Age (yr)			0.316
≥ 60	352 (45.13)	30 (3.85)	
< 60	374 (47.95)	24 (3.08)	
Body mass index (kg/m ²)			0.020
≥ 30	92 (11.79)	14 (1.79)	
25–30	299 (38.33)	17 (2.18)	
< 25	335 (42.95)	23 (2.95)	
Bone density			0.041
T value ≤ -2.5	326 (41.79)	32 (4.10)	
T value > -2.5	400 (51.28)	22 (2.82)	
Preoperative diagnosis			0.899
Thoracolumbar fracture	142 (18.21)	10 (1.28)	
Lumbar disc herniation	179 (22.95)	13 (1.67)	
Lumbar spinal stenosis	197 (25.26)	13 (1.67)	
Lumbar spondylolisthesis	208 (26.67)	18 (2.31)	
Instrumented segment			0.929
T10–L2	138 (17.69)	10 (1.28)	
L3–S1	588 (75.38)	44 (5.64)	
Screw side			0.573
Left	361 (46.28)	29 (3.72)	
Right	365 (46.79)	25 (3.21)	
Distance between the instrumented level and tracker			0.006
1 Level	305 (39.10)	21 (2.69)	
2 Levels	310 (39.74)	16 (2.05)	
≥ 3 Levels	111 (14.23)	17 (2.18)	
Surgical approach			0.030
Percutaneous	432 (55.38)	24 (3.08)	
Open	294 (37.69)	30 (3.85)	
Surgeons			0.634
1st group	153 (19.62)	9 (1.15)	
2nd group	125 (16.03)	7 (0.90)	
3rd group	320 (41.03)	28 (3.59)	
4th group	128 (16.41)	10 (1.28)	

Values are presented as number (%).

Group A, perfect screw positions; group B, unsatisfactory screw positions.

Table 2. Multivariate analysis for potential risk factors of unsatisfactory screw position

Risk factor	OR (95% CI)	p-value
Body mass index (kg/m ²)		
< 25	1.000	
25–30	0.893 (0.464–1.716)	0.734
≥ 30	2.459 (1.199–5.044)	0.014
Bone density		
T value > -2.5	1.000	
T value ≤ -2.5	1.857 (1.046–3.295)	0.034
Distance between the instrumented level and the tracker		
1 Level	1.000	
2 Levels	0.746 (0.380–1.465)	0.395
≥ 3 Levels	2.216 (1.119–4.387)	0.022

OR, odds ratio; CI, confidence interval.

4. Multivariate Analysis

Multivariate logistic regression analysis included the following variables: BMI, bone density, gap distance, and surgical approach.

Multivariate logistic regression analysis (Hosmer-Lemeshow test: chi-square = 3.216, $p = 0.920$) found that the independent risk factors of unsatisfactory screw position were severe obesity (BMI ≥ 30 kg/m²) (OR, 2.459; 95% CI, 1.199–5.044; $p = 0.014$), osteoporosis (OR, 1.857; 95% CI, 1.046–3.295; $p = 0.034$), and gap distance ≥ 3 levels (OR, 2.216; 95% CI, 1.119–4.387; $p = 0.022$) (Table 2).

DISCUSSION

1. Risk Factors of Unsatisfactory Screw Placement

In this study, robot-assisted pedicle screw fixation achieved a perfect position in 93.08% of pedicle screws. We found 3 primary factors that may affect the accuracy of TiRobot robot-assisted pedicle screw placement, including severe obesity (BMI ≥ 30 kg/m²) and osteoporosis (T value ≤ -2.5), and gap distance ≥ 3 levels.

As our previous report, 16.2% of free-hand pedicle screws did not achieve a perfect trajectory (grade A).¹⁴ Some studies have demonstrated that the robot-assisted technique is superior to the free-hand method in terms of pedicle screw accuracy.^{10,15–17} Traditionally, pedicle screws with grades A and B are clinically acceptable. However, we should work towards the most accurate position (grade A) with the application of surgical robots. Similar to our study, Zhang et al.¹⁸ analyzed the risk factors of

Renaissance robot-assisted pedicle screw malposition. They found that obesity, osteoporosis, vertebral rotation, and congenital scoliosis were the risk factors of robot-assisted screw malposition.¹⁸

2. Obesity

Severe obesity is one of the risk factors of unsatisfactory screw position, which may be due to the excessive thickness and pressure of soft tissue. Overweight and obesity are prevalent in patients who underwent spine surgery. Studies have found a linear correlation between the incidence of postoperative complications and BMI in spinal fusion surgery.¹⁹ Excessive soft tissue pressure may compress the guidewire in obese patients, thereby changing the screw trajectory.²⁰ Because the guidewire has a certain elasticity, in patients with excessive soft tissue pressure in the lower back, the guidewire may be challenging to enter the pedicle according to the direction guided by the robotic arm.¹⁸

3. Osteoporosis

Patients with osteoporosis are also more likely to have unsatisfactory screw position. The guidewire could not be firmly fixed to the osteoporotic bone. A slight displacement of the guidewire will cause the screw to deviate from the planned position. Besides, when using the Renaissance robot, osteoporosis may affect the accuracy of image registration, thus compromising the screw accuracy.¹⁸ The biomechanical stability of the pedicle screw fixation mainly depends on the bonding strength of the bone and the screw. The guidewire and the screw could not be firmly fitted with the surrounding bone due to the bone loss caused by osteoporosis, so that displacement may occur.

4. Distance Between the Instrumented Level and the Tracker

The distance between the instrumented level and the patient tracker is also a significant risk factor of unsatisfactory screw position. The results of this study indicate that when the gap distance exceeds 3 levels, the unsatisfactory rate of screw position increases significantly. The patient's spine moves up and down with the respiratory movement.²¹ This physiological movement of each vertebra is different and may not be adequately detected by the real-time navigation system, especially the levels far away from the tracker and unstable levels.²² When the guidewire is inserted, the navigation system is unable to reflect the dynamic changes of each vertebral body in real-time, which may cause the guidewire to deviate from the planned trajectory.

Boon Tow et al.²² found that the accuracy of navigation-assisted pedicle screw placement depends on the distance between the tracker and the screw. Jin et al.²³ also found that the distance between the screw and the tracker over 3 levels is a risk factor for misplacement of navigation-assisted pedicle screws. We suggest that in long-segment surgery, the surgeon can move the patient tracker closer to the instrumented level and reacquire intraoperative CT images for registration.

5. Intraoperative Factors of the Surgeon

In addition to the factors included in this study, many other factors may affect the accuracy of robot-assisted pedicle screw placement. Among them, the doctor's intraoperative manipulation plays an important role.

Any new surgical technique has a specific learning curve.²⁴ When surgeons performed robot-assisted spine surgery initially, there was a cognitive process of the robot's operating principle. In the early stage of robot-assisted surgery, the problem of insufficient screw accuracy may be encountered. Doctors need to complete a certain amount of surgery to acquire robot-assisted surgical techniques.

In robot-assisted surgery, the screw position is planned by the surgeon based on intraoperative 3-dimensional images. Different surgeons may plan various pedicle screw trajectories with discrepant quality, which may also affect the accuracy of the screw. If the planned screw entry point is on a surface with a large slope or an irregular shape, the guidewire and the screw are more likely to slip when inserted. Ghasem et al.²⁰ found that most of the robot-assisted surgical technical problems with screw malposition were related to the bony surface skidding. Ringel et al.²⁵ concluded that slipping of the implantation cannula at the screw entrance point seems a vulnerable aspect potentially leading to screw malposition.

The surgeon's intraoperative error will also affect the accuracy of the screws. If the surgeon accidentally touches the patient tracker, the positioning accuracy of the robotic navigation system may be significantly declined if the registration is not performed again. Besides, the relative position of each vertebra is identified as fixed in the robotic navigation system. Nevertheless, there is a slight motion between each vertebra. During the insertion of the guidewire under the robotic guidance, overexertion may cause the instrumented vertebrae to be displaced relative to the proximal segments.²⁶ Surgeons should avoid using excessive force when inserting the guidewire and the screw. The guide sleeve placed at the distal end of the robotic arm is vulnerable to pressure from surrounding soft tissue, which may

also change the screw position.²⁰ To avoid the effect of soft tissue pressure, sufficient exposure in open surgery or inserting the sleeve through muscles in percutaneous surgery is recommended.

6. Limitations

This study has some limitations. Firstly, this is a single-center retrospective study. A multicenter prospective study with a larger sample size will be required to verify the results of this study in the future. Secondly, due to the limited sample size, anatomical factors and anesthesia factors (such as spinal rotation, instability, deformity, and intraoperative tidal volume) that may affect the screw accuracy were not evaluated in this study. In the next study, we will further observe whether the patient's anatomical features are related to the accuracy of robot-assisted pedicle screw placement.

CONCLUSION

During robot-assisted pedicle screw placement for patients with severe obesity, osteoporosis, and segments 3 levels away from the tracker, vigilance should be maintained during surgery to avoid postoperative complications due to unsatisfactory screw position.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Editorial




Commentary on “Risk Factors of Unsatisfactory Robot-Assisted Pedicle Screw Placement: A Case-Control Study”

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See the article “Risk Factors of Unsatisfactory Robot-Assisted Pedicle Screw Placement: A Case-Control Study” via <https://doi.org/10.14245/ns.2142560.180>.

Zhang et al.¹ have shared their experience with robot-assisted pedicle screw placement from their 163 patients undergoing corrective lumbar posterior fixations, have pin-pointed out the three risk factors that might prelude the accurate screw placement deterrence even under the sophisticated robotics assistance. Despite the pioneering effort from the authors with the inclusion of more than 780 screw placement maneuvers over a year span aided with diverse statistical analyses, the reviewer cannot preclude the feeling that the authors have restrained themselves into the too simplified or anticipated results; ‘obesity, osteoporosis, or remote segments from the tracker matters.’

Technical wisely, even in some fully exposed occasion, it is sometimes not feasible to manually or faithfully obey the route or tract suggested by robotic arms from a fat, fragile subjects intraoperatively due to regional anatomical distortion. Subsequently, as have brought up with the controversies regarding the surgical navigation usage previously, these phenomena or limitations might be fraught with the skepticisms about the robot-assisted spinal surgery efficacy/efficiency both in terms of clinical aspect and cost-utility.

Despite all these elaborations from the authors regarding the beneficial aspects of the robotics application on the spine surgery field, their conclusions still lack the promising impact; from the reviewer’s perspective, ‘it is unclear if the complication rate is significantly different compared to traditional methods of spinal instrumentation.’² Validation on the measurements methods of the screw placements accuracies as well as a fully comparative fashioned analysis even after the few additions of historic data from the previously published references, potential suggestions/ directions that might drive to overcome the current steep learning curves and technological glitches, commitments both from the company and current-in-use institutes on their efforts to dispose of the current financial hurdles, and the necessity of a solid healthcare infrastructure to support these machines³⁻⁵ usage might be able to add the future scientific value for this analysis.

CONFLICT OF INTEREST

The author has nothing to disclose.

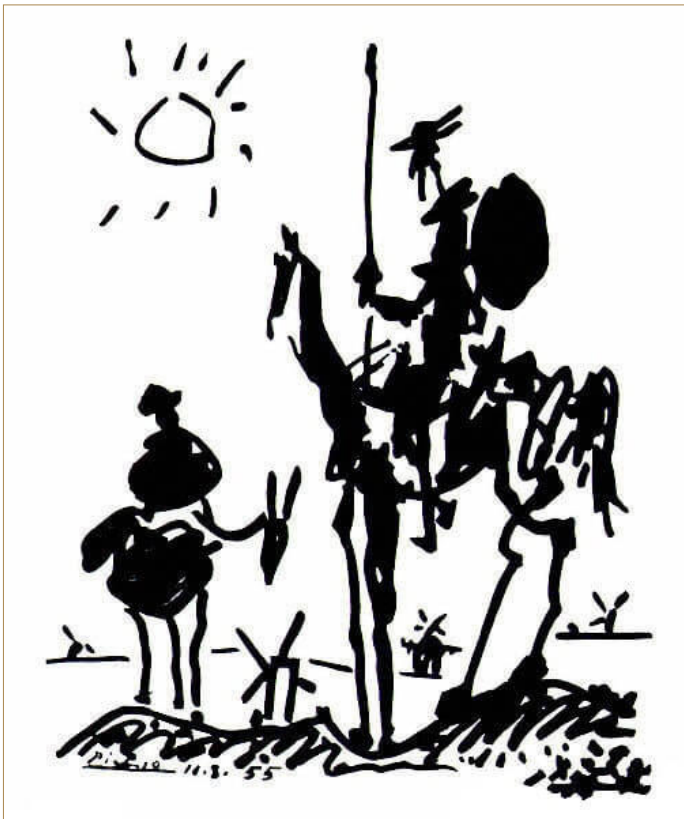


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Title: Don Quixote
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Original Article

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Improvement in Neurogenic Bowel and Bladder Dysfunction Following Posterior Decompression Surgery for Cauda Equina Syndrome: A Prospective Cohort Study

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Objective: The mechanisms of neurogenic bowel dysfunction (NBD) and neurogenic bladder (NB), which are major consequences of spinal cord injury and occasionally degenerative lumbar disease. The following in patients with cauda equina syndrome who underwent posterior decompression surgery was investigated: (1) the preoperative prevalence of NBD and NB, measured using the Constipation Scoring System (CSS) and International Prostate Symptoms Score (IPSS); (2) the degree and timing of postoperative improvement of NBD and NB.

Methods: We administered the CSS and IPSS in 93 patients before surgery and at 1, 3, 6, and 12 months postoperatively. We prospectively examined patient characteristics, Japanese Orthopaedic Association (JOA) score, and postoperative improvements in each score.

Results: The prevalence of symptomatic defecation and urinary symptoms at admission were 37 patients (38.1%) and 31 patients (33.3%), respectively. Among the symptomatic patients with defecation problems, 12 patients had improved at 1 month, 13 at 3 months, 14 at 6 months, and 13 at 12 months postoperatively. Among the symptomatic patients with urinary problems, 5 patients improved at 1 month, 11 at 3 months, 6 at 6 months, and 10 at 1 year postoperatively. Comparing patients with improved versus unimproved in CSS, the degree of JOA score improvement was a significant prognosis factor ($p < 0.05$; odds ratio, 1.05).

Conclusion: The prevalence of symptomatic defecation and urinary symptoms in patients with cauda equina syndrome was 38.1% and 33.3%, respectively. Decompression surgery improved symptoms in 30%–50%. These effects were first observed 1 month after the operation and persisted up to 1 year.

Keywords: Neurogenic bowel dysfunction, Neurogenic bladder, Cauda equina syndrome



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INTRODUCTION

Neurogenic bowel dysfunction (NBD) and neurogenic bladder (NB) are 2 major complications of spinal cord or nerve root

injury. Although neurologic damage secondary to spinal cord injury differs among patients depending on the neurologic level and severity of the lesion, the changes in bowel motility, sphincter control, and gross motor dexterity interact to make bowel

management a major life-style problem limiting quality of life. Hanson and Franklin¹ reported that 80% of male paraplegics and 46% of male tetraplegics would rank bowel and bladder as their greatest functional loss of mobility.

Whereas symptomatic lumbar degenerative disease causes spinal claudication as well as back and radicular leg pain. In severe cases, this can lead to loss of bladder and bowel control, resulting in constipation, frequent urination, and functional obstruction. However, the mechanisms of NBD and NB have not been clearly investigated and few studies have comprehensively evaluated pre-/postoperative NB.²⁻⁶

In this study, we investigated the following matters in patients with cauda equina syndrome who underwent posterior decompression surgery with or without lumbar fusion: (1) the preoperative prevalence of NBD and NB, evaluated using the Constipation Scoring System (CSS) and International Prostate Symptoms Score (IPSS); (2) the degree and timing of postoperative

improvement of NBD and NB.

MATERIALS AND METHODS

We prospectively analyzed data collected from February 2018 to March 2020 for 93 patients who underwent lumbar spinal decompression surgery with or without fusion for the treatment of lumbar degenerative disease. The patient inclusion criteria were as follows: (1) claudication resistant to repeated conservative treatment, (2) neurological deficit such as reduced tendon reflex in the bilateral lower extremities and pain/numbness in the bilateral lower extremities compatible with cauda equina syndrome, (3) central canal stenosis revealed via magnetic resonance imaging and defects and/or blocking of contrast media in the cauda equina revealed via myelography. The exclusion criteria were as follows: (1) lower urinary tract lesions such as those associated with prostatic hypertrophy, (2) coincident cer-

Table 1. Constipation Scoring System

Variable	Score
Frequency of bowel movements	
1–2 times per 1–2 days	0
2 times per week	1
Once per week	2
Less than once per week	3
Less than once per month	4
Difficulty: painful evacuation effort	
Never	0
Rarely	1
Sometimes	2
Usually	3
Always	4
Completeness: feeling incomplete evacuation	
Never	0
Rarely	1
Sometimes	2
Usually	3
Always	4
Pain: abdominal pain	
Never	0
Rarely	1
Sometimes	2
Usually	3
Always	4

(Continued)

Table 1. Constipation Scoring System (continued)

Variable	Score
Time: minutes in lavatory per attempt	
Less than 5	0
5–10	1
10–20	2
20–30	3
More than 30	4
Assistance: type of assistance	
Without assistance	0
Stimulative laxatives	1
Digital assistance or enema	2
Failure: unsuccessful attempts for evacuation per 24 hours	
Never	0
1–3	1
3–6	2
6–9	3
More than 9	4
History: duration of constipation (yr)	
0	0
1–5	1
5–10	2
10–20	3
More than 20	4

The total score ranged from 0 to 30 (asymptomatic to very symptomatic).

vical or thoracic lesions, (3) history of spinal, urological, or gynecological surgery, (4) new medication regiment for treatment of digestive organs, bladder, or prostate problems, (5) medication regiment including opioids that could influence bowel function. All patients underwent urologic evaluation by a urologist to rule out lower urinary tract lesions. Detailed micturition and defecation histories were obtained from each patient using the CSS and IPSS on admission. All of these parameters were evaluated at 1, 3, 6, and 12 months postoperatively. Pre- and postoperative clinical symptoms were assessed using the CSS, IPSS, and the Japanese Orthopaedic Association (JOA) score. Additionally, we measured cross-sectional area of the thecal sac at the spinal segment exhibiting most severe stenosis using the Image J software program.⁷ Regarding defecation and urinary symptoms, we prospectively examined data regarding patient age, sex, disease status, lesion level, and changes in each score, and investigated prognostic factors contributing to the improvement of the defecation and urinary symptoms comparing improved patients with unimproved patients. This study was approved by the Institutional Review Board of Fujieda Heisei Memorial Hospital (FHR 2020-1).

1. Constipation Scoring System

The CSS is based on 8 questions concerning evacuation.⁸ For each question, the patient chooses 1 out of 8 options indicating

the severity of the particular symptom. The answers are assigned points from 0 to 4. The total score can therefore range from 0 to 30. The questions refer to the following evacuation symptoms: (1) Frequency of bowel movements, (2) Difficulty: painful evacuation efforts, (3) Completeness: feeling of incomplete evacuation, (4) Pain: abdominal pain, (5) Time: minutes in lavatory per attempt, (6) Assistance: type of assistance, (7) Failure: unsuccessful attempts at evacuation per 24 hours, (8) History: duration of constipation (Table 1). In this study, a score of more than 4 was defined as symptomatic NBD. Patients who varied from more than 4 preoperatively to less than 3 postoperatively were defined as having experienced “significant improvement” in CSS.

2. International Prostate Symptoms Score

The IPSS is based on the answers to 7 questions concerning urinary symptoms and 1 question concerning quality of life.⁹ For each question concerning urinary symptoms, the patient is asked to choose 1 out of 6 answers indicating the severity of that particular symptom. The answers are assigned points from 0 to 5. The total score can therefore range from 0 to 35 (asymptomatic to very symptomatic). The questions refer to the following urinary symptoms: (1) incomplete emptying, (2) frequency, (3) intermittency, (4) urgency, (5) weak stream, (6) straining, (7) nocturia (Table 2). In this study, a score of more than 8 was de-

Table 2. International Prostate Symptoms Score (minimum score, 0; maximum score, 35)

Question & urinary symptom	Not at all	Less than 1 in 5 times	Less than half the time	About half the time	More than half the time	Almost always
1. Incontinence Emptying						
How often have you had the sensation of not emptying your bladder?	0	1	2	3	4	5
2. Frequency						
How often have you had to urinate less than every 2 hours?	0	1	2	3	4	5
3. Intermittency						
How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
4. Urgency						
How often have you found it difficult to postpone urination?	0	1	2	3	4	5
5. Weak Stream						
How often have you had a weak urinary stream?	0	1	2	3	4	5
6. Straining						
How often have you had to strain to start urination?	0	1	2	3	4	5
	None	1 Time	2 Times	3 Times	4 Times	5 Times
7. Nocturia						
How many times do you typically get up at night to urinate?	0	1	2	3	4	5

defined as indicating “symptomatic” NB. Patients who varied from more than 8 preoperatively to less than 7 postoperatively were defined as having experienced “significant improvement” in IPSS.

3. Statistical Analysis

Statistical analyses were performed using JMP statistical software ver. 13 (SAS Institute Inc., Cary, NC, USA). The chi-square test, Mann-Whitney U-test, and Fisher exact probability test were applied for all of statistical assessments. Logistic regression analysis was used for multivariate analysis. Significance of the obtained results was judged at the 5% level.

Table 3. Demographic and clinical data of all patients with lumbar degenerative disease

Variable	Value
Age (yr)	71.5 (48–92)
Sex, male:female	49:44
Etiology	
Lumbar canal stenosis	57
Lumbar disc hernia	12
Lumbar spondylolisthesis	21
Lumbar facet synovial cyst	2
The ossification of the yellow ligament in the lumbar spine	1
Level of stenosis*	
L2/3	11
L3/4	32
L4/5	71
L5/S1	7
No. of stenosis	
1	72
2	15
3	5
4	1
Cross-sectional area of the thecal sac at the most severe stenosis (mm ²)	48.5 (10–127)
JOA score	
Preoperative score	16.8 (7–25)
Postoperative score	22.1 (12–29)
Preoperative score of IPSS	7.7 (0–31)
Preoperative score of CSS	3.5 (0–16)

Values are presented as mean (range) or number. JOA, Japanese Orthopaedic Association; IPSS, International Prostate Symptoms Score; CSS, Constipation Scoring System. *There are some overlapping.

RESULTS

The patient group constituted 49 men and 44 women with an average age of 71.5 years (range, 48–92 years). The patient diagnoses were as follows: 57 patients had lumbar canal stenosis, 12 had a lumbar disc hernia, 21 had lumbar spondylolisthesis, 2 had a lumbar facet synovial cyst, and 1 had ossification of the yellow ligament in the lumbar spine. The level of stenosis was 11 at L2/3, 32 at L3/4, 71 at L4/5, and 7 at L5/S1 (The total does not add up because of multiple stenoses). The clinical findings are summarized in Table 3. Seventy-two patients received only decompression surgery and 21 patients underwent decompression with interbody fusion. Symptomatic defecation and urinary symptoms were present in 37 (38.1%) and 31 patients (33.3%), respectively. Among the symptomatic patients with defecation problems, 2 were excluded because they began taking new medication for constipation postoperatively. Of the 35 (20 males, 15 females) patients, 12 (5 males, 7 females) improved at 1 month, 13 (6 males, 7 females) improved at 3 months, 14 (7 males, 7 females) improved at 6 months, and 13 (6 males, 7 females) improved at 12 months postoperatively (Fig. 1). In the 13 patients who showed improvement at 12 months postoperatively, the index of “difficulty: painful evacuation efforts” and “failure: unsuccessful attempts at evacuation per 24 hours” ratios had especially improved (Table 4). Among these 13 patients with improved defecation symptoms one year after the operation, 6 patients had preoperative urinary symptoms. Of these 6 patients, 3 did not show improvements in urinary symptoms. Among the symptomatic patients with urinary symptoms, 11 were excluded from the study because they began taking new medication for urinary symptoms postoperatively. Of the remaining

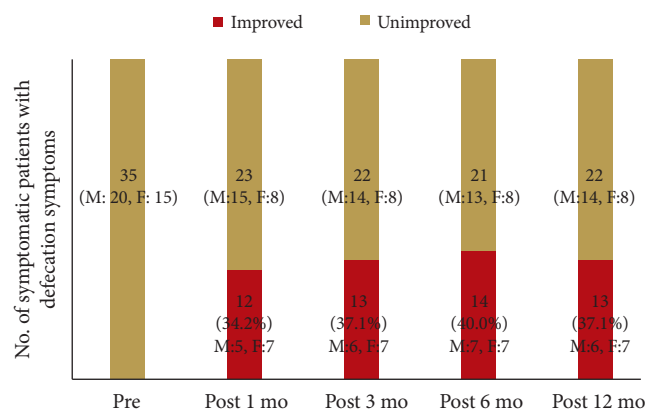


Fig. 1. Graph shows postoperative improvement of Constipation Scoring System in patients with defecation symptoms on admission and at 1, 3, 6, and 12 months postoperatively.

Table 4. The comparison of CSS subcategory on admission and postoperative 12 months

CSS subcategory	Preoperative	Postoperative 12 months	p-value
Frequency of bowel movements	0.15	0	NS
Difficulty: painful evacuation effort	1.85	0.23	<0.05
Completeness: feeling incomplete evacuation	1.08	0.38	NS
Pain: abdominal pain	0.46	0.07	NS
Time: minutes in lavatory per attempt	0.85	0.31	NS
Assistance: type of assistance	0.38	0	NS
Failure: unsuccessful attempts for evacuation per 24 hours	0.77	0.23	<0.05
History: duration of constipation	0.77	0.31	NS

CSS, Constipation Scoring System; NS, not significant.

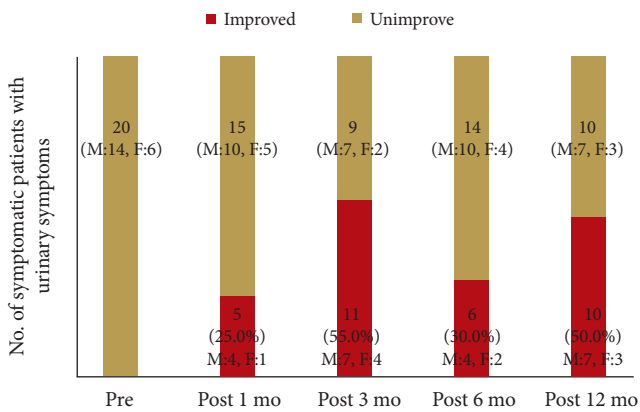


Fig. 2. Graph shows postoperative improvement of International Prostate Symptoms Score in patients with urinary symptoms on admission and at 1, 3, 6, and 12 months postoperatively.

20 (14 males, 6 females) patients, 5 (4 males, 1 female) improved at 1 month, 11 (7 males, 4 females) improved at 3 months, 6 (4 males, 2 females) improved at 6 months, and 10 (7 males, 3 females) improved at 12 months postoperatively (Fig. 2). Among the 10 patients whose urinary symptoms improved at one year postoperatively, 6 patients had defecation symptoms. Of this group, 2 patients did not show improvement of defecation symptoms. The improvement rate of CSS and IPSS at 1 year postoperatively were 30%, 50% in male and 46.7%, 50% in female, respectively. Comparing patients with improved versus unimproved in CSS, the degree of JOA score improvement was a significant prognosis factor ($p < 0.05$; odds ratio, 1.05) (Table 5). Comparing patients with improved versus unimproved symptoms in IPSS revealed no significant difference in each factor (Table 6). Among 18 patients with both preoperative defecation and urinary symptoms, 5 patients (27.8%) showed postoperative improvements in both types of symptoms. However, in the other

Table 5. Prognostic factors for the improvement of CSS

Variable	Odds ratio (95% CI)	p-value
Age	1.16 (0.95–1.41)	0.15
Sex	5.89 (0.58–59.9)	0.13
Etiology	0.29 (0.04–2.45)	0.26
Number of stenosis	0.07 (0.01–8.63)	0.28
Cross-sectional area of the thecal sac*	0.46 (0.97–1.07)	0.46
The improvement of JOA score	1.05 (1.01–1.09)	<0.05

CSS, Constipation Scoring System; CI, confidence interval; JOA, Japanese Orthopaedic Association.

*Cross-sectional area of the thecal sac at the spinal segment exhibiting most severe stenosis.

Table 6. Prognostic factors for the improvement of IPSS

Variable	Odds ratio (95% CI)	p-value
Age	0.69 (0.43–1.15)	0.16
Sex	11.18 (0.17–772.4)	0.26
Etiology	0.18 (0.01–12.85)	0.43
Cross-sectional area of the thecal sac*	0.89 (0.75–1.05)	0.15
The improvement of JOA score	1.08 (0.95–1.23)	0.22

IPSS, International Prostate Symptoms Score; CI, confidence interval; JOA, Japanese Orthopaedic Association.

*Cross-sectional area of the thecal sac at the spinal segment exhibiting most severe stenosis.

13 patients, only either defecation or urinary symptoms improved.

DISCUSSION

NBD following spinal cord injury is increasingly recognized as an area of major physical and psychological difficulty for spi-

nal cord injury patients.¹⁰ NB results from compression of the parasympathetic fibers of the S2–4 nerve roots innervating the bladder, resulting in areflexic or acontractile detrusor. Some researchers have reported that urinary symptoms due to lumbar degenerative diseases improved following decompression surgery.^{2–6} Estimates of the prevalence of lower urinary tract symptoms associated with lumbar degenerative disease vary widely throughout the literature, ranging from 10% to 70%, due to differences in definitions and diagnostic modalities.^{2–6} Further, no reports have examined both NB and NBD in patients with cauda equina syndrome.

In the present study, we meticulously examined defecation and urinary symptoms in patients with lumbar degenerative diseases using the CSS and IPSS, and conducted follow-up assessments until 1 year postoperatively. Our results indicate that about 30%–40% of patients with cauda equina syndrome had symptomatic defecation and urinary symptoms. Improvements in symptoms were found in 30%–50% of these patients following decompression surgery at just 1 month postoperatively, and these effects persisted for at least for 1 year.

Little is known about the pathophysiology of bowel dysfunction in patients with cauda equina syndrome. Stimulatory sympathetic innervation for the bowel orally to the splenic flexure is derived from the vagal nerves, while parasympathetic innervation of the distal colon and rectum is transmitted via the second to fourth sacral roots (S2–4).¹¹ Unlike in the urinary tract, the gut wall contains intrinsic pacemakers and a neural network that is part of the sympathetic and parasympathetic chain that programs the activity of the smooth muscles that are necessary to expel waste material.¹¹ Krogh et al.¹² reported that chronic conal or caudal equina lesions in patients with spinal cord injury significantly prolonged transit times, not only at the transverse and descending clonic segments, but also at the rectosigmoid region. In our study, BSS, which means the parameter of transit time, did not vary. However, the indices of “difficulty: painful evacuation effort” and “failure: unsuccessful attempts at evacuation per 24 hours” in the CSS had significantly improved. To the best of our knowledge, no studies have described the relationship between constipation and cauda equina syndrome. We speculated that a reduction in the frequency of bowel movements might be caused by compression of the cauda equina, resulting in constipation.

Previous reports on treatments for bladder dysfunction have demonstrated improvements in 56.5% to 75% of patients.^{3–6} This variation in the degree of improvement may be influenced by differences not only in the modality used to treat urinary symp-

toms but also in the definition of impairment. Although the muscles responsible for bowel movements and bladder function are innervated by the S2–4 spinal nerves, discrepancies in postoperative improvement have been observed between defecation and urinary function, as shown in the present study. The mechanisms underlying this discrepancy have not been comprehensively investigated. The difference in the storage volume of stool and urine may be one important factor.

Male and female have comparable anorectal anatomy, yet they differ significantly in gross anatomy and physiology of the lower urinary tract.¹³ In this study, the improvement rate of CSS and IPSS at 1 year postoperatively were 30%, 50% in male and 46.7%, 50% in female, respectively. There was no significant difference about the improvement of CSS and IPSS. We could not analyze prognostic factors because of small numbers in each group, which could be one of limitations.

The present study has several other limitations. First, the causes of constipation were varied and may be multifactorial to include mental status, meal contents, and activities of daily living. Particularly, the relationship between leg pain and constipation should be taken into consideration. It is well known that pain due to sympathetic hyperactivity can cause micturition or defecation difficulties.¹⁴ Second, the cutoff value of the CSS for symptomatic patients was not absolute. Although we used a CSS score cutoff of “4,” the rate of symptomatic patients with defecation could have varied further. Despite these limitations, we believe that the current article provides important information regarding defecation and urinary symptoms in patients with cauda equina syndrome.

CONCLUSION

The prevalence of symptomatic defecation and urinary symptoms in patients with lumbar degenerative diseases were 38.1% and 33.3%, respectively. Decompression surgery could improve symptoms in 30%–50% of patients, and the positive effects emerged at one month after the operation and persisted for at least one year.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Original Article

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Outcomes of Transforaminal Lumbar Interbody Fusion Using Unilateral Versus Bilateral Interbody Cages

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Objective: To assess the impact of bilateral versus unilateral interbody cages on outcomes for minimally invasive transforaminal lumbar interbody fusion (MIS TLIF) procedures.

Methods: A retrospective review for primary, elective, single-level MIS TLIF procedures with bilateral posterior instrumentation from 2008–2020 was performed. Patients were grouped according to unilateral or bilateral interbody cage use. Procedures performed without static interbody cages or indicated for trauma, infection, malignancy were excluded. Patient-reported outcomes (PROs) included visual analogue scale (VAS), Oswestry Disability Index, 12-item Short Form health survey physical composite score (SF-12 PCS), Patient-Reported Outcome Measurement Information System physical function (PROMIS-PF). PROs were collected preoperatively and postoperatively. Change in PROs (Δ) was calculated and compared between groups. Achievement of minimum clinically important difference (MCID) was calculated using established values from the literature. Achievement rates were compared between groups using logistic regression.

Results: The study included 151 patients, with 111 unilateral and 40 bilateral cage placements. Charlson Comorbidity Index, diabetes, and insurance status differed between groups ($p < 0.050$). Prevalence of degenerative and isthmic spondylolisthesis (both $p \leq 0.002$), operative level ($p = 0.003$), and postoperative length of stay ($p = 0.022$) significantly differed between groups. The unilateral group had lower 1-year arthrodesis rates ($p = 0.035$). Preoperative VAS leg ($p = 0.017$) and SF-12 PCS ($p = 0.045$) were worse for the unilateral group. Δ PROMIS-PF was greater for the bilateral group at 2 years ($p = 0.001$). Majority of patients achieved an overall MCID for all PROs, except VAS leg (bilateral group).

Conclusion: While preoperative status and postoperative arthrodesis rates differed, patients achieved an MCID at similar rates regardless of use of unilateral or bilateral cages.

Keywords: Interbody cage, Instrumentation, Patient-reported outcomes, Transforaminal lumbar interbody fusion, Lumbar fusion

INTRODUCTION

Recent years have seen a steep increase in the number of elective lumbar fusions performed in the United States.¹ While a number of lumbar fusion techniques exist, the minimally invasive transforaminal lumbar interbody fusion (MIS TLIF) was more recently introduced to mitigate risks associated with established fusion procedures such as nerve root damage and

trauma to surrounding soft tissue.²⁻⁴ MIS TLIF has several advantages over more traditional fusion procedures including shorter operative times and more rapid postoperative recovery.^{2,4,5} This technique involves a posterolateral approach to the disc space followed by insertion of a spacer between vertebral bodies to help maintain adequate distance. The most common type of spacer is an interbody cage, which helps maintain intervertebral height and rigidity while reducing the chances of graft

collapse. Surgeons have a number of options regarding interbody cages, including the placement of either unilateral or bilateral cages, a choice that may vary based on patient-specific complexities or limited disc space.⁶

Currently, literature is limited regarding the impact of unilateral or bilateral placement of interbody cages on postoperative outcomes following TLIF. Results of some studies have suggested that unilateral cages may be associated with shorter operative duration and decreased blood loss,^{7,8} while others suggest that unilateral cage placement may result in decreased stability or increased risk of cage failure compared to other techniques.^{9,10} Furthermore, Aoki et al.⁷ have suggested that similar rates of definitive arthrodesis may be achieved with either type of cage placement. However, many of these previous studies have not adequately controlled for the effects of pedicle screw instrumentation, which has a number of important implications for postoperative outcomes.¹¹⁻¹³

In addition to more objective biomechanical models and perioperative measurements, surgeons may turn to Patient-Reported Outcome Measures (PROMs) to better quantify patients' actual perceptions in order to evaluate interventional effectiveness. Massel et al. compared visual analogue scale (VAS) back pain between cage techniques and Aoki et al. utilized VAS back and leg as well as Japanese Orthopaedic Association scores to compare patient-reported outcomes (PROs).^{7,8} Although both studies offered insight into how cage technique may alter PROMs, the former specifically aimed to compare outcomes for isthmic vs degenerative spondylolisthesis while the latter failed to control for posterior instrumentation.^{7,8}

Given limited literature available regarding the use of unilateral vs bilateral cages for TLIF procedures, the present study employs a broader range of PROMs to assess pain, disability, and physical function. Additionally, our analysis considers these postoperative outcomes in terms of the minimum clinically important difference (MCID), which measures the smallest magnitude of change in scores that a patient still perceives as beneficial¹⁴ and can therefore be helpful in assessing the true benefit of an intervention. Furthermore, by including only patients with bilateral posterior instrumentation, we seek to provide a less biased assessment of objective outcomes such as rates of arthrodesis, cage subsidence, and need for revision surgery. This study aims to expand upon the available literature by assessing whether comparable outcomes can be achieved through the use of bilateral vs unilateral interbody cages for MIS TLIF procedures with the use of bilateral posterior instrumentation.

MATERIALS AND METHODS

1. Patient Population

Informed patient consent and Institutional Review Board approval (ORA 14051301) were obtained prior to study onset. We conducted a retrospective review of a prospectively maintained surgical registry for lumbar fusion patients from April 2008 to September 2020. Patients undergoing primary, elective, single-level MIS TLIF procedures with bilateral pedicle screw instrumentation performed for degenerative spinal pathology were included. Exclusion criteria were procedures that did not include the use of an interbody cage, used an expandable (non-static) cage, or were indicated due to trauma, infection, or malignancy. All procedures were performed by a single attending spine surgeon at a single academic institution.

2. Data Collection

Information regarding patient demographics, preoperative spinal pathology, and perioperative characteristics were collected. Demographic information consisted of age, sex, body mass index (BMI), smoking status, diabetic status, American Society of Anesthesiologists (ASA) physical status classification, Charlson Comorbidity Index (CCI), and insurance/payment type. Preoperative spinal pathology was categorized in terms of recurrent herniated nucleus pulposus, degenerative spondylolisthesis, and isthmic spondylolisthesis. Operative levels as well as the type of bone graft material used were recorded for all patients. Perioperative variables included operative duration (from skin incision to skin closure, in minutes), estimated blood loss (EBL; in mL), and postoperative length of stay (in days). Arthrodesis was assessed based on computed tomography of the lumbar spine at 1-year follow-up. PROMs including VAS back, VAS leg, Oswestry Disability Index (ODI), 12-item Short Form health survey physical composite score (SF-12 PCS), and Patient-Reported Outcomes Measurement Information System Physical Function (PROMIS-PF) were administered at preoperative and 6 weeks, 12 weeks, 6 months, 1 year, and 2 years postoperative timepoints.

3. Surgical Technique

All MIS TLIF procedures were performed utilizing the Wiltse technique. Fluoroscopic guidance was used to identify the level of interest. For patients undergoing unilateral cage placement, a 2- to 3-cm incision was made lateral to midline on side of intended cage facilitating a paramedian approach. Sequential dilators were used to enlarge the pathway progressively. Unilateral

laminectomy and facetectomy were performed through a single 20-mm nonexpandable tubular retractor.

For patients undergoing bilateral cage placement, 2 separate 2- to 3-cm incisions were made lateral to midline facilitating paramedian approaches bilaterally. Sequential dilators were used to enlarge the pathways progressively. Bilateral laminectomy and facetectomy were performed through bilateral 20-mm nonexpandable tubular retractors.

After decompression, the intervertebral disc was identified, incised, and removed; the end plates were prepared with sequential end plate cutters either unilaterally or bilaterally. Local allograft collected during laminectomy and facetectomy was prepared and impacted anteriorly before interbody cage placement. Cages were packed with local bone graft, iliac crest bone graft, and/or bone morphogenetic protein-2 (BMP-2)/synthetic bone graft substitute. A single interbody cage was impacted into place for unilateral cases, and equivalent bilateral interbody cages were impacted for bilateral cases. Interbody cages primarily consisted of T-PAL and Concorde cages (DePuy Synthes, Raynham, MA, USA). Percutaneous pedicle screws were placed bilaterally over guide wires which were connected with rods and set screws.

4. Statistical Analysis

All calculations and statistical tests were performed using StataIC 16.1 (StataCorp., College Station, TX, USA). Patients were grouped according to whether they received unilateral or bilateral interbody cages. Demographics, prevalence of preoperative spinal pathologies, perioperative characteristics, and arthrodesis rates were compared between groups using chi-square and Student t-test for categorical and continuous variables, respectively.

Improvement in PROM scores (Δ) from preoperative baseline values were quantified at all postoperative timepoints. Preoperative PROM scores and Δ values were compared between groups using Student t-test. Achievement of MCID was determined by comparing Δ values to the following previously established thresholds: VAS back ≥ 2.2 ,¹⁵ VAS leg ≥ 5.0 ,¹⁵ ODI ≥ 8.2 ,¹⁵ SF-12 PCS ≥ 2.5 ,¹⁵ PROMIS-PF ≥ 4.5 .¹⁶ The proportion of patients achieving MCID in each measure at each timepoint was assessed between groups using logistic regression. In order to account for significant baseline differences between groups, 1-way analysis of covariance (ANCOVA) and multiple logistic regression analyses were used to assess postoperative improvement and rates of MCID achievement, respectively, while accounting for effects of significant covariates. Significant covari-

ates were considered as any baseline characteristics that significantly differed between groups, as well as preoperative values for respective PROMs. An α of 0.05 was set for all statistical tests.

RESULTS

A total of 151 patients were included with 111 receiving a unilateral cage and 40 receiving bilateral cages. The cohort's mean age was 52.1 years, 39.1% were female, and 49.0% were obese (BMI ≥ 30 kg/m²). Mean CCI score was significantly higher for the unilateral cage group (2.0 ± 1.5 vs. 1.2 ± 1.1 , $p = 0.003$). Diabetes status and insurance/payment type were significantly associated with cage type ($p = 0.041$ and $p = 0.010$) (Table 1). No other demographic variable significantly differed between groups.

Degenerative spondylolisthesis was significantly more prevalent among the unilateral cage group (51.4% vs. 22.5%, $p < 0.001$), while isthmic spondylolisthesis was significantly more prevalent among the bilateral cage group (21.6% vs. 70.0%, $p < 0.001$) (Table 2). A majority of procedures in the unilateral group were

Table 1. Patient demographics

Demographic	Unilateral cage (n = 111)	Bilateral cages (n = 40)	p-value
Age (yr)	53.1 \pm 11.4	49.2 \pm 10.5	0.058
Sex			0.538
Female	45 (40.5)	14 (35.0)	
Male	66 (59.5)	26 (65.0)	
Body mass index (kg/m ²)			0.554
< 30	55 (49.6)	22 (55.0)	
≥ 30	56 (50.5)	18 (45.0)	
Smoking status			0.339
Nonsmoker	93 (83.8)	36 (90.0)	
Smoker	18 (16.2)	4 (10.0)	
Diabetes			0.041*
Nondiabetic	95 (85.9)	39 (97.5)	
Diabetic	16 (14.4)	2.5 (1)	
ASA PS classification grade	2.1 \pm 0.5	2.0 \pm 0.5	0.242
CCI score	2.0 \pm 1.5	1.2 \pm 1.1	0.003*
Insurance			0.010*
Medicare/medicaid	11 (9.9)	0 (0)	
Workers' compensation	45 (40.5)	10 (25.0)	
Private	55 (49.6)	30 (75.0)	

Values are presented as mean \pm standard deviation or number (%). ASA PS, American Society of Anesthesiologists physical status; CCI, Charlson Comorbidity Index; SD, standard deviation.

* $p < 0.05$, statistical significance.

performed at the L4/L5 level (53.2%) while most procedures in the bilateral group were at the L5/S1 level (75.0%), which represented a significant difference in distribution between groups ($p = 0.003$). Most patients in both groups received BMP-2 intraoperatively (87.4% unilateral, 85.0% bilateral) and the type of bone graft used did not significantly differ by group ($p = 0.069$). Postoperative length of stay was significantly longer for the unilateral cage group (56.3 ± 32.1 vs. 43.2 ± 21.8 , $p = 0.022$). Neither operative duration (138.3 ± 33.3 vs. 143.2 ± 32.1 , $p = 0.429$) nor EBL (64.0 ± 32.0 vs. 66.9 ± 51.4 , $p = 0.680$) significantly differed between groups. All patients in the bilateral group demonstrated solid arthrodesis at 1-year follow-up, while a significantly lower proportion in the unilateral group had achieved fusion at the 1-year timepoint (100% vs. 89.0%, $p = 0.035$). In total, 12 patients underwent index-level revision procedures, all of whom were in the unilateral group. All patients with radiographically confirmed pseudoarthrosis subsequently underwent revision

Table 2. Perioperative characteristics

Characteristic	Unilateral cage (n = 111)	Bilateral cages (n = 40)	p-value
Spinal pathology			
Recurrent herniated nucleus pulposus	9 (8.1)	2 (5.0)	0.517
Degenerative spondylolisthesis	57 (51.4)	9 (22.5)	0.002*
Isthmic spondylolisthesis	24 (21.6)	28 (70.0)	<0.001*
Fusion level			
L3/L4	3 (2.7)	0 (0)	0.003*
L4/L5	59 (53.2)	10 (25.0)	
L5/S1	49 (44.1)	30 (75.0)	
Bone graft			
BMP-2	97 (87.4)	34 (85.0)	0.069
Iliac crest bone graft	1 (0.9)	3 (7.5)	
Other [†]	13 (11.7)	3 (7.5)	
Operative time (min)	138.3 ± 33.3	143.2 ± 32.1	0.429
Estimated blood loss (mL)	64.0 ± 32.0	66.9 ± 51.4	0.680
Length of stay (hr)	56.3 ± 32.1	43.2 ± 21.8	0.022*
Arthrodesis by 1 year[‡]			
Nonunion	12 (11.0)	0 (0)	0.035*
Solid fusion	97 (89.0)	37 (100)	

Values are presented as number (%) or mean ± standard deviation. BMP-2, bone morphogenic protein-2. * $p < 0.05$, statistical significance. [†]Other synthetic bone graft substitute+ local bone graft without the use of BMP-2 or iliac crest bone graft. [‡]Arthrodesis status was not able to be assessed for 5 patients due to unavailable postoperative computed tomography scans.

Table 3. Patient-reported outcomes

PROM	Unilateral cage	Bilateral cages	p-value [†]	p-value [‡]
VAS back				
Preoperative	6.8 ± 2.1	6.8 ± 2.4	0.932	
6 Weeks (Δ)	2.8 ± 2.7	2.4 ± 3.4	0.487	0.551
12 Weeks (Δ)	3.0 ± 2.8	3.6 ± 3.0	0.282	0.888
6 Months (Δ)	3.2 ± 2.9	4.0 ± 3.1	0.226	0.277
1 Year (Δ)	3.1 ± 2.4	3.9 ± 3.1	0.352	0.412
2 Years (Δ)	3.7 ± 3.1	2.9 ± 4.6	0.606	0.212
VAS leg				
Preoperative	6.1 ± 2.5	4.6 ± 3.2	0.017*	
6 Weeks (Δ)	3.1 ± 3.4	2.0 ± 4.1	0.214	0.995
12 Weeks (Δ)	3.0 ± 2.8	2.3 ± 3.5	0.308	0.805
6 Months (Δ)	3.3 ± 2.8	2.0 ± 3.1	0.084	0.393
1 Year (Δ)	3.9 ± 2.9	2.8 ± 2.5	0.199	0.054
2 Years (Δ)	3.8 ± 3.1	3.0 ± 3.4	0.547	0.380
ODI				
Preoperative	45.1 ± 17.2	39.6 ± 15.6	0.145	
6 Weeks (Δ)	7.9 ± 17.4	4.9 ± 21.7	0.511	0.259
12 Weeks (Δ)	13.2 ± 16.3	17.4 ± 17.8	0.296	0.615
6 Months (Δ)	17.7 ± 15.3	18.3 ± 22.2	0.888	0.930
1 Year (Δ)	19.0 ± 17.5	18.4 ± 14.6	0.915	0.412
2 Years (Δ)	25.8 ± 23.5	8.2 ± 29.6	0.118	0.026*
SF-12 PCS				
Preoperative	30.0 ± 9.0	34.9 ± 12.4	0.045*	
6 Weeks (Δ)	0.9 ± 9.4	-0.4 ± 8.4	0.642	0.666
12 Weeks (Δ)	7.2 ± 9.4	10.8 ± 11.4	0.307	0.611
6 Months (Δ)	9.8 ± 12.0	12.9 ± 12.4	0.469	0.663
1 Year (Δ)	13.6 ± 9.8	9.8 ± 8.3	0.212	0.170
2 Years (Δ)	11.9 ± 11.3	7.4 ± 11.1	0.289	0.253
PROMIS-PF				
Preoperative	34.0 ± 5.6	37.0 ± 4.7	0.165	
6 Weeks (Δ)	1.4 ± 5.3	-0.2 ± 6.2	0.556	0.108
12 Weeks (Δ)	2.9 ± 6.7	7.4 ± 5.5	0.120	0.434
6 Months (Δ)	8.5 ± 9.2	11.2 ± 5.0	0.469	0.436
1 Year (Δ)	7.2 ± 5.4	13.8 ± 8.6	0.091	0.423
2 Years (Δ)	3.7 ± 4.0	13.7 ± 4.4	0.001*	0.060

Values are presented as mean ± standard deviation. PROM, Patient-Reported Outcome Measures; VAS, visual analogue scale; ODI, Oswestry Disability Index; SF-12 PCS, 12-item Short Form health survey physical composite score; PROMIS-PF, Patient-Reported Outcome Measurement Information System physical function. * $p < 0.05$, statistical significance. [†]p-values calculated using Student t-test to compare mean preoperative scores and mean postoperative improvement between groups. [‡]p-values calculated using 1-way analysis of covariance to compare mean postoperative improvement between groups while accounting for significant covariates.

procedures. Of these patients with pseudoarthrosis, 3 demonstrated significant concomitant subsidence. No additional inci-

dences of index-level revision or clinically significant subsidence were observed.

Table 4. Achievement of MCID

PROM	Unilateral cage	Bilateral cages	OR (95% CI)	p-value [†]	p-value [‡]
VAS back					
6 Weeks	54 (55.1)	160 (50.0)	0.8 (0.4–1.8)	0.615	0.662
12 Weeks	49 (55.7)	20 (62.5)	1.3 (0.6–3.0)	0.505	0.749
6 Months	53 (63.9)	19 (67.9)	1.2 (0.5–3.0)	0.701	0.510
1 Year	15 (62.5)	12 (66.7)	1.2 (0.3–4.3)	0.780	0.226
2 Years	9 (60.0)	6 (60.0)	1.0 (0.2–5.2)	0.999	0.996
Overall	73 (73.0)	26 (74.3)	1.1 (0.4–2.6)	0.882	0.208
VAS leg					
6 Weeks	16 (36.4)	9 (30.0)	0.8 (0.3–2.0)	0.570	0.943
12 Weeks	14 (32.6)	8 (26.7)	0.8 (0.3–2.1)	0.590	0.428
6 Months	13 (32.5)	5 (18.5)	0.5 (0.1–1.5)	0.210	0.361
1 Year	9 (37.5)	4 (21.1)	0.4 (0.2–1.8)	0.249	0.020*
2 Years	4 (33.3)	3 (27.3)	0.8 (0.1–4.5)	0.753	-
Overall	26 (57.8)	110 (33.3)	0.4 (0.1–0.9)	0.035*	0.077
ODI					
6 Weeks	22 (46.8)	14 (46.7)	1.0 (0.4–2.5)	0.990	0.219
12 Weeks	26 (59.1)	21 (70.0)	1.6 (0.6–4.3)	0.340	0.892
6 Months	31 (75.6)	20 (74.1)	0.9 (0.3–2.8)	0.886	0.573
1 Year	16 (64.0)	14 (73.7)	1.6 (0.4–5.8)	0.496	0.962
2 Years	9 (69.3)	8 (72.7)	1.2 (0.2–7.0)	0.851	0.544
Overall	39 (81.3)	27 (79.4)	0.9 (0.3–2.7)	0.836	0.699
SF-12 PCS					
6 Weeks	9 (42.9)	8 (42.1)	1.0 (0.3–3.4)	0.962	0.898
12 Weeks	11 (57.9)	13 (72.2)	1.9 (0.5–7.5)	0.364	0.835
6 Months	15 (75.0)	11 (73.3)	0.9 (0.2–4.2)	0.911	0.745
1 Year	18 (85.7)	15 (79.0)	0.6 (0.1–3.2)	0.576	0.850
2 Years	12 (75.0)	9 (69.2)	0.8 (0.1–3.8)	0.730	0.796
Overall	25 (80.7)	22 (84.6)	1.3 (0.3–5.3)	0.695	0.807
PROMIS-PF					
6 Weeks	3 (37.5)	3 (25.0)	0.6 (0.1–3.9)	0.552	0.995
12 Weeks	3 (42.9)	10 (76.9)	4.4 (0.6–32.1)	0.139	0.878
6 Months	3 (50.0)	8 (88.9)	8.0 (0.6–110.3)	0.120	0.149
1 Year	5 (71.4)	10 (90.9)	4.0 (0.3–55.5)	0.301	0.585
2 Years	3 (50.0)	8 (100)	-	-	-
Overall	7 (77.8)	14 (87.5)	2.0 (0.2–17.3)	0.529	0.460

Values are presented as number (%).

MCID, minimum clinically important difference; PROM, Patient-Reported Outcome Measures; OR, odds ratio; CI, confidence interval; VAS, visual analogue scale; ODI, Oswestry Disability Index; SF-12 PCS, 12-item Short Form health survey physical composite score; PROMIS-PF, Patient-Reported Outcome Measurement Information System physical function.

* $p < 0.05$, statistical significance. [†]p-values calculated using logistic regression to assess rates of MCID achievement between groups. [‡]p-values calculated using multiple logistic regression to assess rates of MCID achievement between groups while accounting for significant covariates.

Preoperatively, VAS leg (6.1 ± 2.5 vs. 4.6 ± 3.2 , $p=0.017$), SF-12 PCS (30.0 ± 9.0 vs. 34.9 ± 12.4 , $p=0.045$) were significantly worse for the unilateral cage group (Table 3). Preoperative VAS back, ODI, and PROMIS-PF scores did not significantly differ between groups (all $p > 0.05$). Student t-test determined that postoperative Δ values were greater only for the bilateral group in PROMIS-PF at 2 years (3.7 ± 4.0 vs. 13.7 ± 4.4 , $p=0.001$), but did not significantly differ between groups for any other PROM at any timepoint (all $p > 0.05$). One-way ANCOVA revealed that when significant covariates were accounted for, improvement in ODI at 2 years was significantly greater for the unilateral group (25.8 ± 23.5 vs. 8.2 ± 29.6 , $p=0.026$). A majority of patients achieved an MCID overall for each PRO, with the exception of VAS leg for the bilateral group. Simple logistic regression demonstrated a significantly greater MCID achievement rate in the unilateral group only for overall VAS leg (57.8% vs. 33.3%, $p=0.035$). Multiple logistic regression revealed that when significant covariates were accounted for, unilateral cage placement significantly predicted greater achievement rates for VAS leg at 1 year ($p=0.020$) (Table 4).

DISCUSSION

MIS TLIF has a strong record of achieving favorable clinical outcomes while minimizing disruption of paraspinal musculature and surrounding structures.^{2,3,17,18} Although a number of aspects and variations of the TLIF procedure have been described, literature regarding the use of unilateral or bilateral interbody cages is limited. A few studies have examined immediate perioperative outcomes or biomechanical differences, however, most of these have not adequately controlled for the role of posterior instrumentation.^{7,9,10} Furthermore, the association of interbody cage placement with PROs has not been thoroughly assessed. The present study compared achievement of MCID in a number of PROMs based on the use of unilateral or bilateral cage placement in a cohort of patients undergoing MIS TLIF with bilateral pedicle screw instrumentation.

The topic of interbody cage placement and architecture is complex and multifaceted. Lee et al.¹⁰ conducted a biomechanical study of 3 different cage conditions in a cadaveric PLIF model and determined that 2 cages placed bilaterally achieved greater stability and decreased stress compared with single cage techniques. Wang and Guo⁹ performed a similar study of 3 interbody cage techniques in a biomechanical model of physiological loading and vibration following TLIF. The authors reported that unilateral cages may be associated with increased risk of

cage failure or adjacent segment degeneration, while the crescent shaped cage imparted increased stability and potentially decreased subsidence risk. However, neither Lee et al.⁹ nor Wang and Guo¹⁰ included the use of posterior fixation constructs in their cadaveric models of the spine. Posterior instrumentation has been demonstrated to have a number of significant effects on the outcomes of TLIF procedures, including segmental stability and endplate stress.^{11,12,19} This discrepancy is addressed by Ambati et al.,¹¹ who utilized a cadaveric finite element model of the lumbar spine to explore the biomechanical effects of a variety of combinations of unilateral, bilateral, or crescent shaped cages with either unilateral or pedicle screw instrumentation for single-level TLIF. Their main conclusion was that bilateral pedicle screw fixation provides superior spinal stability compared with unilateral posterior instrumentation. Interestingly, Ambati et al. concluded that neither cage shape nor number significantly affected segmental stability when accompanied by bilateral posterior instrumentation, as was used in our cohort.

Preoperatively, there were several important differences between groups in our cohort. Of particular note, most patients receiving unilateral cages had a diagnosis of degenerative spondylolisthesis, while isthmic spondylolisthesis was the prevailing spinal diagnosis among patients receiving bilateral cages. Massel et al.⁸ have previously published on a similar trend, noting a unilateral approach for patients with degenerative spondylolisthesis or grade I isthmic spondylolisthesis and bilateral cage placement for patients with grade II isthmic spondylolisthesis. In spite of the potentially more complex pathology among the patients receiving bilateral cage placement, they noted no difference in VAS back improvement through 6-months postoperative, nor in rates of fusion, revision, blood loss, or length of stay. An additional study by Massel et al.²⁰ directly comparing grade I and grade II isthmic spondylolisthesis with the same division by cage placement likewise demonstrated no significant differences in the above outcomes. Importantly, all patients in both studies by Massel et al. underwent bilateral posterior instrumentation.

Aoki et al.⁷ performed a randomized clinical trial of 50 TLIF patients assigned to receive either unilateral cage placement with unilateral pedicle screw instrumentation or bilateral cages with bilateral pedicle screws. The investigators demonstrated that while the unilateral group experienced shorter operative durations and less blood loss, they also reported significantly less improvement in leg pain (as measured by VAS leg) and numbness following their procedures. Aside from these findings, Aoki et al. reported no significant differences in back pain

(VAS back or JOA back pain) or fusion rates between groups. While the prospective, randomized nature of their study is compelling, as with many other previous studies, interpretation of Aoki et al.'s results regarding cage placement may be confounded by the choice of unilateral vs bilateral pedicle screw instrumentation. This factor is especially important to account for as it has been shown to independently affect postoperative outcomes in lumbar fusion.^{11,13,21} A systematic review and meta-analysis by Ren et al.,¹³ as well as a randomized clinical trial by Choi et al.²¹ comparing unilateral and bilateral pedicle screw instrumentation for TLIF procedures both demonstrated significantly lower rates of fusion with unilateral posterior instrumentation. Furthermore, the finite element model of Ambati et al.¹¹ demonstrated decreased stability among lumbar fusion constructions using unilateral instrumentation. Our study controlled for the effects of posterior instrumentation by including only patients who received placement of bilateral pedicle screws. Given this important methodological distinction, our results differed from that of Aoki et al.⁷ in several ways. First, we observed no significant differences in EBL or operative duration, likely due to the use of uniform posterior instrumentation procedures, regardless of cage placement. However, we did observe that patients who received unilateral cages had significantly longer postoperative stays. This may be interpreted as a result of differences in cage placement or may be related to the increased comorbidity burden observed in the unilateral cage group. In terms of PROMs, unlike Aoki et al.,⁷ patients in our study demonstrated minimal differences in postoperative improvement based on their cage status. However, after accounting for significant covariates, we did observe greater rates of MCID achievement for VAS leg at 1 year among the unilateral cage group. These observed differences could potentially be related to the significantly more severe leg pain observed preoperatively among the unilateral group. While we did take measures to statistically account for these differences, the worse baseline leg pain among the unilateral group may have allowed these patients greater "room" to improve. A previous study by Jenkins et al.²² concluded that, for patients undergoing MIS TLIF, postoperative physical function, as measured by PROMIS-PF, was significantly more strongly correlated with VAS back scores than VAS leg. This conclusion may help explain the minimal differences in overall physical health improvement in spite of transient differences in leg pain. Based on more global trends in PROM values, our results suggest that patients may perceive similar levels of improvement with the use of a unilateral cage compared to bilateral.

However, we did observe one significant difference between

groups that was not demonstrated in cohort of Aoki et al.⁷ Specifically, all patients that received bilateral cages had demonstrated solid fusion by the 1-year timepoint, while only 89.0% of patients that received unilateral cages were fused at this timepoint. Perhaps the most straightforward explanation for this difference in fusion rates is decreased segmental stability or increased range of motion with a unilateral cage. However, the results of biomechanical analysis of Ambati et al.¹¹ demonstrated similar stability between unilateral and bilateral cages when accompanied by bilateral pedicle screw instrumentation. Another possible contribution to differences in rates of arthrodesis is the incidence of cage subsidence, as both implant type/shape and position have been demonstrated as risk factors for the complication.^{23,24} This may be a less likely scenario, but a possibility nonetheless, as only 3 patients underwent an index-level revision procedure due to pseudarthrosis with concomitant cage subsidence. Our results regarding fusion rates are especially interesting considering the lack of significant difference observed in MCID achievement, implying that patients reported similar improvements in spite of these differing arthrodesis rates. Additional high-quality studies of radiographic and biomechanical outcomes to study the clinical effects of cage placement while controlling for posterior instrumentation may be necessary to fully elucidate the mechanism of these observed differences.

To our knowledge, this is the first study to comprehensively explore the effects of unilateral versus bilateral cage placement on MCID achievement following TLIF procedures while controlling for posterior instrumentation. However, the present study is not without limitations. All procedures were performed by a single surgeon at a single academic institution, which may limit the generalizability of our findings to other providers and patients. Furthermore, self-reported data such as PROMs are inherently prone to recall bias, non-response bias, and other potentially confounding effects. Nonetheless, quantifying these patient perceptions is vital to understanding postoperative outcomes in a clinically relevant, patient-centered manner. Finally, limited response rates at long-term follow-ups may have limited our ability to detect statistical effects at these more longitudinal timepoints.

CONCLUSION

Among patients undergoing MIS TLIF with bilateral pedicle screw instrumentation, minimal differences were observed in terms of blood loss, operative duration, or PROs based on the use of unilateral versus bilateral interbody cages. Specifically,

patients achieved a clinically important difference in pain, disability, and physical function at similar rates regardless of cage placement. However, all patients receiving bilateral cage placement had demonstrated solid fusion by 1 year, while the rate of fusion was significantly lower for patients receiving unilateral cage placement.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Original Article

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INTRODUCTION

Minimally invasive lumbar decompression (MIS LD) is an effective treatment option for individuals experiencing degenerative spinal pathologies such as lumbar stenosis. Although its minimally invasive nature and proven efficacy make it a desirable procedure for individuals that have failed conservative management,^{1,2} complications and persistent symptoms following MIS LD may require some patients to undergo a revision procedure. Significant efforts should be made to avoid repeat lumbar surgeries, as prior studies have demonstrated revision lum-

Change in Patient-Reported Outcome Measures as Predictors of Revision Lumbar Decompression Procedures

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Objective: To assess change in Patient-Reported Outcome Measures (PROM) as predictors for revision lumbar decompression (LD).

Methods: Patients who underwent primary, single or multilevel LD were retrospectively reviewed. Patients were categorized according to whether or not they underwent revision LD within 2 years of the primary procedure. Visual analogue scale (VAS), Oswestry Disability Index (ODI), 12-item Short Form Health Survey and 12-item Veterans RAND physical component score (SF-12 PCS and VR-12 PCS), and Patient-Reported Outcome Measurement Information System physical function (PROMIS-PF) were recorded. Delta PROM scores were evaluated for differences between groups and as a risk factor for a revision LD.

Results: The study included 135 patients, 91 undergoing a primary procedure only and 44 undergoing a primary and revision procedure. Matched patients did not demonstrate any significant differences in demographics or perioperative characteristics. Patients who underwent a revision had a mean time to revision of 7.4 ± 5.7 months. Primary cohort significantly improved for all PROMs (all $p < 0.05$), while the primary plus revision cohort significantly improved for VAS back, ODI, and PROMIS-PF (all $p < 0.05$). However, cohorts differed in VAS back and PROMIS-PF ($p < 0.05$). Delta PROMs were not a significant risk factor for revision except at 6 months for PROMIS-PF ($p = 0.024$).

Conclusion: LD has been associated with reliable outcomes, but early identification of patients at risk for revision is critical. This study suggests that tools such as PROMIS-PF may serve a role in predicting who is at risk and the 6-month follow-up period may be valuable for counseling patients who are not experiencing improvement.

Keywords: Lumbar vertebrae, Decompression, Patient-Reported Outcome Measures

bar procedures to be associated with higher complication rates and worse outcomes than primary surgical intervention. Proietti et al.³ demonstrated revision cases had a higher rate of infection and unintended durotomy compared to primary procedures. Additionally, Singh et al.⁴ reported revision lumbar discectomy patients had higher postoperative narcotic utilization, prolonged hospital stay, and higher postoperative pain scores at 6 weeks. Therefore, it is critical to identify possible predictors of revision procedures in an attempt to modify risk factors and counsel those at risk.

Identifying predictors can serve as an effective way to proac-

tively determine individuals likely to require revision surgery following MIS LD, thus avoiding a second surgery and the negative outcomes associated with it. Several past studies of the lumbar spine have established various predictors of revision, most of which focus on an individual's pathological diagnoses or radiographic imaging. Hwang et al.⁵ and Deyo et al.⁶ identified moderate disk degeneration in lower lumbar segments and history of a lumbar procedure prior to the index operation to be strong clinical predictors of reoperation following surgery for lumbar spinal stenosis. Additionally, Abdul Jalil et al.⁷ used preoperative magnetic resonance imaging to identify presence of retrolisthesis or foraminal disc herniation to be predictive of higher risk for revision following lumbar discectomy. While these results provide meaningful insight, it is critical to look beyond objective diagnoses and work to identify additional predictors that include a patient's own perception of their health and well-being.

Patient-Reported Outcome Measures (PROMs) are self-reported questionnaires that allow clinicians to understand a patient's perception of their own pain, disability, and physical function.⁸ PROMs have become increasingly relied on to quantify postoperative outcomes and define the success of surgery, making it important to determine whether or not they can also be used for identifying patients at risk for revision surgery. Due to the lack of literature focusing on PROMs in this context, our study aims to quantify differences in the incremental changes of PROMs following a primary MIS LD between patients who did or did not subsequently undergo revision surgery. It is critical to understand this relationship, as we would expect patients requiring a future revision to have a significantly different postoperative course regarding improvement in postoperative outcomes. Using PROMs specific for pain, disability, and physical function, we hypothesize that patients that undergo subsequent revision MIS LD procedures will experience less improvement in PROMs between postoperative timepoints than those patients that do not undergo a revision procedure.

MATERIALS AND METHODS

1. Inclusion Exclusion Criteria

Eligible study participants were identified through a retrospective review of a prospective single surgeon database for spinal procedures performed at a single academic medical institution between May 2008 and January 2020. Inclusion criteria were set as patients undergoing primary, elective, single, or multilevel MIS LD for a degenerative spinal pathology. Exclusion

criteria were set as patients undergoing surgery for trauma, infection, or malignancy, or a revision procedure greater than 2 years after their primary MIS LD procedure. All aspects of the current study were approved by the Institutional Review Board of Rush University Medical Center (ORA 14051301) and all participants provided written informed consent prior to commencement of the study.

Patients were categorized into 2 groups: those who underwent only a primary procedure and those who underwent both a primary and subsequent revision procedure within 2 years of the primary surgery. All surgeries, primary and revision, were performed using either a microscopic or microtubular approach and included laminectomy, hemilaminectomy, discectomy, foraminotomy, or facetectomy. All revision decompression surgeries involved the same level of the primary decompression.

2. Data Collection

Demographic information and perioperative characteristics were collected through a retrospective review. Demographic information included age, self-identified gender, body mass index (BMI), active smoker status, diabetic status, and insurance collected. Additionally, appropriateness for surgery and comorbidity burden were recorded and collected using the American Society of Anesthesiologists physical status classification and Charlson Comorbidity Burden, respectively. Perioperative information included associated preoperative spinal pathology, number of operative levels, operative duration, intraoperative estimated blood loss (EBL), postoperative length of stay (LOS), and time to revision procedure.

The primary outcome of interest was PROMs which were evaluated using the visual analogue scale (VAS), Oswestry Disability Index (ODI), 12-item Short Form and Veterans RAND physical composite score (SF-12 PCS and VR-12 PCS), and Patient-Reported Outcome Measurement Information System physical function (PROMIS-PF). All outcome measures were collected at a baseline preoperative timepoint and subsequently at 6 weeks, 12 weeks, 6 months, and 1 year postoperatively following the primary procedure. If a patient were to undergo revision surgery within 2 years of the primary, their subsequent PROMs following the primary procedure were not included in analysis. For example, a patient in the primary plus revision cohort who underwent the revision procedure at 9 months from the primary procedure would not have a 1-year PROM included in analysis. Change in PROMs between consecutive timepoints was calculated as follows: Delta (Δ) = [timepoint 1 value – timepoint 2 value].

3. Statistical Analysis

As previously described, patients were divided and analyzed in 2 cohorts; those who underwent only a primary procedure and patients who underwent both a primary and subsequent revision procedure. To control for significant differences in demographic variables between groups, a propensity score was calculated for all patients and a nearest neighbor match performed. Patients were matched based on age, sex, BMI, smoker, and diabetic status. Unmatched patients were excluded from analysis. Following propensity score matching, groups were evaluated for differences in demographics, perioperative characteristics using chi-square test for categorical variables and an unpaired Student t-test for continuous variables. PROM scores associated with the primary procedure that were collected after the date of revision of index-level surgery were excluded from analysis. As such, delta PROM comparisons were ensured to be between primary cohort and primary plus revision cohort for each index operation without factoring in PROM scores taking place after revision procedure. Groups were evaluated for significant differences in PROM score improvements from their respective baseline value using a paired Student t-test and any differences in PROM scores between groups were evaluated at each timepoint using an unpaired Student t-test. To evaluate delta PROM values between timepoints as a predictor of undergoing an MIS LD revision, a simple logistic regression was performed. All statistical tests and analyses were performed using StataIC 16.1 (StataCorp, College Station, TX, USA) and an alpha value was set to 0.050 to reject the null hypothesis.

RESULTS

A total of 135 propensity score matched patients were included in the final study cohort with 91 undergoing only a revision procedure and 44 having undergone a revision procedure. The cohort had a mean age of 42.7 years with majority (75.8%) being male and nonobese (BMI < 30 kg/m²). The 2 cohorts did not demonstrate any significant differences in baseline characteristics (Table 1). Majority of patients were associated with a preoperative spinal pathology of herniated nucleus pulposus (70.0%) and underwent a procedure at a single level (73.8%). Mean operative duration was 55.2 minutes with an associated EBL of 55.8 mL and LOS of 11.4 hours. Mean time to revision was 7.4 months.

Comparison of perioperative characteristics between groups did not demonstrate significant differences (Table 2).

Table 3 summarizes mean PROM scores by group. Patients

Table 1. Propensity matched demographics

Characteristic	Total (n = 135)	Primary only (n = 91)	Primary+ revision (n = 44)	P- value*
Age (yr)	42.7 ± 15.0	42.3 ± 14.7	43.6 ± 15.8	0.652
Sex				0.315
Female	32 (24.2)	19 (21.6)	13 (29.5)	
Male	100 (75.8)	69 (78.4)	31 (70.4)	
Body mass index (kg/m ²)				0.533
< 30	77 (58.3)	53 (60.2)	24 (54.5)	
≥ 30	55 (41.7)	35 (39.8)	20 (45.5)	
Smoking status				0.869
Nonsmoker	100 (83.3)	73 (82.9)	37 (84.1)	
Smoker	22 (16.7)	15 (17.1)	7 (15.9)	
Diabetic status				1.00
Nondiabetic	120 (90.9)	80 (90.9)	40 (90.9)	
Diabetic	12 (9.1)	8 (9.1)	4 (9.1)	
ASA PS classification				0.880
≤ 2	93 (89.4)	57 (89.1)	36 (90.0)	
> 2	11 (10.6)	7 (10.9)	4 (10.0)	
CCI score				0.892
< 1	58 (50.4)	39 (50)	19 (51.3)	
≥ 1	57 (49.6)	39 (50)	18 (48.7)	
Insurance				0.869
Medicare/medicaid	10 (7.6)	7 (7.9)	3 (6.8)	
Workers' compensation	47 (35.6)	30 (34.1)	17 (38.6)	
Private	75 (56.8)	51 (58)	24 (54.6)	

Values are presented as mean ± standard deviation or number (%). ASA PS, American Society of Anesthesiologists physical status; CCI, Charlson Comorbidity Index.

*p-value was calculated using chi-square or t-test.

who underwent a primary procedure demonstrated significant improvements in VAS back, ODI, and PROMIS-PF from baseline values at 6-week, 12-week, and 6-month follow-up ($p \leq 0.050$, all). Similarly, improvement from baseline values was demonstrated at the 6-week and 12-week timepoint for both VAS leg and VR-12 PCS ($p \leq 0.003$, all). Patients who underwent both a primary and revision procedure demonstrated significant improvements in VAS back (6 weeks, 12 weeks, and 1 year) ($p \leq 0.002$, all), ODI (6 weeks and 12 weeks) ($p \leq 0.035$), and PROMIS-PF (6 weeks and 12 weeks) ($p \leq 0.028$) when compared to preoperative PROM score prior to index operation. Comparison of mean PROM scores between groups demonstrated significantly worse values for VAS back and PROMIS-PF at the preoperative timepoint for patients who underwent both pri-

Table 2. Perioperative characteristics

Characteristic	Total (n = 135)	Primary only (n = 91)	Primary+revision (n = 44)	p-value*
Spinal pathology				
HNP	105 (70.0)	72 (70.6)	35 (68.7)	0.164
Central stenosis	90 (60.0)	65 (63.7)	25 (52.1)	0.175
Foraminal stenosis	41 (27.3)	29 (28.4)	12 (25.0)	0.660
Operative levels				
1 Level	93 (73.8)	63 (72.4)	30 (76.9)	0.528
2 Levels	21 (16.7)	14 (16.1)	7 (17.9)	
3 Levels	12 (9.5)	10 (11.5)	2 (5.1)	
Operative time (min)	55.2 ± 31.0	55.2 ± 31.0	57.2 ± 28.4	0.707
Estimated blood loss (mL)	55.8 ± 30.1	46.7 ± 68.6	39.5 ± 24.5	0.501
Length of stay (hr)	11.4 ± 27.7	12.1 ± 31.2	9.9 ± 19.1	0.665
Time to revision (mo)	-	-	7.4 ± 5.7	-

Values are presented as number (%) or mean ± standard deviation.

HNP, herniated nucleus pulposus.

*p-value was calculated using chi-square or t-test.

mary and revision procedures ($p \leq 0.020$, both). Additionally, these patients also demonstrated significantly worse PROMIS-PF scores at the 6-week and 6-month timepoint ($p \leq 0.032$, both).

Delta (Δ) values for VAS back, VAS leg, ODI, SF-12 PCS, and VR-12 PCS at all postoperative timepoints were not significant predictors for undergoing a revision procedure (Table 4). A similar observation was made for Δ PROMIS-PF at all timepoints except for 6 months ($p = 0.024$). Preoperative PROM scores for index operation and subsequent revision operation for patients in primary+revision cohort were not significantly different from one another (Table 5).

DISCUSSION

The timely identification of patients at risk for requiring revision LD surgery is valuable, but unfortunately has remained a challenge for care providers.⁶ Prior research has suggested that several demographic and surgical factors may be associated with a higher likelihood of revision surgery, including younger age, male sex, and positive smoking status.⁹⁻¹² Similar studies have also shown that revision surgery is frequently associated with a lesser degree of improvement in patient-reported outcomes (PROs).¹²⁻¹⁵ However, there has been a paucity of literature examining the relationship between PROs following the primary surgery, and the likelihood of subsequent revision surgery. Although PROs as a predictor of revision have been analyzed in trauma surgery and total joint arthroplasty, the potential association has yet to be explored in spine surgery.¹⁶⁻¹⁸

In the present study, we sought to analyze the relationship between both the absolute and change in PROMs for patients who underwent primary LD alone versus primary and revision LD within 2 years. Following the primary surgery, there were no significant differences between postoperative absolute and change in VAS, ODI, SF-12 PCS, or VR-12 PCS scores. The 2 cohorts did however have significant differences in absolute PROMIS physical function scores at 6 weeks, 6 months, and 1 year postoperative from the primary procedure, with the primary plus revision cohort reporting worse scores at each time point. Similarly, the degree of improvement in PROMIS-PF scores at 6-month follow-up was significantly smaller for the primary plus revision cohort.

These findings suggest that although legacy metrics such as VAS and ODI may not be as predictive as demographic and surgical factors for the likelihood of revision surgery, the PROMIS-PF assessment may play a unique and valuable role in identifying patients at risk for requiring revision surgery. The PROMIS system offers a computer-based, efficient, flexible, and precise tool that may carry distinct advantages compared to previously utilized PRO assessment tools.¹⁹ In fact, PROMIS-PF has been shown to outperform the ODI and 36-item Short Form Health Survey in the spine patient population in its ability to provide a more accurate measure of function, while taking less time to administer and fewer questions to answer.^{20,21} It is therefore feasible that PROMIS-PF may be more accurately illustrating the postoperative experience, and therefore providing a more reliable indicator of the likelihood of revision surgery.

Table 3. PROM scores for lumbar decompression patients

PROM	Primary only	p-value [‡]	Primary+revision	p-value [‡]	p-value [†]
VAS back					
Preoperative	6.8±2.3 (71)	-	5.7±2.6 (36)	-	0.020*
6 Weeks	3.2±2.8 (63)	<0.001*	3.6±2.5 (29)	<0.001*	0.523
12 Weeks	3.5±3.0 (30)	<0.001*	2.6±2.8 (17)	<0.001*	0.303
6 Months	3.7±2.4 (12)	0.004*	4.3±3.4 (20)	0.094	0.653
1 Year	3.6±3.8 (5)	0.196	3.9±3.4 (9)	0.002	0.869
VAS leg					
Preoperative	6.3±2.8 (43)	-	6.1±3.6 (22)	-	0.823
6 Weeks	2.8±3.0 (37)	<0.001*	3.3±2.9 (16)	0.079	0.573
12 Weeks	3.4±3.8 (16)	0.003*	3.1±2.4 (8)	0.069	0.828
6 Months	2.9±3.1 (7)	0.074	5.3±3.3 (14)	0.381	0.118
1 Year	3.1±2.7 (5)	0.347	3.5±2.9 (9)	0.196	0.796
ODI					
Preoperative	43.5±19.9 (44)	-	46.0±26.6 (22)	-	0.647
6 Weeks	26.3±19.6 (37)	<0.001*	29.1±15.3 (16)	0.004*	0.607
12 Weeks	28.7±22.3 (18)	<0.001*	21.1±13.4 (9)	0.035*	0.359
6 Months	28.0±21.8 (9)	0.050*	40.2±25.4 (14)	0.448	0.248
1 Year	35.7±28.3 (8)	0.199	29.0±23.0 (10)	0.065	0.584
SF-12 PCS					
Preoperative	32.5±9.1 (42)	-	32.4±7.8 (20)	-	0.964
6 Weeks	38.6±8.5 (33)	0.001*	34.7±8.4 (17)	0.429	0.127
12 Weeks	39.2±9.7 (17)	<0.001*	35.7±7.7 (12)	0.139	0.313
6 Months	37.5±9.9 (9)	0.282	33.4±6.4 (14)	0.622	0.282
1 Year	39.6±10.5 (9)	0.194	37.9±9.9 (14)	0.059	0.694
VR-12 PCS					
Preoperative	33.1±9.7 (41)	-	34.2±9.8 (20)	-	0.668
6 Weeks	42.8±8.6 (32)	<0.001*	37.7±10.7 (17)	0.155	0.083
12 Weeks	42.2±10.1 (16)	<0.001*	38.2±8.7 (11)	0.196	0.299
6 Months	40.8±11.5 (5)	0.279	35.5±8.1 (14)	0.635	0.271
1 Year	44.6±11.1 (7)	0.169	39.9±10.5 (14)	0.106	0.356
PROMIS-PF					
Preoperative	39.1±7.8 (29)	-	33.2±6.9 (19)	-	0.011*
6 Weeks	42.6±6.7 (22)	0.002*	38.1±5.2 (16)	0.009*	0.032*
12 Weeks	46.6±7.5 (12)	<0.001*	40.8±7.2 (10)	0.028*	0.078
6 Months	52.3±11.0 (7)	0.006*	37.7±6.9 (12)	0.102	0.002*
1 Year	46.8±4.7 (6)	0.060	37.9±9.6 (12)	0.242	0.052

Values are presented as mean ± standard deviation (number).

PROM, Patient-Reported Outcome Measures; VAS, visual analogue scale; ODI, Oswestry Disability Index; SF-12 PCS, 12-item Short Form Health Survey physical composite score; VR-12 PCS, 12-item Veterans RAND physical component score; PROMIS-PF, Patient-Reported Outcome Measurement Information System physical function.

*p < 0.05, statistical significance. †p-values calculated using paired t-test. ‡p-values calculated using unpaired t-test. Indicates significance for mean PROM scores at specific time point between primary cohort and primary+revision cohort.

Table 4. Delta PROM for lumbar decompression patients

PROM	Primary only	Primary+revision	p-value [†]
Δ VAS back			
6 Weeks	3.5 ± 3.3	2.6 ± 2.8	0.192
12 Weeks	0.57 ± 2.3	1.1 ± 3.3	0.535
6 Months	0.23 ± 1.6	1.3 ± 3.6	0.334
1 Year	1.5 ± 2.5	0.25 ± 3.5	0.531
Δ VAS Leg			
6 Weeks	3.6 ± 3.1	2.4 ± 5.1	0.305
12 Weeks	0.42 ± 1.8	0.36 ± 2.9	0.393
6 Months	0.07 ± 2.9	2.5 ± 3.3	0.126
1 Year	0.33 ± 4.1	1.6 ± 4.6	0.632
Δ ODI			
6 Weeks	16.8 ± 21.5	19.7 ± 23.6	0.662
12 Weeks	4.5 ± 12.6	4.9 ± 10.6	0.956
6 Months	4.2 ± 10.6	7.0 ± 14.9	0.662
1 Year	0.66 ± 11.0	10.7 ± 19.4	0.357
Δ SF-12 PCS			
6 Weeks	7.3 ± 9.8	1.9 ± 9.8	0.079
12 Weeks	1.8 ± 8.4	0.71 ± 5.1	0.712
6 Months	0.49 ± 11.9	2.7 ± 9.9	0.561
1 Year	5.6 ± 1.7	3.8 ± 10.9	0.809
Δ VR-12 PCS			
6 Weeks	9.6 ± 9.5	4.3 ± 11.6	0.108
12 Weeks	1.1 ± 7.3	0.33 ± 7.1	0.613
6 Months	0.55 ± 9.5	2.1 ± 10.8	0.775
1 Year	5.1 ± 1.4	4.3 ± 12.2	0.924
Δ PROMIS-PF			
6 Weeks	4.4 ± 5.8	5.8 ± 7.5	0.512
12 Weeks	4.6 ± 7.2	3.5 ± 4.3	0.659
6 Months	6.9 ± 8.7	3.8 ± 7.5	0.024*
1 Year	9.9 ± 12.2	0.48 ± 10.6	0.105

Values are presented as mean ± standard deviation. PROM, Patient-Reported Outcome Measures; VAS, visual analogue scale; ODI, Oswestry Disability Index; SF-12 PCS, 12-item Short Form Health Survey physical composite score; VR-12 PCS, 12-item Veterans RAND physical component score; PROMIS-PF, Patient-Reported Outcome Measurement Information System physical function. *p < 0.05, statistical significance. †p-values calculated using logistic regression.

Absolute preoperative PROMIS-PF score may also play a valuable predictive role. Despite propensity matching, our primary plus revision cohort reported worse mean preoperative PROMIS-PF scores compared to the primary alone cohort. A similar

Table 5. Preoperative PROM scores for lumbar decompression patients in primary+revision cohort

PROM	Index operation for primary+revision cohort	Revision operation for primary+revision	p-value [†]
VAS back			
Preoperative	5.7 ± 2.6 (36)	6.1 ± 2.7 (26)	0.951
VAS leg			
Preoperative	6.1 ± 3.6 (22)	6.2 ± 2.7 (32)	0.564
ODI			
Preoperative	46.0 ± 26.6 (22)	45.5 ± 20.7 (23)	0.582
SF-12 PCS			
Preoperative	32.4 ± 7.8 (20)	29.7 ± 6.6 (32)	0.187
VR-12 PCS			
Preoperative	34.2 ± 9.8 (20)	31.6 ± 8.5 (31)	0.655
PROMIS-PF			
Preoperative	33.2 ± 6.9 (19)	32.5 ± 6.8 (21)	0.537

Values are presented as mean ± standard deviation (number). PROM, Patient-Reported Outcome Measures; VAS, visual analogue scale; ODI, Oswestry Disability Index; SF-12 PCS, 12-item Short Form Health Survey physical composite score; VR-12 PCS, 12-item Veterans RAND physical component score; PROMIS-PF, Patient-Reported Outcome Measurement Information System physical function. †p-values calculated using 2-sample t-test.

finding was made by Karhade et al.,²² who reviewed 909 patients undergoing LD and found that lower preoperative PROMIS-PF score was the lone independent PRO metric to predict failure of achieving MCID in PROMIS-PF at final postoperative follow-up. One explanation for this may be that patients with a more severe baseline pathology, and therefore a worse preoperative PROMIS-PF score, may benefit from a more meticulous decompression during the primary procedure when compared to patients with higher preoperative PROMIS-PF.

It should also be noted that the degree of change in PROMIS-PF scores was statistically significant at the 6-month follow-up appointment, and patients within our study population underwent revision surgery at an average of 7.4 months. Prior to this timepoint, there were no significant differences in the degree of change. Hung et al.²³ established a repository of MCID values for patients with spinal conditions, and found the MCID for improvement in PROMIS-PF score at 6-month follow-up to range from 5.3 to 7.9 points. Given the common use of the 6-month follow-up appointment following common lumbar spine surgeries, this may be a valuable time for clinicians to carefully assess patients and consider if a revision surgery is indicated for those with a total change in PROMIS-PF score of approximate-

ly 5 points or fewer.^{23,24}

Interestingly, there was no difference in the degree of change in PROMIS-PF scores at 1-year follow-up, though it did trend towards statistical significance. This may be explained by the fact that the majority of patients that required revision surgery within 2 years had already been identified by that time, thereby decreasing statistical power. In fact, most patients who have not undergone revision surgery are likely to have experienced a plateau in their clinical status by the 1-year postoperative mark. In a large PRO analysis of 909 patients undergoing lumbar surgery, for example, Adogwa et al.²⁵ found that that outcome measures obtained at 12 months postoperatively were highly predictive of and consistent with outcomes at 24 months.

The present study has important limitations. These data are not reflective of our comprehensive patient population, but were rather presented using a propensity matched analysis in order to more fully understand associations with PROMs. Furthermore, in an effort to focus on acute and subacute revisions, data was not analyzed beyond two-years postoperative and longer term insights are therefore not available. However, outcomes at one-year postoperative are likely representative of long-term follow-up for the majority of patients undergoing LD.²⁵ In addition, despite our propensity matching strategy, there was a trend towards a difference in the prevalence of lumbar pathology (central stenosis versus herniated nucleus pulposus) between the 2 cohorts. Given an inherent difference in the natural history and likelihood of recurrence for both of these pathologies, this may have influenced the degree of patient improvement for the respective cohorts.^{9,15}

CONCLUSION

LD surgery has generally been associated with reliable outcomes, but early identification of the few patients that may be at risk for requiring a revision surgery is critical. The findings of the present study suggest that although legacy outcome metrics may not provide insights, novel tools such as PROMIS-PF may serve a valuable role in predicting who is at risk. Furthermore, the 6-month follow-up period may be particularly valuable for counseling patients who are not experiencing improvement in their symptoms relative to their peers. Clinicians may use these findings to better identify and educate patients both before and after LD surgery in order to maximize the likelihood of an optimal outcome.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Original Article

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INTRODUCTION

Extraforaminal stenosis in L5–S1, or far-out syndrome (FOS), was initially reported by Wiltse et al.¹ in 1984, who demonstrated that an L5 nerve could be compressed by the transverse process (TP) of the L5 and the ala of the sacrum. A preoperative diagnosis of extraforaminal stenosis at L5–S1 is important be-

Unilateral Biportal Endoscopy for Decompression of Extraforaminal Stenosis at the Lumbosacral Junction: Surgical Techniques and Clinical Outcomes

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Objective: The aims of this study were to describe the unilateral biportal endoscopic (UBE) technique for decompression of extraforaminal stenosis at L5–S1 and evaluate 1-year clinical outcomes. Especially, we evaluated compression factors of extraforaminal stenosis at L5–S1 and described the surgical technique for decompression in detail.

Methods: Thirty-five patients who underwent UBE decompression for extraforaminal stenosis at L5–S1 between March 2018 and February 2019 were enrolled. Clinical results were analyzed using the MacNab criteria, the visual analogue scale (VAS) for back and leg pain, and the Oswestry Disability Index (ODI). Compression factors evaluated pseudoarthrosis within the transverse process of L5 and ala of sacrum, disc bulging with or without osteophytes, and the thickened lumbosacral and extraforaminal ligament.

Results: The mean back VAS was 3.7 ± 1.8 before surgery, which dropped to 2.3 ± 0.8 at 1-year postoperative follow-up ($p < 0.001$). There was a significant drop in postoperative mean VAS for leg pain from 7.2 ± 1.1 to 2.3 ± 1.2 at 1 year ($p < 0.001$). The ODI was 61.5 before surgery and 28.6 ($p < 0.001$). Pseudoarthrosis between the transverse process and the ala was noted in all cases (35 of 35, 100%). Pure disc bulging was seen in 12 patients (34.3%), and disc bulging with osteophytes was demonstrated in 23 patients. The thickened lumbosacral and extraforaminal ligament were identified in 19 cases (51.4%). No complications occurred in any of the patients.

Conclusion: In the current study, good surgical outcomes without complications were achieved after UBE decompression for extraforaminal stenosis at L5–S1.

Keywords: Endoscopic spinal surgery, Extraforaminal stenosis, Far-out syndrome, Lumbosacral ligament, Paraspinal approach, Unilateral biportal endoscopy

cause a lack of diagnosing extraforaminal stenosis at L5–S1 can result in failed back surgery syndrome.^{2,3} In the past, using a paraspinal approach for microsurgical decompression of foraminal lesions had been considered the gold standard for surgical treatment of lumbar foraminal or extraforaminal stenosis.^{1,4,5} But, access to the L5–S1 extraforaminal region is difficult for 2 reasons: (1) the distance between the L5 TP and sacral ala is

short, and (2) the iliac crest generally makes the operative corridor very narrow.^{6–9} Furthermore, significant manipulation of the dorsal root ganglion can result in postoperative leg pain or dysesthesia, and the surgery is technically challenging and more invasive due to the deep location. As a result, some studies report a high rate of chronic or recurrent radiculopathy following FOS microsurgical decompression.^{10,11}

Lately, due to advancements in endoscopic spine surgery, the unilateral biportal endoscopic (UBE) technique has been applied in the cervical, thoracic and lumbar spine.^{12–15} For extraforaminal stenosis at L5–S1, the UBE technique, which can go further into the extraforaminal lesion less invasively, is becoming widespread and surpassing microscopic surgery in popularity. The purpose of this study is to present the UBE technique for complete decompression of extraforaminal stenosis at L5–S1 and evaluate 1-year clinical outcomes. Additionally, we evaluated the compression factors of extraforaminal stenosis at L5–S1 and described the surgical technique for complete decompression in detail compared to previous reports. Especially, we describe (1) a surgical corridor that can allow for effective removal of the thickened lumbosacral and extraforaminal ligament and (2) an anatomical landmark (thickened lumbosacral and extraforaminal ligament), one of the compression factors of extraforaminal stenosis at L5–S1 that shows how far to decompress laterally.

MATERIALS AND METHODS

1. Patient Population

After obtaining informed consent from Institutional Review

Board approval (P01-202003-21-005), we retrospectively reviewed patients with extraforaminal stenosis at L5–S1 who underwent decompression using UBE between March 2018 and February 2019 at our institution. The indications for UBE decompression for extraforaminal stenosis at L5–S1 were the same as those for microsurgical decompression. The patients were eligible if they fulfilled the following inclusion criteria: (1) medically intractable unilateral L5 radiculopathy for at least 6 weeks; (2) L5–S1 extraforaminal stenosis with or without disc herniation confirmed on computed tomography and magnetic resonance imaging (MRI); (3) minimum follow-up for 1 year; and (4) no segmental instability. The exclusion criteria included multiple-level surgery, spondylolisthesis, or comorbid pathological conditions such as infection and compression fractures. The records of these patients were reviewed retrospectively and analyzed for demographic data, side of the surgery, duration of symptoms, follow-up period, operation time, hospital stay, and concomitant foraminal stenosis.

2. Clinical and Radiological Assessment

Three clinical and radiological subjects were evaluated: (1) clinical results, (2) compression factors of extraforaminal stenosis at L5–S1, and (3) surgical complications.

Clinical results were analyzed using a questionnaire for outcome scores (MacNab criteria, visual analogue scale [VAS] for back and leg pain, and Oswestry Disability Index [ODI]) preoperatively and 1 year postoperatively. Compression factors were analyzed using preoperative images as follows: (1) pseudoarthrosis between the TP of L5 and ala of sacrum, (2) ventral factor (disc bulging or disc bulging with osteophytes), and (3)

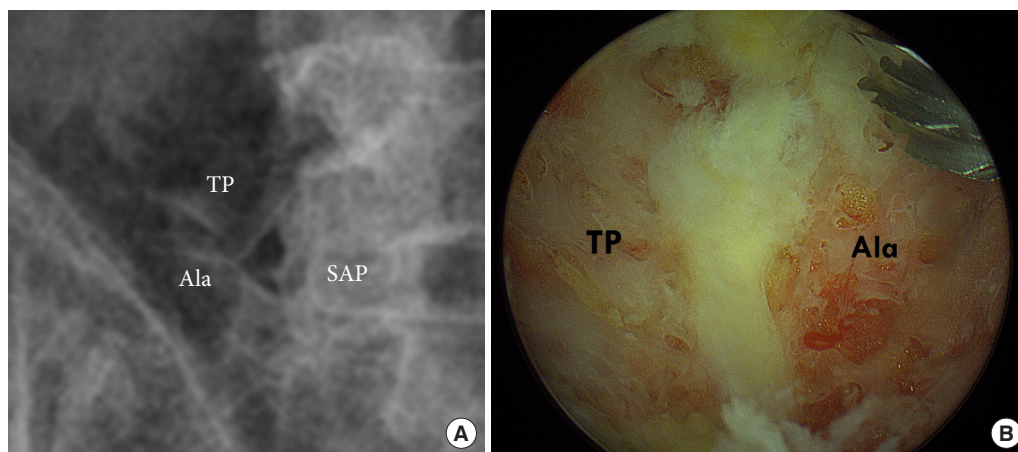


Fig. 1. Preoperative lumbar simple x-ray (A) and intraoperative finding (B) showed contact within the transverse process of L5 and sacral ala. TP, transverse process; SAP, superior articular process.

the thickened lumbosacral and extraforaminal ligament. Pseudoarthrosis between the TP of L5 and ala was defined as contact between the TP of L5 and sacral ala on radiography (Fig. 1). Our study classified ventral factors into 2 subgroups: disc bulging with osteophytes and without osteophytes. Disc bulging with osteophytes was defined as calcification as seen in coronal CT. On the lumbar MRI, we checked the thickened lumbosacral and extraforaminal ligament at the intersection of the vertebral body, disc, TP of L5, and ala (Fig. 2). As a result of degeneration, the disc height is lowered, the gap between the TP of L5 and ala becomes narrower, and the lumbosacral and extraforaminal ligament buckles and becomes thicker. As a result, the hypertrophied lumbosacral and extraforaminal ligament create a pathologic structure that compresses the L5 nerve root.

Surgical complications were analyzed according to the incidence of dural tear and nerve root injury, reoperation due to postoperative hematoma, and infection during a year.

3. Surgical Techniques

Under general anesthesia, the patient is prepared in the prone position over a radiolucent chest frame. The operator stands on the ipsilateral side of the pathology. An assistant is on the opposite side of the operator to hold the retractor (Fig. 3).

1) Skin marking

The target is the superior sacral notch (the junction between the lateral aspect of the superior articular process [SAP] and sacral ala) on an anteroposterior view of the C-arm fluoroscopy. For right-handed surgeons, a left-side incision is made for a scopic portal for endoscopic viewing, and a right-side incision is made for a working portal to manipulate the surgical instruments. The incisions are approximately 3 cm apart, where the center of both incisions are placed 1 cm lateral to the target (Fig. 4). When the caudal incision has interference from the iliac crest, a caudal incision can be made medially to avoid the iliac crest.

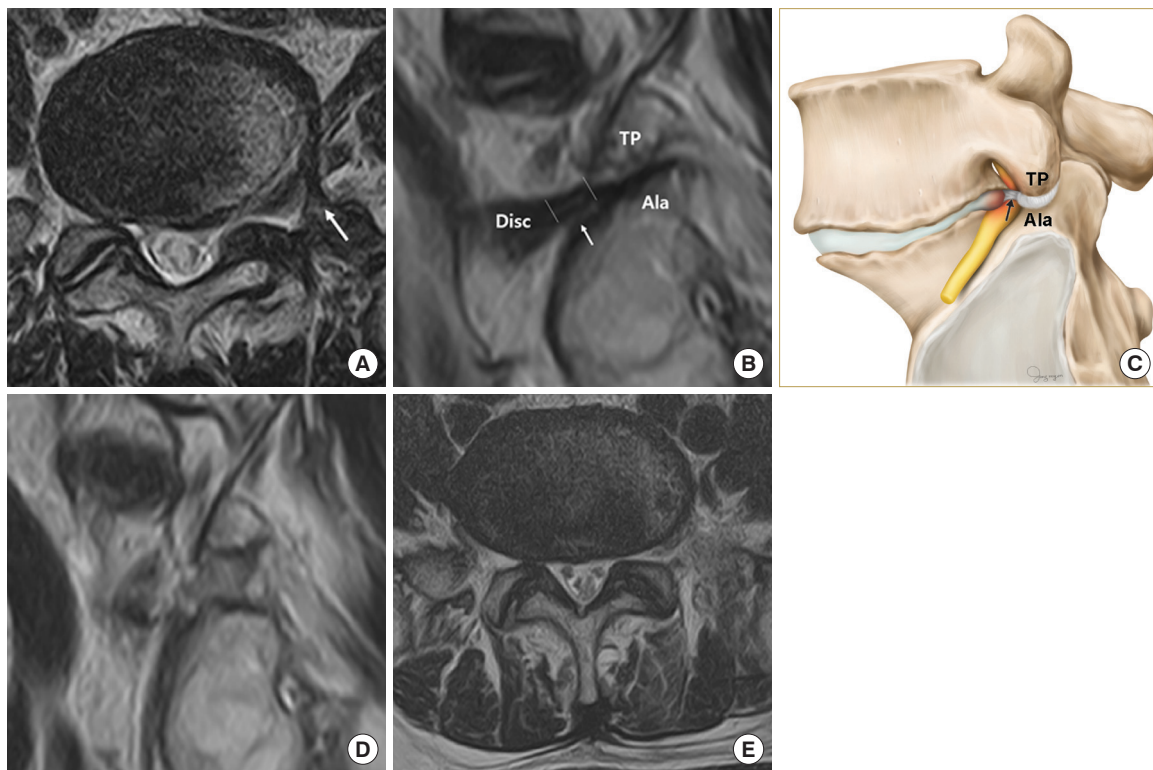


Fig. 2. The magnetic resonance imaging (MRI) images and schematic representation of the thickened lumbosacral ligament and extraforaminal ligament. (A) MRI in the axial plane of the thickened lumbosacral and extraforaminal ligament (white arrow). (B) MRI in the sagittal plane of the thickened lumbosacral and extraforaminal ligament. The between white line indicates the thickened extraforaminal ligament. The white arrow indicates the root compressed by the thickened lumbosacral and extraforaminal ligament. (C) Schematic anatomy of the sagittal plane of the thickened lumbosacral and extraforaminal ligament (black arrow). Sagittal T2-weighted (D) and axial T2-weighted (E) postoperative MRI demonstrating removal of the thickened lumbosacral and extraforaminal ligament. TP, transverse process.

2) Creating the portal and working space

Using fluoroscopic guidance, serial dilators are passed through the working portal and obturator, and a scopic sheath is advanced to the targeting point through the scopic portal. It is necessary to make a triangular position of the scopic sheath and serial dilator at a target point using the C-arm fluoroscopic view. Constant saline irrigation through 2 portals makes a clear surgical view during surgery. After confirmation of the correct positioning for both portals, a radiofrequency coagulator is coagulated



Fig. 3. The operator is on the ipsilateral side of the pathology. An assistant is on the opposite side of the operator to hold the retractor.

to clean the soft tissues and muscles to make clear the anatomy. The surgical anatomy is first noticed as a landmark, including the inferior aspect of TP of L5, the supramedial part of the sacral ala, and the lateral aspect of the SAP of S1 (Fig. 5A).

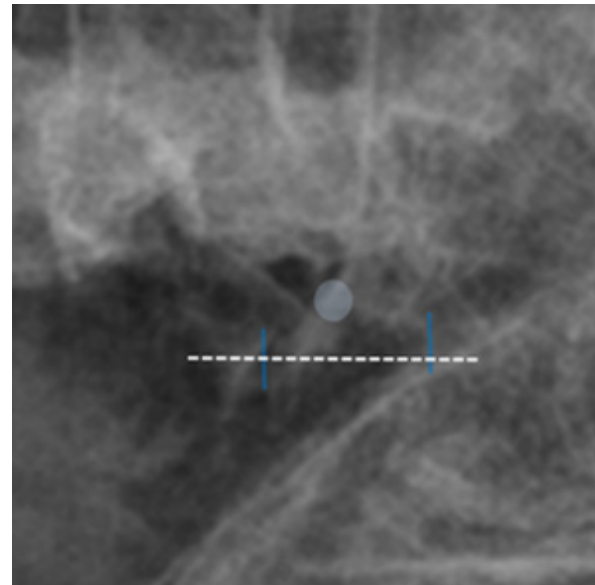


Fig. 4. Skin incision and target point on the fluoroscopic anteroposterior view. The target (white circle) is the superior sacral notch. The 2 incisions (blue lines) are approximately 3 cm apart, where the center of the incision is made 1 cm lateral to the target (dotted line). A scope is placed through the left incision and a working tool is placed through the right incision.

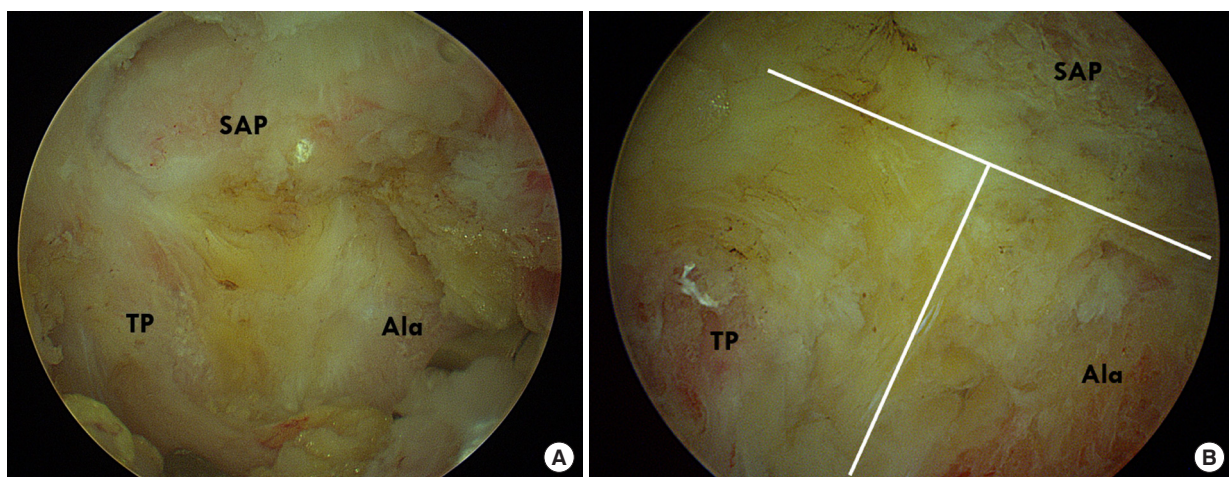


Fig. 5. Intraoperative images showing the steps in order of exposure and decompression in a case of extraforaminal stenosis at L5–S1. (A) The surgical anatomy is first noticed as a landmark, including the inferior aspect of L5 TP, the supramedial part of the sacral ala, and the lateral aspect of the SAP of S1. (B) After drilling of these bony structures, a T-shape figure made of partially removed inferior aspect of TP of L5, the supramedial part of the sacral ala, and the lateral aspect of the SAP of S1 is identified as a landmark for decompression. TP, transverse process; SAP, superior articular process.

3) Bone working and ligament removal

The inferior aspect of TP of L5, the supramedial part of the sacral ala, and the lateral aspect of the SAP of S1 are removed with a high-speed drill and Kerrison rongeur. After drilling these bony structures, a T-shape figure made of a partially removed inferior aspect of TP of L5, the supramedial part of the sacral ala, and the lateral aspect of the SAP of S1 is identified as a landmark for decompression (Fig. 5B). This bony landmark is removed until the ligament is released from the bony structures. The lower part of the TP is removed from medial to lateral until the ligament is detached. After bone working is completed, the proximal portion of the ligament is detached from SAP using a freer elevator and Kerrison rongeur. After ligament removal, the exiting nerve root can be identified.

4) Removal of disc/osteophytes, thickened lumbosacral and extraforaminal ligament

After root confirmation, cautious and complete decompression of the root is made through the entire extraforaminal area. It is essential to completely remove the bulging disc and osteophytes that compress the exiting root ventrally. After flavectomy completion, the annulus is exposed right below the root. Then

we use a radiofrequency probe to undergo the annulotomy and insert straight or curved pituitary forceps to remove disc fragments or osteophytes through Kambin's triangle (Fig. 6A). The authors propose a new surgically corridor called "Son's corridor," because removal of the thickened lumbosacral and extraforaminal ligament via the Kambin triangle needs much retraction of the nerve root and may result in incomplete decompression. The boundaries of Son's corridor are the remaining TP of L5, the lumbosacral ligament, and the exiting nerve root, as depicted in Fig. 6B. Son's corridor serves as a strategic site of the superiolateral area of the L5 exiting root, which allows access to the thickened lumbosacral and extraforaminal ligament for complete decompression of extraforaminal stenosis at L5–S1. After ventral lesions removal, decompression continues laterally towards the thickened lumbosacral and extraforaminal ligament. The L5 root is compressed by a thickened lumbosacral and extraforaminal ligament that is the lateral margin of decompression for extraforaminal stenosis at L5–S1 (Fig. 6C). In addition, Son's corridor considers the surgical corridor for removal of osteophytes from the L5 vertebral body, with a particular focus on removing the thickened lumbosacral and extraforaminal ligament. The arthroscopy basket punch is useful when

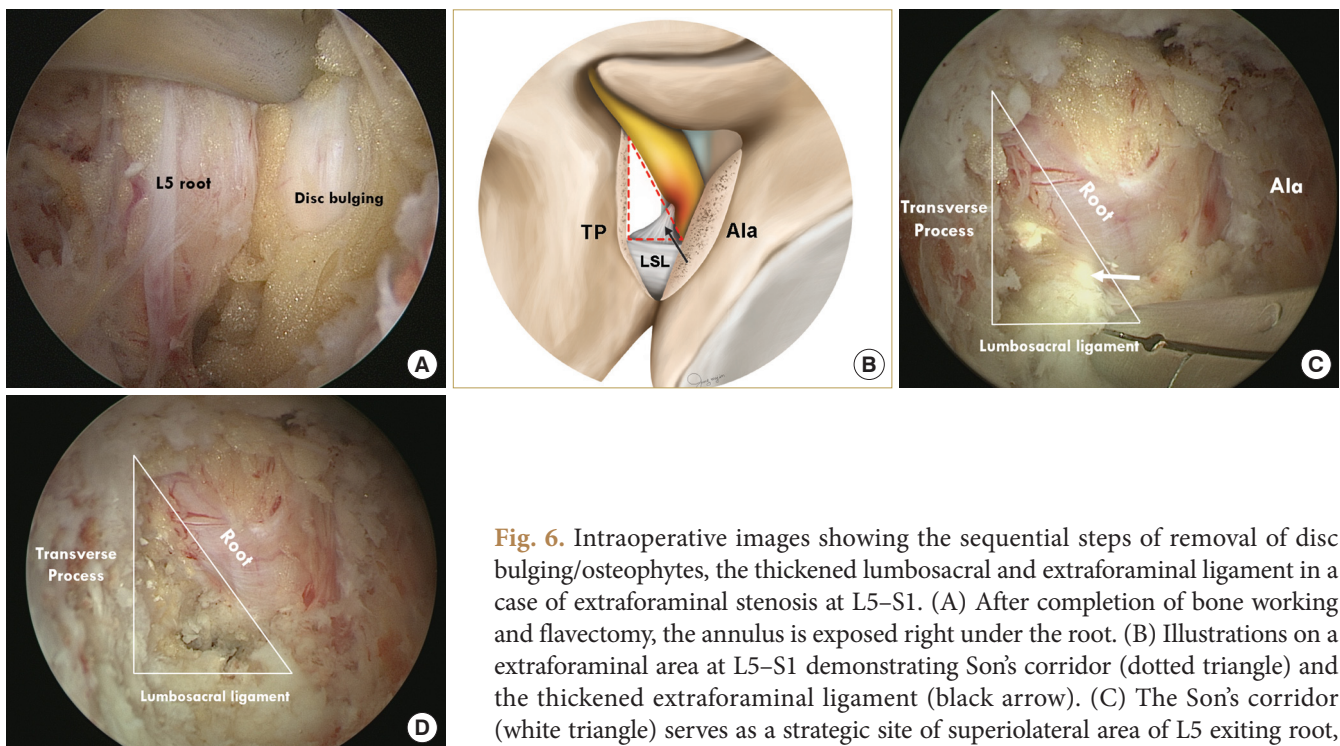


Fig. 6. Intraoperative images showing the sequential steps of removal of disc bulging/osteophytes, the thickened lumbosacral and extraforaminal ligament in a case of extraforaminal stenosis at L5–S1. (A) After completion of bone working and flavectomy, the annulus is exposed right under the root. (B) Illustrations on an extraforaminal area at L5–S1 demonstrating Son's corridor (dotted triangle) and the thickened extraforaminal ligament (black arrow). (C) The Son's corridor (white triangle) serves as a strategic site of superiolateral area of L5 exiting root, access to the thickened lumbosacral and extraforaminal ligament (white arrow)

for complete decompression of extraforaminal stenosis at L5–S1. (D) The endpoint of extraforaminal stenosis at L5–S1 decompression is removal of the thickened lumbosacral and extraforaminal ligament compressed L5 root and free root mobilization, which can be demonstrated with endoscopic viewing. TP, transverse process; LSL, lumbosacral ligament.

removing the thickened lumbosacral and extraforaminal ligament (Supplementary video clip 1). The endpoint of extraforaminal stenosis at L5–S1 decompression is removal of thickened lumbosacral and extraforaminal ligament compressed L5 root and free mobilization of the root, which endoscopic viewing can confirm (Fig. 6D).

4. Statistical Analysis

All statistical analyses were performed using IBM SPSS ver. 18.0 (IBM Co., Armonk, NY, USA). All data are reported as mean \pm standard deviation. Significant differences in preoperative and postoperative VAS scores were determined using the paired t-test. The threshold for statistical significance was set at $p < 0.05$.

RESULTS

1. Demographic Results

Between March 2018 and February 2019, 72 patients with extraforaminal stenosis at L5–S1 were treated decompression using UBE. Thirty-seven patients were excluded because of multiple-level surgery, spondylolisthesis, or less than 1 year of follow-up. Thirty-five consecutive patients who met the inclusion criteria with extraforaminal stenosis at L5–S1 underwent decompression by UBE. The study group consisted of 16 men and 19 women with a mean age at surgery of 68.4 ± 6.6 years. The mean duration of symptoms was 17.1 weeks. The mean

follow-up was 14.9 months. The mean operative time was 63.5 minutes. The mean hospital stay was 6.9 days. Concomitant foraminal stenosis was found in 10 cases (28.6%) (Table 1).

2. Clinical Results

The MacNab criteria were “excellent” in 11 (31.4%), “good” in 17 (48.6%), “fair” in 5 (14.3%), and “poor” in 2 (5.7%) (Table 1). Out of 2 poor patients, one patient underwent lumbar fusion surgery 3 months after the operation and the other patient showed controlled symptoms with conservative treatment. The average VAS for back pain was 3.7 ± 1.8 before surgery, and this value dropped to 2.3 ± 0.8 at 1-year follow-up ($p < 0.001$). There was a significant drop in average postoperative VAS for leg pain from 7.2 ± 1.1 to 2.3 ± 1.2 at 1-year follow-up ($p < 0.001$). The ODI score was 61.5 points before surgery and 28.6 points at the 1-year follow-up and improved significantly after surgery ($p < 0.001$) (Table 2).

3. Surgical Complications

No serious complications occurred for any patient, including dural tear and nerve root injury, reoperation due to postoperative hematoma, and infection within a year.

4. Compression Factors of Extraforaminal Stenosis at L5–S1

All patients had extraforaminal stenosis at L5–S1 with a decreased disc height. There were no extraforaminal lumbar disc herniations or far-lateral disc herniations at L5–S1 with a maintained disc height. Pseudoarthrosis between the TP of L5 and

Table 1. Demographic findings of the study patients (n = 35)

Characteristic	Value
Sex, male:female	16:19
Age (yr)	68.4 ± 6.6
Side of the surgery, right:left	15:20
Duration of symptoms (wk)	17.1 ± 17.8
Follow-up period (mo)	14.9 ± 4.2
Operation time (min)	63.5 ± 14.4
Hospital stay (day)	6.9 ± 2.9
MacNab criteria	
Excellent	11
Good	17
Fair	5
Poor	2
With foraminal stenosis, n (%)	10 (28.6)

Values are presented as mean \pm standard deviation unless otherwise indicated.

Table 2. Preoperative and postoperative clinical scores (n = 35)

Variable	Preoperative	12 Months	p-value
VAS back	3.71 ± 1.75	2.34 ± 0.76	< 0.001
VAS leg	7.23 ± 1.08	2.26 ± 1.17	< 0.001
ODI	61.5 ± 7.8	28.6 ± 6.2	< 0.001

Values are presented as mean \pm standard deviation.

VAS, visual analogue scale; ODI, Oswestry Disability Index.

Table 3. Compression factors of extraforaminal stenosis at L5–S1

Factor	No. (%)
Pseudoarthrosis between transverse process and ala	37 (100)
Ventral factor	
Disc bulging	12 (34.3)
Disc bulging+osteophytes	23 (65.7)
Thickened lumbosacral and extraforaminal ligament	19 (51.4)

the sacral ala was noted in all cases (37 of 37, 100%). On preoperative imaging, pure disc bulging was noted in 12 patients (34.3%), and the presence of osteophytes with disc bulging was noted in 23 patients (65.7%). The thickened lumbosacral and extraforaminal ligament was found in 19 cases (51.4%) (Table 3).

DISCUSSION

Traditional microscopic foraminotomy via the Wiltse paraspinal approach has been seen as an effective surgical treatment in treating FOS, but the procedure has drawbacks. UBE purports to mitigate those drawbacks, as it can allow for reaching deeper into the foraminal region less invasively.^{6–9,16} Our preliminary results on UBE for extraforaminal stenosis at L5–S1 showed that (1) extraforaminal stenosis at L5–S1 has 3 compression factors: (i) pseudoarthrosis between the TP of L5 and sacral ala, (ii) osteophytes and disc bulging, and (iii) the thickened lumbosacral and extraforaminal ligament; (2) UBE has good clinical outcomes, including lower postoperative VAS of back and leg and ODI scores; and (3) no patients in our preliminary study had complications arising from the technique.

As mentioned, surgical access to the L5–S1 extraforaminal area is difficult.^{7,16,17} Further, a prominent iliac crest sometimes may prevent a surgical corridor through the paraspinal Wiltse approach.^{17,18} Perhaps as a consequence, several researchers have reported poor outcomes after microscopic foraminotomy for extraforaminal stenosis at L5–S1.^{10,11} Many researchers have reported concomitant foraminal stenosis along with inadequate decompression as predictors of poor outcomes of microscopic foraminotomy for extraforaminal stenosis at L5–S1.^{7,19} Intra- and extraforaminal space decompression in such patients can only happen with sufficient removal of the facet joint with microscopic foraminotomy, which can result in further degeneration with secondary instability and chronic back pain.⁷

UBE has several advantages over microscopic foraminotomy for extraforaminal stenosis at L5–S1. First, UBE enables the surgeon to reach a deep site quickly and provides a well-illuminated surgical field with proper magnification.^{12,20–22} Second, the technique avoids unneeded invasion of surrounding tissues and preserves the facet joint, which consequently provides advantages for patients, such as reduced postoperative back pain and early resumption of routine activities.¹² Third, necessary bone removal can be assessed in cases of concomitant foraminal stenosis. Decompressing an intraforaminal lesion has been considered difficult with microscopic surgery in many cases.²⁰ In contrast, UBE allows for specific assessment of the needed

degree of facet resection, which minimizes the risk for residual stenosis or instability.²⁰

We identified 3 compression factors in the present study: (1) pseudoarthrosis between the TP and ala, (2) osteophytes and disc bulging, and (3) the thickened lumbosacral and extraforaminal ligament. First, Wiltse et al.¹ demonstrated an extraforaminal stenosis at L5–S1 characterized by L5 nerve entrapment caused by a descending TP of L5 and the superior portion of the medial sacral ala. In our study, the affected roots were compressed within the TP and the sacral ala at the medial aspect of articulation in all cases. Second, another cause of extraforaminal stenosis at L5–S1 was osteophytes/disc bulging of the lateral margin of the vertebral body on the L5 and S1 vertebrae. Osteophytes/disc bulging were identified and seen to compress the L5 nerve root in recent studies.^{23,24} We believe that removal of disc bulging or osteophytes is important in extraforaminal stenosis at L5–S1, because if these compression factors are not removed, the symptoms may remain or the root may be compressed over time. Third, Nathan et al.²⁴ showed in a cadaveric study that the lumbosacral ligament, where the L5 spinal nerve passes, could be entrapped. Furthermore, several authors have indicated that the transforaminal or extraforaminal ligament, which is attached between the facet joints or TP and the intervertebral disc, could compress the lumbar nerve root in the extraforaminal area.^{25,26} Degenerative changes of intervertebral discs, lumbosacral ligament, and extraforaminal ligament make a pathologic structure, which could compress the L5 nerve root at the lumbosacral tunnel. To summarize, the lumbosacral and extraforaminal ligaments have no compression effect on the nerve root in normal circumstances, but with degeneration, the thickened lumbosacral and extraforaminal ligaments may play a role in causing radiculopathy. In our study, in cases where the thickened lumbosacral and extraforaminal ligaments were observed on MRI, it was shown that these pathologic bands compressed the superolateral aspect of the L5 nerve root under intraoperative endoscopic viewing (Fig. 6C). Earlier, we described the usefulness of “Son’s corridor” for complete removal of the thickened lumbosacral and extraforaminal ligaments. Detailed understanding of this strategic triangle can provide for precise and safe removal of the thickened lumbosacral and extraforaminal ligaments without much retraction of the nerve root.

Retroperitoneal fluid collection is one of the most fatal complications in the paraspinal approach using the UBE technique.¹² There is a possibility of fluid accumulating into the retroperitoneal space if fluid out is poor.¹² The barrier between the extraforaminal area and retroperitoneal area could be damaged when

the thickened lumbosacral and extraforaminal ligaments are removed, which may result in retroperitoneal fluid collection.¹² Therefore, special care should be taken to not proceed ventrally farther than where the psoas muscle is. That is why we need to pay more attention to fluid coming out in the extraforaminal stenosis at L5–S1 using the UBE technique.

One limitation of the current study is that this was retrospective with a small sample size and the focus was on surgical techniques. Due its retrospective nature, there is a potential for selection bias within the patient cohorts. Detailed prospective trials using a larger cohort that compares UBE with other techniques, such as conventional surgery, are needed for a deeper analysis of this topic.

CONCLUSION

In the current study, good surgical outcomes after UBE decompression were achieved without complications for patients with extraforaminal stenosis at L5–S1. UBE decompression can avoid certain technical difficulties associated with conventional procedures for extraforaminal stenosis at L5–S1. It is necessary to achieve an accurate diagnosis based on MRI, and complete decompression based on analyzing the extraforaminal anatomy is necessary. It is possible that the UBE technique can replace conventional surgical procedures to become the standard operating procedure for extraforaminal stenosis at L5–S1.

CONFLICT OF INTEREST

The authors have nothing to disclose.

SUPPLEMENTARY MATERIAL

Supplementary video clip 1 can be found via <https://doi.org/10.14245/ns.2142146.073>.

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Editorial



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Commentary on “Unilateral Biportal Endoscopy for Decompression of Extraforaminal Stenosis at the Lumbosacral Junction: Surgical Techniques and Clinical Outcomes”

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The extraforaminal region at the lumbosacral junction is difficult to access due to the narrow corridor and its deep location. Therefore, it is easy to overlook symptomatic extraforaminal stenosis of the lumbosacral junction, known as far-out syndrome or Bertolotti syndrome, in conventional magnetic resonance imaging.¹ This pathology may thus be considered in cases of failed back surgery syndrome with L5 root symptoms.

Decompressive microscopic surgery through the paraspinal approach has been performed for extraforaminal stenosis, but it has its own problems, including postoperative radicular pain, dysesthesia, and a limited field of view leading to incomplete decompression.² Fusion surgery with total facetectomy is sometimes considered.

Endoscopic spine surgery, which has many advantages including less postoperative pain with small incision and less soft tissue injury, short hospitalization, rapid functional recovery, and the possibility of being performed without general anesthesia in some cases, is popular among spine surgeons worldwide.³⁻⁵ Moreover, its technical and instrumental advancements have been tremendous. The authors introduced the unilateral biportal endoscopic (UBE) technique for extraforaminal stenosis at the L5–S1 level.⁶ The high quality of endoscopic imaging and application of a continuous irrigation fluid system make it possible to access any lesions around the foramen and extraforaminal region easily.² The approach to extraforaminal lesions, including L5–S1, is sometimes challenging with conventional microscopes or endoscopes due to the iliac crest and hypertrophied L5 transverse process or sacral ala, which are major obstacles. Because the dual portals can be moved independently and are not interrupted by the endoscope, UBE may be feasible for pathology at narrow and deep locations.

As the authors described 3 compression points for extraforaminal stenosis at L5–S1—the pseudoarticulation between the L5 transverse process and sacral ala, the osteophyte and disc bulging, and the thickened lumbosacral and extraforaminal ligament—it is necessary to consider those factors in cases of insufficient decompression. Although UBE is a developing endoscopic surgical technique and has expanding surgical indications for spine surgery, research targeting specific topics, such as the safe bone working limit and fluid pres-

sure relationship, should be conducted. Prospective or randomized studies, as well as those with long-term follow-up results, are mandatory. Thanks to the authors, we have another weapon for challenging pathology. I congratulate the authors for their pioneering endoscopic surgery technique.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Title: The Old Guitarist
Artist: Pablo Picasso
Year: 1903
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Technical Note

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INTRODUCTION

Ossification of the posterior longitudinal ligament (OPLL) is a representative disease that compresses the spinal cord and causes cervical myelopathy. If the patient develops neurological symptoms, surgical treatment should be considered first.^{1,2} Most OPLL appear downwards, including C2, but it sometimes appears upward from C2 because posterior longitudinal ligament originates from the tectorial membrane.²⁻⁴ If it develops in the caudal area of C2, dome laminoplasty of C2 could be a good option; however, it requires an even cranial area behind dens, and adequate decompression technique has not yet been developed. Furthermore, the destruction of the semispinalis cervicis (SSC) insertion during laminoplasty of the conventional C2

Double Dome Laminoplasty: A Novel Technique for C2 Decompression

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Objective: To introduce a new surgical technique - double dome laminoplasty for decompression of the entire C2 lamina and preservation of an extensor muscle insertion.

Methods: Eleven consecutive cervical myelopathy patients due to ossification of the posterior longitudinal ligament involving the Axis (C2) area were contained at this study. Direct decompression was evaluated as an increasing rate in space available cord (%) and posterior cord shift (mm) at C2 level. The Japanese Orthopaedic Association (JOA) score, visual analogue scale, and C2-7 Cobb angle in a neutral lateral x-ray were analyzed.

Results: The mean increase in space available for spinal cord at the C2 level, average posterior cord shift, and JOA recovery rate were 69.7%, 5.3 ± 0.15 mm, and 58.0%, respectively. Cervical lordotic angle was maintained in all patients. One patient reported neck pain (visual analogue scale 6) postoperatively. No specific complications such as C2 laminar fracture or insufficient decompression were observed.

Conclusion: We recommend double dome laminoplasty for treating patients with cervical myelopathy involving the C2 area to avoid C2 laminectomy, reduce postoperative neck pain, and maintain lordotic cervical spine alignment.

Keywords: Cervical spine, C2, Myelopathy, OPLL, Dome laminoplasty

cranial area is unavoidable because most of the SSC muscles are attached to C2 spinous process.⁵⁻¹¹ Therefore, many patients complain of neck pain after this conventional laminoplasty and also, decrease in the range of neck motion.^{12,13} Therefore, SSC insertion into the caudal half of C2 should be preserved to minimize axial pain and loss of lordosis. A technique for splitting laminoplasty of C2 has been developed to prevent these complications; however, splitting laminoplasty of C2 also increases the excursion of semispinalis, which results in muscle weakness.

To reduce these complains and to achieve effective direct decompression, we developed a new surgical technique - C2 double dome laminoplasty. The basic concept of this surgical method is that it can widen the spinal canal very appropriately by a posterior approach and preserve the SSC muscle in order to de-

crease axial neck pain and maintain the neck lordosis.

The purpose of this study is to evaluate the technical feasibility, efficiency, and safety of this surgical procedure.

MATERIALS AND METHODS

1. Study Population

This study was approved by the Institutional Review Board of Asan Medical Center (AMC 2020-1410). All cases were performed by a single operating surgeon and were studied retrospectively. Eleven cervical myelopathy patients (female:male, 5:6) who underwent C2 double dome laminoplasty between March 2016 and March 2018 at our institution were included. The including criteria were follows: (1) cervical myelopathy patients with symptoms such as gait disturbance, hand clumsiness, and so on; (2) those who underwent C2 double dome laminoplasty due to OPLL involving the C2 cranial area; and (3) 24 months or longer follow-up period. Excluding criteria are as follows: revision operation, infection patients, cervical spondylosis radiculopathy, and so on. The pre- and postoperative clinical neurologic status of all cases were measured by the Japanese Orthopaedic Association for cervical myelopathy (C-JOA) score, and the recovery rate, using the Hirabayashi method: (postoperative score–preoperative score) \times 100/(17–preoperative score). Axial neck pain was assessed according to the visual analogue scale (VAS). And all patients were checked radiographically

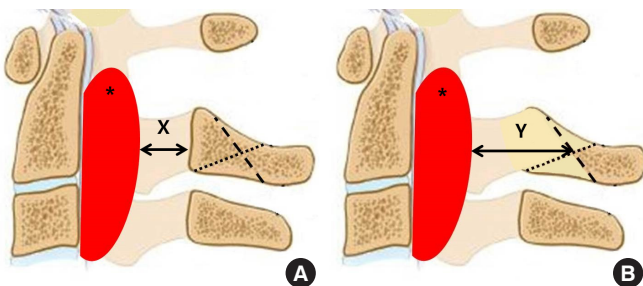


Fig. 1. Diagram of C2 double dome osteotomy. (A) There is the diffuse OPLL (black star) at C2 level, preoperatively. The 2 dotted lines indicate the part where osteotomy will be performed using high-speed burr. (B) This is the diagram after surgery with double dome osteotomy is performed, the enlarged spinal canal can be observed (Y). The spinal canal dimension of the midsagittal C2 vertebral body level (Y) and the spinal cord dimension (X) at the corresponding level were determined after the surgery. An increasing rate of SAC (%) was calculated as $(Y-X) \times 100/Y$. OPLL, ossification of the posterior longitudinal ligament; SAC, space available for spinal cord.

with cervical spine x-ray at 3 months, 6 months, 1 year, and 2 years after surgery. Computed tomography (CT) scan and magnetic resonance images were conducted for all patients at 1 and 2 years after operation.

Radiologic parameter of the C2–7 Cobb angle was measured by the angle between the lower end-plates of C2 and C7 in the cervical spine via a neutral lateral x-ray of the patient. Decompression was evaluated as an increase in space available for spinal cord (SAC) at the C2 level via a midsagittal CT scan. Preoperatively, the spinal canal dimension of the midsagittal C2 vertebral body level (Y) and the spinal cord dimension (X) at the corresponding level were determined after the surgery. An increasing rate of SAC (%) was calculated as $(Y-X) \times 100/Y$ (Fig. 1). Posterior cord shift (mm) was evaluated according to the average anterior cord space of the C2 level on a midsagittal magnetic resonance image. The distance of the posterior cord shift was measured as the distance from the posterior edge of the C2 OPLL to the posterior edge of the spinal cord. Initially was measured by magnetic resonance imaging before and approximately 1 year and 2 years after the surgery.

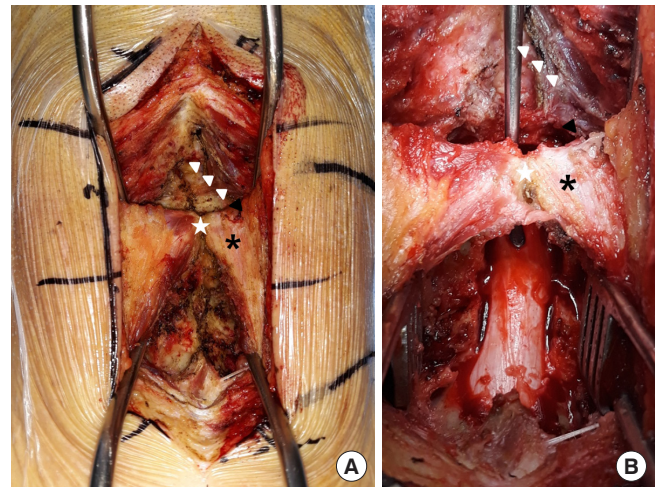


Fig. 2. These serial photos were taken during surgery through a microscope. In each medical photos, the top is the cranial side and the bottom is the caudal side. (A) And C2 spinous process indicates the white star. Through the posterior mid-line approach, the semispinalis cervicis (black star) insertion at the caudal half of the C2 lamina was minimally detached and the rectus capitis posterior major (white arrowheads) and obliques capitis inferior (black arrowhead) were partially detached from the cranial one-third of the C2 lamina. (B) For fenestrating tunnel which is made underneath the entire C2 lamina, we confirmed safely using by the penfield.

2. Surgical Technique

Patients were placed in the standard prone position. Through the posterior midline approach, the SSC insertion at the caudal half of the C2 lamina was minimally detached and conventional dome-like laminoplasty was performed first by using a high-speed burr. Then, the rectus capitis posterior major and obliques capitis inferior were partially detached from the cranial one-third of the C2 lamina, and another dome-like laminoplasty was performed downwards (Fig. 1). All procedures were performed safely under a microscope. After confirming that the fenestration tunnel was made underneath the entire C2 lamina, all the detached muscles were repaired meticulously (Fig. 2). And additionally, we provided meticulously repairing the muscles such as rectus capitis posterior major and obliques capitis inferior, located in the proximal portion of the C2 spinous process, which play an important role as the secondary stabilizer of neck and head extension for maintaining the muscles as much as possible and reducing neck pain. So, these muscles were performed tight and layer by layer sutures. And simultaneously, we tried to keep the anatomy of each muscle as much as possible around C2 area. Finally, we confirmed that the surgical site was well decompression through the 3-dimensional CT scan after operation (Fig. 3).

3. Statistical Analysis

Data management and statistical analyses were conducted using the Wilcoxon signed-rank test for continuous variables and discrete variables via the IBM SPSS ver. 18.0 (IBM Co., Ar-

monk, NY, USA). Significance was set at $p < 0.05$. The distributions of variables are presented as means and standard deviations.

RESULTS

The clinical and radiologic data of the 11 patients who underwent C2 double dome laminoplasty are listed in Table 1. For this study, we enrolled 5 women and 6 men with a mean age of

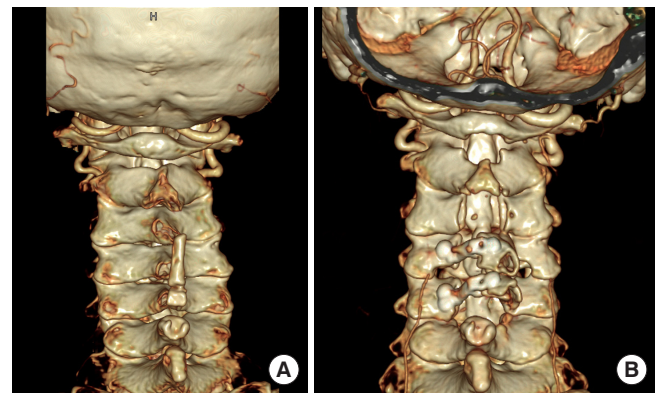


Fig. 3. Preoperative and postoperative 3-dimensional (3D) reconstruction computed tomography (CT) images. (A) This 3D CT image shows a well of the patient's bone structure, pre-operatively. (B) Postoperative 3D CT image which was taken postoperative 2 years shows definitely decompression at the C2 area through the double dome laminoplasty. And patient underwent the partial laminectomy of C3 and conventional laminoplasty of C4 and C5 for additional decompression.

Table 1. Clinical data and surgical outcomes of all patients

Age (yr)/ sex	F/U (mo)	Increasing rate of SAC (%)	Posterior cord shift (mm)	C-JOA score		VAS		C2-7 Lordosis*	
				Pre-OP	Post-OP	Pre-OP	Post-OP	Pre-OP	Post-OP
51/M	46	71.1	5.3	11	13	2	2	-8	-9
55/F	44	68.4	5.2	14	17	2	6	-10	-10
60/M	40	69.6	5.3	11	14	2	2	-11	-10
57/M	37	69.3	5.6	10	13	3	3	-11	-10
63/F	36	70.1	5.1	12	14	3	3	-13	-12
59/M	34	68.5	5.2	13	17	2	1	-11	-11
73/F	31	70.2	5.1	13	16	2	2	-15	-14
61/M	31	70.6	5.4	10	13	2	2	-12	-11
69/F	30	69.8	5.3	14	17	1	1	-14	-13
64/F	25	68.8	5.4	13	17	1	1	-9	-9
68/M	24	70.5	5.4	11	13	2	2	-13	-13

SAC, space available for cord; C-JOA, Japanese Orthopaedic Association for cervical myelopathy; VAS, visual analogue scale; F/U, follow-up; OP, operation.

*Negative means lordotic.

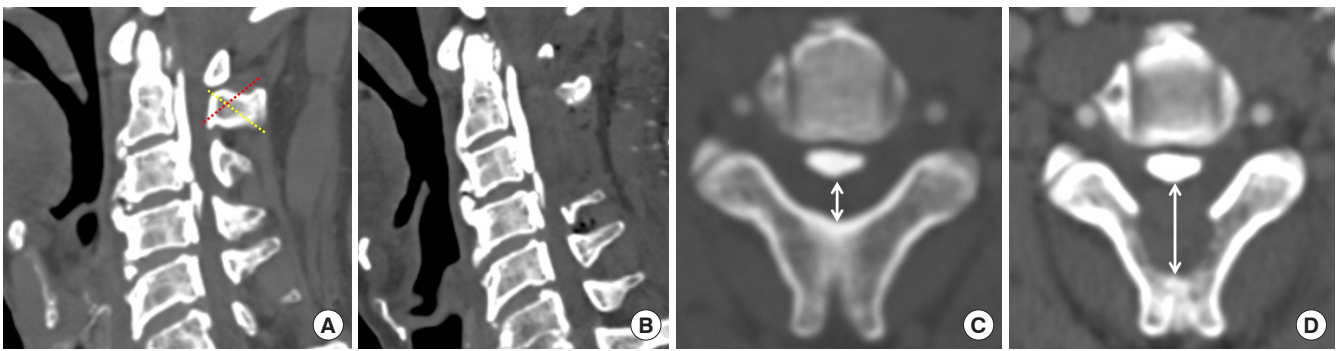


Fig. 4. Preoperative and postoperative sagittal/axial computed tomography (CT) images. (A, C) Preoperative image demonstrates severe spinal canal stenosis due to huge OPLL at C2 level. And red dotted line represents cranial cutting line, also yellow dotted line represents caudal cutting line. (B, D) This CT image which was taken postoperative 2 years shows definitely decompression at the same area. Spinal canal diameter indicates the white line with both arrows. OPLL, ossification of the posterior longitudinal ligament.

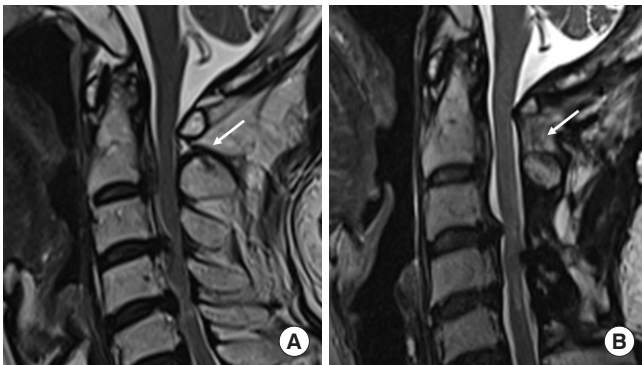


Fig. 5. Magnetic resonance sagittal image before and after surgery. (A) The preoperative magnetic resonance image shows that the spinal cord is severely compressed due to C2 OPLL (white arrow). (B) This magnetic resonance image was taken postoperative 2 years. In this image, C2 double dome osteotomy was performed, resulting in sufficient decompression of the spinal canal at the same level (white arrow). OPLL, ossification of the posterior longitudinal ligament.

61.3 ± 6.5 years. The average follow-up period was 34.3 ± 7.1 months.

The mean C-JOA score improved from 12.0 ± 1.4 preoperatively to 14.9 ± 1.9 at the final follow-up ($p = 0.015$). The mean recovery rate of the C-JOA score at the final follow-up was $58.0\% \pm 10.8\%$, and there was no neurologic deficit in all cases after the surgery. The axial neck pain VAS scores did not significantly differ before and after the operation. Only one patient reported persistent axial neck pain (VAS score of 6) at the final follow-up.

As an indicator of C2 decompression, the mean SAC improved from 6.7 ± 1.3 mm preoperatively to 15.2 ± 2.4 mm at the final follow-up ($p < 0.001$). The mean increase in SAC at the C2 level

was 69.7% (Fig. 4). Furthermore, the average posterior cord shift statistically improved from 3.3 ± 1.1 mm preoperatively to 8.7 ± 1.2 mm at the final follow-up ($p < 0.001$). The average posterior cord shift was 5.3 ± 0.2 mm (Fig. 5). Neck alignment was well-maintained in all cases after the operation.

No specific complications, such as C2 laminar fracture or insufficient decompression, were observed. Furthermore, no perioperative complications were observed.

DISCUSSION

Cervical spine laminoplasty surgery is accepted as a safe and effective surgery for cervical myelopathy patients.^{14,15} However, the following complications - decreased range of motion, loss of cervical spine lordotic angle, and the axial neck pain that occur after laminoplasty surgery have often been a problem.¹⁶⁻¹⁸ Interlaminar fusion and radiologic change have been reported after surgery.^{18,19} And in particular, neck pain is often complained of due to disruption of the posterior neck deep muscle including the SSC.^{20,21} In particular, SSC is attached to C2 spinous process and acts as a dynamic stabilizer.²² And this muscle acts as the most powerful extensor in the cervical spine.^{23,24} However, in order to perform surgery using the conventional laminoplasty technique such as C2 laminoplasty or multilevel laminoplasty including C3, at least some of the SSC attached to C2 spinous process has to be removed. Of course, we would suture the SSC to the C2 spinous process again after surgery, but it might be difficult to restore it to the original state before surgery. Iizuka et al.²³ researched the condition of the SSC muscle using magnetic resonance image after conventional laminoplasty and reported that only approximately 18% of the SSC is

maintained after surgery even if we tight repair the SSC muscle to the C2 spinous process. Therefore, many methods have been introduced to effectively decompress cervical spine without damaging not only the SSC but also the multifidus muscles.^{20,25,26}

Above mentioned, to overcome several complications of conventional laminoplasty and decompress the spinal cord of cervical spine, we developed a new and safe method for C2 area – C2 Double dome laminoplasty. Lee et al.²⁷ show that emergency reoperation was needed in patients that underwent the incomplete C2 dome shape one directional decompression surgery. However, in this study, we confirmed that cord compression of the C2 area by OPLL was effectively decompressed by double dome laminoplasty. The improvement of SAC and posterior cord shift were statistically significant compared with that before and after the surgery. The mean SAC improved from 6.7 ± 1.3 mm to 15.2 ± 2.4 mm at the final follow-up ($p < 0.001$). The average increasing SAC value at C2 was 69.7%. Furthermore, the average posterior cord shift significantly improved from 3.3 ± 1.1 mm to 8.7 ± 1.2 mm at the final follow-up ($p < 0.001$), and the average posterior cord shift was 5.3 ± 0.2 mm.

The changes were also related to clinical outcome, as demonstrated by the significant improvements in C-JOA scores (from 12.0 ± 1.4 to 14.9 ± 1.9 ; mean recovery rate, $58.0\% \pm 10.8\%$). A high C-JOA score means that the quality of life and function are improved, and appropriate decompression surgery is correlated with a high C-JOA score.²⁸ Therefore, C2 double dome laminoplasty can be considered as an effective technique for decompression of the C2 area.

The most important concept of this technique is to reduce axial neck pain after surgery by taking an approach without damaging the SSC muscle. In particular, SSC of the posterior cervical muscle acts as a dynamic stabilizer, and the most powerful extensor in the cervical spine so maintain the neck alignment and lordotic angle.^{29,30} Anatomically, the SSC originates from the upper thoracic transverse process and inserts to C2 spinous process. So that tis the main part among the posterior cervical spine muscles. Vasavada et al.³¹ reported that SSC provides powerful extension moment-generating quantity. Therefore, we performed a tight suture in order to completely restore the SSC after laminoplasty surgery. However, if the SSC cannot return as completely as it was before surgery, then we should avoid damaging it as much as possible. Thus, the preservation of SSC muscles is associated with a reduction in axial neck pain, which prevents deterioration in the patient's quality of life due to postoperative neck pain. In addition, we provided meticu-

lously repairing the muscles such as rectus capitis posterior major and obliques capitis inferior, located in the proximal portion of the C2 spinous process, which play an important role as the secondary stabilizer of neck and head extension for maintaining the muscles as much as possible and reducing neck pain.

Qi et al.²⁸ demonstrated that the group that underwent cervical deep muscle preserving laminoplasty showed better results in cervical spine function than the group that received conventional laminoplasty. Another study reported that among these extensor muscles, SSC, in particular, acts as a key muscle in maintaining neck function and neck alignment.³² This effort to preserve the cervical deep extensor muscle preserves blood flow to that muscle and maintains the muscle volume, so prevents atrophy of the theses muscle as well as surrounding ligaments contracture. And this procedure would make decrease the patient's complications and increase the function of the neck. And the patient's quick recovery can be expected even after muscle preserving laminoplasty technique. And therefore, the recovery of muscle control is promoted.²⁸ Furthermore, in this study, there was almost no difference in neck pain before and after surgery, and cervical lordosis was well-maintained. However, in one case, the patient experienced an increase in neck pain at the final follow-up, which may have been due to the additional detachment of the SSC during the initial steps of this technique.

C2 double dome laminoplasty is a safe and useful technique for patients with cervical myelopathy due to C2 OPLL. However, the surgeon should check whether there is any anatomical variation in the surrounding the structure when performing this operation. Therefore, we recommend that you check the surgical site through CT scan and magnetic resonance image before surgery.

CONCLUSION

We recommend double dome laminoplasty for treating patients with cervical myelopathy, especially involving the C2 area. And we believe that this surgical technique can not only avoid C2 laminectomy, but also decrease the neck pain and maintain the cervical alignment, which surgeon wanted to overcome in the conventional laminoplasty. Furthermore, this new technique is a safe and effective way to decompress the spinal canal in the cervical area. Double dome laminoplasty might be a widely used method without complications for C2 decompression surgery.

CONFLICT OF INTEREST

The authors have nothing to disclose.

SUPPLEMENTARY MATERIAL

Supplementary video clip can be found via <https://doi.org/10.14245/ns.2143028.514>.

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Editorial

Double Dome Laminoplasty: Works Well but There Are Exceptions




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The authors describe a novel technique for decompressing the C2 region without performing a C2 laminectomy or laminoplasty.¹ In 11 consecutive ossification of the posterior longitudinal ligament (OPLL) cases causing cord compression and myelopathy at C2, the authors performed a double dome laminoplasty. The rationale behind the procedure is to leave the dorsal cortex of the C2 spinous process and lamina intact, since the major extensor muscle of the neck, the semispinalis cervicis, inserts there. The authors noted improved Japanese Orthopaedic Association scores in all 11 patients, suggesting that myelopathy improved in all 11 patients.

This is yet another innovative technique to treat OPLL from the inventive mind of Professor Dong Ho Lee, who also invented the vertebral body sliding osteotomy technique for OPLL.² For the patient who has OPLL extending cranially behind the C2 body, I agree that there are substantial advantages to this technique over the alternatives. I too have independently thought of and utilized this technique several times over the past 20 years but not to the extent that Professor Lee has. There are 2 reasons that I have not used this as frequently as he has. First, the prevalence of OPLL is less common in the United States than in Korea. Second, I have switched to fusing most patients who have extensive OPLL that extend behind C2. The rationale for this is that fusion is known to slow the growth of OPLL. If a patient has extensive OPLL such that a double dome laminoplasty can only give a few millimeters of extra room, and the patient's life expectancy is more than 1–2 decades, I am concerned that further growth of the OPLL is likely to occur. The problem then is that the patient could be elderly and there are few treatment options other than a C2 total laminectomy (with resultant loss of the semispinalis insertion point). That could potentially result in cervical kyphosis. The elderly often have thoracic hyperkyphosis and compensate with increased cervical lordosis. So, losing that compensatory mechanism can result in a dropped head syndrome. In the case that is illustrated in this paper, the postoperative magnetic resonance imaging shows an adequate decompression. However, let's assume that this patient is 40 years old. If one assumes that the OPLL started growing when the patient reached age 20, then it is not unreasonable to assume that the OPLL could double in size by the time the patient reaches age 60 and triple by age 80. If that occurs and there is recurrent cord compression with myelopathy, the treatment might necessitate a total C2 corpectomy with a combined transoral and upper cervical approach, followed by posterior occipitocervical fusion. Doing that on an elderly patient, with possibly an ossified dura, is not likely to be easy. For this reason, I prefer to use this technique for patients who are already elderly or

have demonstrated slow growing OPLL that is not likely to progress to cause recurrent cord compression and myelopathy in the patient's remaining lifetime.

CONFLICT OF INTEREST

The author has nothing to disclose.

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INTRODUCTION

Infectious spondylodiskitis presents as severe infection that may lead to disability and death,¹ and is the third most common form of osteomyelitis in persons aged over 50 years.² Sometimes it presents as a postoperative complication, or as severe endplate destruction or massive paraspinous abscess in patients who have

Percutaneous Endoscopic Interbody Debridement and Fusion for Pyogenic Lumbar Spondylodiskitis: Surgical Technique and the Comparison With Percutaneous Endoscopic Drainage and Debridement

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Objective: Surgical treatment of severe infectious spondylodiskitis remains challenging. Although minimally invasive percutaneous endoscopic drainage and debridement (PEDD) may yield good results in complicated cases, outcomes of patients with extensive structural damage and mechanical instability may be unsatisfactory. To address severe infectious spondylodiskitis, we have developed a surgical technique called percutaneous endoscopic interbody debridement and fusion (PEIDF), which comprises endoscopic debridement, bone-graft interbody fusion, and percutaneous posterior instrumentation.

Methods: Outcomes of PEIDF in 12 patients and PEDD in 15 patients with infectious spondylodiskitis from April 2014 to July 2018 were reviewed retrospectively. Outcome were compared between 2 kinds of surgical procedures.

Results: Patients in PEIDF group had significantly lower rate of revision surgery (8.3% vs. 58.3%), better kyphosis angle ($-5.73^\circ \pm 8.74$ vs. $1.07^\circ \pm 2.70$ in postoperative; $7.09^\circ \pm 7.23$ vs. $0.79^\circ \pm 4.08$ in kyphosis correction at 1 year), and higher fusion rate (83.3% vs. 46.7%) than those who received PEDD.

Conclusion: PEIDF is an effective approach for treating infectious spondylodiskitis, especially in patients with spinal instability and multiple medical comorbidities.

Keywords: Infectious spondylodiskitis, Kyphosis, Percutaneous endoscopic debridement, Spine instability

not undergone previous spine surgery.³⁻⁵ Patients with identified pathogen treated with appropriate antibiotics are effective.¹ However, surgical treatment is indicated when patients are unresponsive to antibiotics, have progressive spinal deformity or instability, and when acute neurological impairment occurs.⁶

Because the focus of infection is at the anterior column of vertebrae, direct and radical surgical debridement direct to anterior

or infectious foci is considered as the effective surgical treatment.³ Percutaneous endoscopic drainage and debridement (PEDD) was the first endoscopic procedure developed to treat infectious spondylodiskitis and it reportedly provides effective infection control, except in the presence of extensive infection and structural instability.⁷⁻¹⁰ However, anterior instrumentation may be tenuous because the concomitant osteoporosis associated with infection renders the vertebrae structurally weak and may prevent adequate fixation.^{11,12} Stable posterior fixation is considered a major factor for successful infection control and satisfactory outcomes.^{13,14} Particularly, patients with advanced infectious spondylodiskitis leading to mechanical instability should still receive anterior debridement and stable fixation with autograft interbody fusion surgery.⁹ A combined anterior open surgery plus posterior instrumentation helps to overcome stability-related drawback of anterior approach alone.^{4,15} By contrast, it entails 2 surgeries with additional morbidity.^{16,17}

To address the complex issues of patients with infectious spondylodiskitis and to ultimately provide more effective treatment, the surgical technique, percutaneous endoscopic interbody debridement and fusion (PEIDF), was developed. The procedure comprises endoscopic debridement, bone-graft interbody fusion and posterior instrumentation. We evaluated the efficacy of the PEIDF technique in treating patients with infectious spondylodiskitis and compared them with those receiving PEDD. The hypothesis of this work is the efficiency of PEIDF would be at least equal or even better than PEDD, especially in the reoperation rate and kyphosis correction.

MATERIALS AND METHODS

1. Patients

Patients with infectious lumbar spondylodiskitis who received either PEIDF or PEDD at our hospital from April 2014 to July 2018 were recruited. They were selected to undergo PEIDF or PEDD due to poor overall health status with severe comorbidities for whom open surgeries were considered to be relatively contraindicated by orthopedic surgeons and infectious disease specialists. Infectious spondylodiskitis was diagnosed based on clinical symptoms, elevated inflammatory markers, and imaging results. Patients enrolled in our study were all transferred from Department of Internal Medicine at our institute, a 3,700-bed tertiary referral center. In our clinical practice, empirical antibiotics were started since initial diagnosis of infectious spondylodiskitis. Most patients suffered from 2 to 4 weeks of medical treatment course without clinical improvement, and all of

them presented with intractable back pain and required narcotics for pain control preoperatively. PEIDF and PEDD were performed by 2 separate spine surgeons and the type of procedures was decided by the patient's preference after thorough preoperative discussion and explanation. Surgical indications were infectious lumbar spondylodiskitis with intractable back pain, unknown pathogen, and poor response to medical treatment. Exclusion criteria were follow-up of less than one year, fungal or mycobacterial infection, neurologic deficits, multilevel spine infection, and complications from previous spine surgeries. In addition, patients with critically unstable status compromising the basic cardiac and pulmonary function were excluded, including recent ischemic heart disease with percutaneous coronary intervention, severe cardiac valvular disease, congestive heart failure, pulmonary hypertension, acute exacerbation of chronic obstructive pulmonary disease, and recent stroke. This study was approved by the Institutional Review Board (IRB) of Chang Gung Medical Foundation (IRB No. 201801219B0) and waived the requirement for informed consent due to the retrospective nature of the study.

Intravenous antibiotics were administered immediately after surgeries based on the culture reports and suggestions from the infectious disease specialists for 3–4 weeks according to the improvement of inflammatory markers, and then followed by oral antibiotics until at least 3 months of total antibiotic therapy (intravenous and oral antibiotics). All patients were encouraged to wear a brace while ambulating for at least 3 months, and they were under outpatient followed-up postoperatively at 3, 6 months, and then annually.

2. Surgical Procedure of PEIDF

Patients undergoing PEIDF were positioned prone with general anesthesia on a radiolucent table and intraoperative neuro-monitor was used to prevent nerve roots injury. After sterile preparation, the spinal needle was inserted directly into the target infected disc from the posterolateral side of the waist under the guidance of fluoroscopy. A guidewire was introduced through the spinal needle, and the needle was subsequently withdrawn. Dilators followed to create a larger space for the insertion of a working sleeve. Once the working portal was established and confirmed by fluoroscopy, necrotic tissue from the infected disc space was obtained for culture prior to any normal saline irrigation. Debridement of the infected disc was performed using grasping forceps, Kerrison punches, and endoscopic scissors. Multidirectional debridement was performed by adjusting the direction and depth of the working sleeve (Fig. 1). Disc space

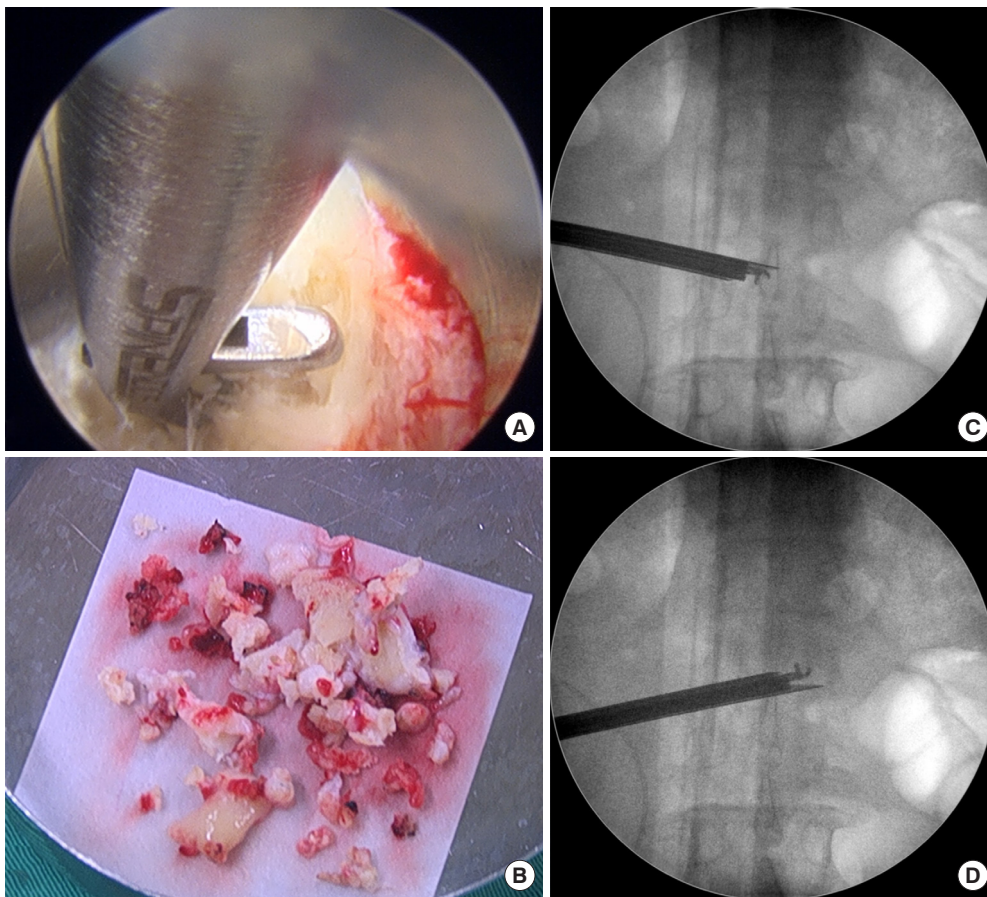


Fig. 1. (A) Discectomy and debridement of the infected disc were performed using grasping forceps, Kerrison punches, and endoscopic scissors under fluoroscopic guidance. (B) Necrotic tissues from the infected disc space were sent for histopathological and microbiological studies. (C, D) Multidirectional debridement was performed by adjusting the direction and the depth of the working portal.

reconstruction and intervertebral fusion were performed after radical debridement of infected disc foci and more than 1,000-mL normal saline irrigation. We filled up the hollow intervertebral space defect with morselized femoral-head-bone allograft. The allograft bone chips were placed into the disc space through the working sleeve, which was then compressed with an endoscopic impactor to increase the density of the allograft (Fig. 2). Posterior percutaneous screws insertion at 1 level above and below was performed under the guidance of fluoroscopy to avoid back muscle dissection and soft tissue injury (Fig. 3). Posterior instrumentation provides posterior support, and anterior bone grafting provides anterior column stability and interbody fusion. The combination provides a 3-dimensional stable construct for infection control and bone fusion. The comparison between PEIDF and PEDD procedures were shown in Table 1.

3. Surgical Procedure of PEDD

Like PEIDF, patients receiving PEDD were under a prone position via a posterolateral percutaneous approach. PEDD was performed under local or intravenous general anesthesia. After sterile preparation, the spinal needle was inserted directly into the target infected disc under the guidance of fluoroscopy. A guidewire was introduced through the spinal needle, and the needle was subsequently withdrawn. Dilators followed to create a larger space for the insertion of a working sleeve. Once the working portal was established and confirmed by fluoroscopy, necrotic tissue from the infected disc space was obtained for culture prior to any interference, including normal saline irrigation. Debridement of the infected disc was performed using grasping forceps, Kerrison punches, and endoscopic scissors. Multidirectional debridement was performed by adjusting the direction and depth of the working sleeve into the intervertebral space. The surgical endpoint was defined when all necrotic

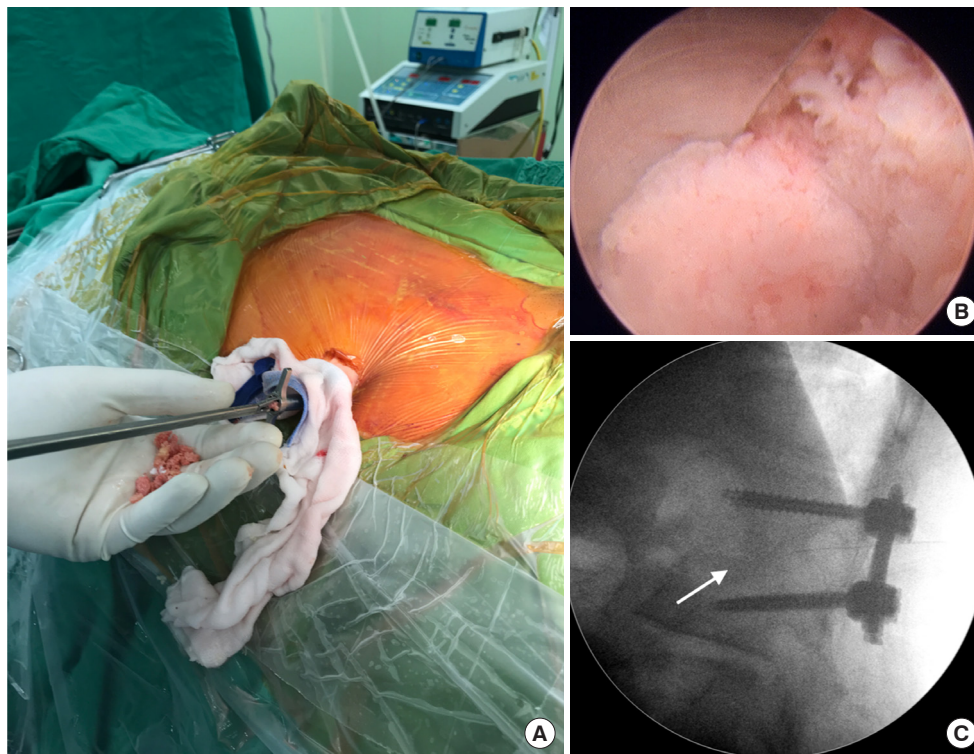


Fig. 2. (A, B) Morselized bone graft was put into the disc space defect through the working portal, and was then compressed with an endoscopic impactor to make it denser. (C) Fluoroscopy image of impacted morselized bone graft in the disc space (white arrow).

tissues were removed with healthy cancellous bone bleeding seen. After radical debridement, more than 1,000-mL normal saline irrigation was performed to decrease the bacteria loading and wash out necrotic debris as much as possible. Finally, a drainage catheter connecting with a negative-pressure Hemovac was inserted into the infectious intervertebral space through the working sleeve.

4. Clinical Evaluation

Data collected and analyzed from all patients included demographic data, clinical images, laboratory data, and culture reports. Preoperative magnetic resonance imaging was assessed for diagnosis, and plain radiographs of the lumbar spine before surgery, after surgery, and at follow-up were assessed for kyphosis correction. The segmental kyphosis angle of the lesion sites was measured using the superior endplate of the infected vertebral body above and inferior endplate of the infected vertebra below as reference points. Computed tomography (CT) was obtained one year after surgery to examine fusion status. Each intraoperative specimen was submitted immediately and was examined for microorganisms. Bone-graft fusion status was classified by Eck fusion criteria.¹⁸ The functional outcomes be-

tween 2 groups were investigated with visual analogue scale (VAS) to assess lower back pain and Oswestry Disability Index (ODI) to evaluate the level of disability. The VAS evaluations were done at preoperation, postoperation (1 week after surgery), and postoperative 3-month follow-up. And the ODI was assessed at preoperation and postoperative 3-month follow-up. We excluded the patients who died or received reoperations to truly evaluate the functional outcomes between the 2 procedures.

5. Statistical Analysis

All statistical calculations were performed using IBM SPSS Statistics ver. 22.0 (IBM Co., Armonk, NY, USA). Quantitative variables are expressed as mean \pm standard deviation. Changes in variables at different time points were examined using the t-test, Mann-Whitney U-test for continuous variables, and Fisher exact test for categorical variables. The threshold for statistical significance was set at $p < 0.05$.

RESULTS

Twelve patients underwent PEIDF and 15 received PEDD

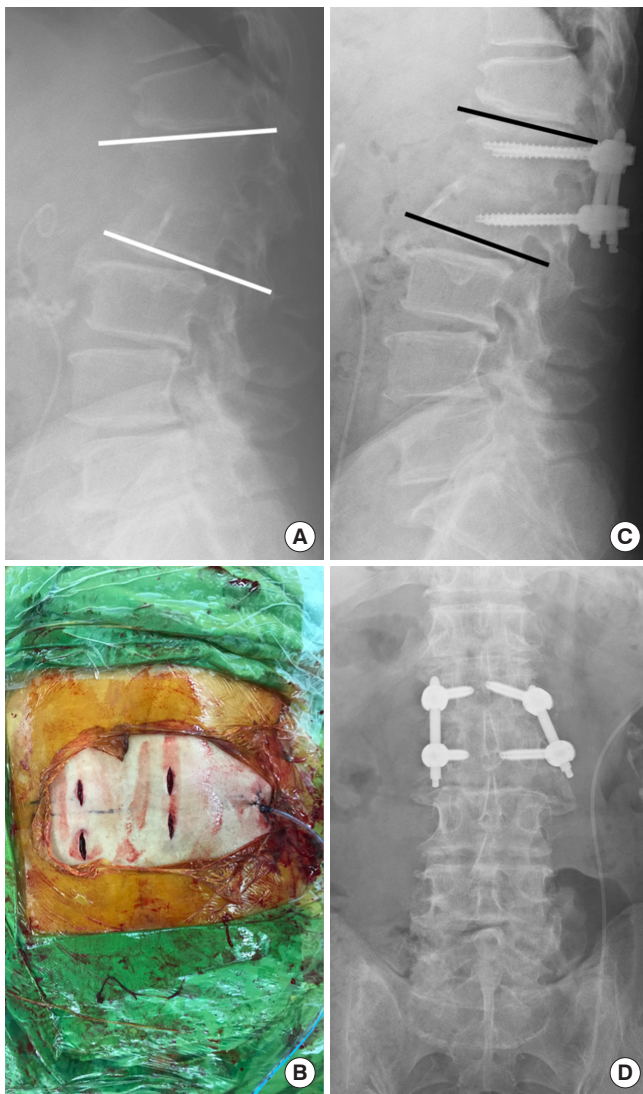


Fig. 3. (A) Preoperative lumbar spine lateral plain film revealed L1–2 discs destruction and endplate erosion with local kyphosis (white lines). (B) Posterior percutaneous pedicle screw insertion at 1 level above and below the index level. Percutaneous insertion avoided back muscle dissection and soft tissue injury, and only required 4 small skin incisions. (C, D) Postoperative lumbar plain films showed that kyphosis correction was maintained (black lines) by anterior defect reconstruction and posterior percutaneous instrumentation.

during the period from April 2014 to July 2018. The mean age of patients in PEIDF group was 68.17 ± 14.56 with 7 males and 5 females; PEDD group had the mean age, 63.07 ± 14.95 , comprised of 12 males and 3 females. The most common infectious levels were L3–4 and L4–5 in all patients. Demographic data of the 2 groups were summarized in Table 2 and there was no statistical significance in age, sex, infectious level, and comorbidity between the 2 groups.

Table 1. The comparison of surgical procedures between PEIDF and PEDD

Characteristic	PEIDF	PEDD
Position	Prone	Prone
Anesthesia	General	Local or intravenous
Approach	Posterolateral percutaneous	Posterolateral percutaneous
Debridement & discectomy	Via percutaneous endoscopy	Via percutaneous endoscopy
Intraoperative culture	Via percutaneous endoscopy	Via percutaneous endoscopy
Irrigation	Via percutaneous endoscopy	Via percutaneous endoscopy
Interbody fusion	Allograft, via endoscopic sheath	None
Fixation	Percutaneous pedicle screw	Postop brace

PEIDF, percutaneous endoscopic interbody debridement and fusion; PEDD, percutaneous endoscopic drainage and debridement.

Two patients in PEIDF group did not have satisfactory outcome. One patient experienced a recurrent spine infection with septic nonunion and adjacent level spondylodiskitis. The patient was seen in the outpatient clinic at 2 months after discharge and readmitted due to elevated C-reactive protein (CRP) level and obvious posterior pedicle screws loosening. Six weeks of intravenous antibiotics did not control the recurrent spine infection, and she received the anterior open surgery. The other patient had the preoperative traumatic subdural hemorrhage. This patient had an excellent CRP level decrease at 1 and 3 weeks after surgery, and intraoperative tissue culture showed *Staphylococcus aureus* infection. However, this patient experienced a sudden onset subarachnoid hemorrhage in the intensive care unit at 1 month postoperatively. Compared with PEIDF group, there were 2 patients in PEDD group underwent revision surgeries for further debridement and posterior instrumentation within postoperative 3 months because of unrelieved back pain and infection control. Five patients in PEDD group suffered from residual back pain and soreness and then received fusion surgeries within postoperative 1 year. One PEDD patient's clinical outcome was complicated by septic shock and he expired during hemodialysis after 2 weeks of PEDD.

1. Clinical and Functional Results

Both groups reported immediate back pain relief postoperatively, and CRP improvement was obvious at postoperative 1 and 3 weeks. Although the infection control was similarly effective

Table 2. Demographic and clinical data of patients who received PEIDF and PEDD

Variable	PEIDF (n = 12)	PEDD (n = 15)	p-value
Age (yr)	68.17 ± 14.56	63.07 ± 14.95	0.583
Sex, female:male	5:7	3:12	0.221
Infected level			0.281
L1–2	2 (16.7)	1 (6.7)	
L2–3	3 (25)	1 (6.7)	
L3–4	5 (41.7)	4 (26.7)	
L4–5	2 (16.7)	7 (46.7)	
L5–S1	0 (0)	2 (13.3)	
Comorbidity			
Malignant history	2 (16.7)	3 (20)	0.825
Liver cirrhosis	5 (41.7)	3 (20)	0.221
ESRD	2 (16.7)	2 (13.3)	0.809
DM	4 (33.3)	4 (26.7)	0.706
CAD, heart failure	4 (33.3)	4 (26.7)	0.706
Clinical data			
Preoperative CRP (mg/L)	135 ± 84.86	122 ± 64.9	0.095
Preoperative 1 week CRP (mg/L)	35.55 ± 28.34	43 ± 24.08	0.706
Preoperative 3 weeks CRP (mg/L)	16.09 ± 17.23	23.43 ± 11.69	0.455
CRP improvement at 3 weeks	89%	77%	0.143
Surgical blood loss (mL)	< 50	< 50	
Surgical time (min)	114.27 ± 38.84	71.93 ± 22.22	0.047*
Shift to open surgery	1 (8.3)	7 (58.3)	0.030*
Expired	1 (8.3)	1 (6.7)	0.869
Functional outcome			
Preoperative VAS	6.91 ± 1.14	7.00 ± 1.07	0.836
Postoperative VAS, 1 week	2.36 ± 0.92	2.13 ± 0.92	0.534
Postoperative VAS, 3 months	1.36 ± 0.50	1.80 ± 0.68	0.084
Preoperative ODI	70.46 ± 7.90	70.67 ± 8.77	0.95
Postoperative ODI, 3 months	26.18 ± 4.58	28.07 ± 8.46	0.51

Values are presented as mean ± standard deviation or number (%).

PEIDF, percutaneous endoscopic interbody debridement and fusion; PEDD, percutaneous endoscopic drainage and debridement; ESRD, end-stage renal disease; DM, diabetes mellitus; CAD, coronary artery disease; CRP, C-reactive protein; VAS, visual analogue scale; ODI, Oswestry Disability Index.

* $p < 0.05$, statistical significance.

tive between PEIDF and PEDD group, there were 7 patients in PEDD group undergoing revised open fusion surgeries due to persistent back pain and residual infection within postoperative 1 year, significantly more than that in PEIDF group ($p = 0.030$) (Table 2). The surgical time of PEIDF group was significantly longer than that of PEDD group ($p = 0.047$), but the surgical blood loss was both minimal, less than 50 mL because all procedures in PEIDF and PEDD were minimally invasive. The functional outcomes were assessed by VAS (preoperative, post-

operative 1 week and 3 months) and ODI (preoperative and postoperative 3 months). We excluded 2 patients from PEIDF group and 8 from PEDD group because of either death or reoperation. Between PEIDF and PEDD patients without death and reoperation, 2 procedures had the same postoperative back pain relief and functional recovery (Table 2). There was no surgery-related major complication. However, 2 patients in PEIDF group (2 of 12, 16.7%) and 1 in PEDD group (1 of 15, 6.7%) complained about transient leg paresthesia. The symptoms were mild and

Table 3. Culture reports and radiographic outcomes

Variable	PEIDF (n = 12)	PEDD (n = 15)	p-value
Partial or solid fusion	10 (83.3)	7 (46.7)	0.050
Segmental kyphosis angle			
Preoperative	4.00 ± 11.39	3.21 ± 5.54	0.065
Postoperative	-5.73 ± 8.74	1.07 ± 2.70	0.004*
Postoperative 1 year	-3.30 ± 8.25	2.33 ± 4.93	0.089
Kyphosis correction at 1 year	7.09 ± 7.23	0.79 ± 4.08	0.049*
Culture rate	10 (83.3)	12 (80.0)	0.825
Methicillin-resistant <i>Staphylococcus aureus</i>	3	3	
Methicillin-sensitive <i>Staphylococcus aureus</i>	2	3	
<i>Escherichia coli</i>	1	2	
<i>Streptococcus</i> spp.	2	2	
<i>Klebsiella pneumoniae</i>	1	1	
<i>Enterococcus</i> spp.	0	1	
<i>Pseudomonas aeruginosa</i>	1	1	
No growth	2	3	

Values are presented as number (%) or mean ± standard deviation. PEIDF, percutaneous endoscopic interbody debridement and fusion; PEDD, percutaneous endoscopic drainage and debridement.

Kyphosis angle: kyphosis +, lordosis -.

*p < 0.05, statistical significance.

disappeared within 1 month.

2. Pathogens and Radiographic Outcomes

Causative bacteria were successfully identified in 10 patients of PEIDF group (the culture-positive rate, 83.3%) and 12 of PEDD group (80%) (Table 3). There was no significant difference about the culture-positive rate between the 2 groups (p = 0.825). Among those 22 patients, *S. aureus* was the predominant pathogen and 11 patients (6 methicillin-resistant and 5 methicillin-sensitive) were infected with it. The other causative microorganisms included *Escherichia coli* (3), *Streptococcus* spp. (4), *Klebsiella pneumoniae* (2), *Enterococcus* spp. (1), and *Pseudomonas aeruginosa* (2).

In follow-up radiographs, bone-graft interbody fusion of the infected segments was successful in most patients of PEIDF group, with the fusion rate was 83.3%. CT at postoperative one year showed, 7 had partial fusion (Fig. 4) and 3 solid fusion (Fig. 5). In PEIDF group, only 2 patients had no radiographic evidence of partial or solid fusion. One underwent anterior debridement and reconstruction with a struct allograft due to pseudoarthrosis, and the other died during hospitalization at 1

month postoperatively. Intraoperative interbody fusion with disc height restoration by allograft and posterior instrumentation of PEIDF supported the patients to get better postoperative segmental kyphosis angle (-5.73 ± 8.74 in PEIDF vs. 1.07 ± 2.70 in PEDD, p = 0.004) (Table 3) and kyphosis angle correction at postoperative 1 year (7.09 ± 7.23 in PEIDF vs. 0.79 ± 4.08 in PEDD, p = 0.049).

DISCUSSION

Our study is the first one to investigate the efficiency of 2 kinds of endoscopic procedures to treat infectious spondylodiskitis. PEIDF was developed under the basis of PEDD with bone-graft interbody fusion and percutaneous posterior instrumentation to enhance infection control, kyphosis correction, and spinal stability. According to our preliminary results, PEIDF had many similar advantages as PEDD in minimally invasion, well infection control, high pathogen identification rate, and back pain relief. Furthermore, PEIDF performed better kyphosis correction, less reoperation rate, and higher fusion rate than PEDD. Mechanical instability and kyphosis caused by vertebrae destruction of infectious spondylodiskitis would be solved by intervertebral bone grafting and percutaneous posterior instrumentation in PEIDF. In our point of view, PEIDF could be widely applied in treating infectious spondylodiskitis of patients without neurologic deficits.

For infectious spondylodiskitis, conservative treatment with pathogen-sensitive antibiotics is adequate for most patients. However, there is a high rate of treatment failure for nonsurgical methods if the pathogen is not detected at an early stage. Rezai et al.¹⁹ reported that 25% of patients initially treated medically would eventually need surgical treatment. Common surgical indications for infectious spondylodiskitis include failed antibiotic therapy, intractable back pain, neurological deficits, epidural abscesses, extensive spine instability, and kyphotic deformity. In cases with severe spine instability or deformity, anterior debridement and reconstruction with or without posterior instrumentation is considered the mainstream surgical treatment, and results in satisfactory outcomes. Nonetheless, open anterior debridement surgery is associated with a high complication and mortality rate.²⁰ Many patients with infectious spondylodiskitis are immunocompromised patients with multiple comorbidities, which make them poor candidates for open anterior surgeries. Prior studies have shown that the 1-stage posterior transforaminal approach with posterior instrumentation for infectious thoracic and lumbar spondylodiskitis can reduce



Fig. 4. A 55-year-old man with L1–2 infectious spondylodiskitis (*Escherichia coli*) underwent percutaneous endoscopic interbody debridement and fusion treatment. (A) Preoperative magnetic resonance imaging revealed L1–2 infectious spondylodiskitis with severe disc destruction and large bony defect. (B) Postoperative radiography showed kyphosis correction fixed with posterior instrumentation and bony defect reconstruction filled up with cancellous allograft bone chips. (C) Bony bridges were found at plain films at postoperative 1 year and (D) only mild defect was noted without fusion in computed tomography scan.

the rate of complications in open anterior surgeries and is associated with decreased blood loss, a good fusion rate, a satisfactory culture rate, and early postoperative ambulation with better functional outcomes.^{13,21} Nevertheless, there are still concerns with the 1-stage posterior procedure such as infectious contamination from anterior infectious foci to posterior virgin site, less visibility of the infected disc, posterior ligamentous complex injury, and the risks associated with manipulation of the spinal cord.

Some minimally invasive methods for treating spine infections have been described by other authors. CT-guided drain-

age had long been an alternative treatment for patients whose pathogen was not identified or who failed medical treatment.^{22–24} As an extension of percutaneous abscess drainage, first PEDD was described by Yang et al.²⁵ in 2007. The procedure yielded a high rate of pathogen identification and infection control using only 1 or 2 small incisions. Subsequently, many similar methods were then described including different endoscope approaches, bilateral portal use, and irrigation with diluted beta iodine solution.^{9,26,27} The indications of PEDD were also extended to treat some cases of complicated infectious spondylodiskitis. According to Yang et al.⁹ patients with large paraspinal abscess-



Fig. 5. A 58-year-old woman had liver cirrhosis and renal function impairment. (A) She suffered from L3–4 *Staphylococcus caprae* spondylodiskitis with severe back pain and massive paraspinal abscess. (B) After percutaneous endoscopic interbody debridement and fusion treatment, she got back pain relief and postoperative radiography showed disc defect filled up with allograft bone chips for interbody fusion. (C) Solid bony bridge and interbody fusion were obvious in radiography after postoperative 1 year, (D) especially in 3-dimensional computed tomography scans.

es or postoperative recurrent infection could be treated by PEDD. However, in the same study, they reported failure of PEDD in patients with severe endplate destruction and spinal instability. The authors suggested that debridement alone could not address mechanical problems, and mechanical instability of spine was one of the main reasons for revision surgeries. In our study, we did not exclude the patients with spinal instability, severe local kyphosis, and extensive bony defects preoperatively. Although, most of patients in PEDD group got immediate relief of back pain and infection control after the surgeries, 7 of them suffered from residual back pain during ambulation within postoperative 3 months and one year. Unrelieved motion pain with mechanical instability was the major factor which contributed to

more subsequent revision fusion surgeries in PEDD group than that in PEIDF group (58.3% vs. 8.3%, $p = 0.030$). Firm fixation could also rapidly reduce back pain and consolidate infection control, even in the absence of debridement of infected tissue.¹⁴ Yang et al.²⁵ also demonstrated that surgical stabilization for infectious spondylodiskitis was associated with faster recovery, lower pain scores, and improved quality of life.

Surgical treatment for infectious spondylodiskitis remains challenging, especially for patients with comorbidities such as diabetes mellitus, immunosuppression, heart failure, liver cirrhosis, and renal failure.²⁸ In this study, we introduced a newly developed surgical technique, PEIDF that simultaneously comprises anterior endoscopic debridement, reconstruction, bone-

grafting interbody fusion, and posterior instrumentation. The goals of surgical treatment of spinal infections are to debride the infected tissue, identify the pathogen, and restabilize the deformed spine. There were 2 major parts of our PEIDF procedure. One was anterior procedure, infectious foci debridement and reconstruction, and the other was posterior procedure, stabilization via posterior instrumentation. Both anterior and posterior procedures could be done under prone position. In the anterior procedure of our PEIDF, infectious foci debridement of the intervertebral space, which was traditionally conducted via anterior open surgery, were performed through the endoscopic working sleeve via a 1-cm incision at the posterolateral side of the waist, as in Fig. 2. Endoscopy and fluoroscopy provided a clear and detailed view of the surgical fields, and they allowed us to do radical sequestrectomy and debridement of all necrotic disc tissue with minimal soft tissue damage and blood loss, as in Fig. 1. There was no concern for posterior contamination due to the intact fascia and posterior longitudinal ligament, which acted as a natural barrier to prevent infection spreading. Furthermore, intervertebral reconstruction and fusion via impacted cancellous allograft bone chips through the endoscopic working sleeve would decrease the postoperative instability and back pain. Posterior instrumentation with percutaneous pedicle screw insertion comprised the posterior procedure of PEIDF, along with the benefits of preserving back erector muscles, facet joints, and bony structures. From reviewing the literature, posterior transforaminal debridement and fusion via impacted cancellous bone chips with pedicle screw fixation was proven effective and offered good clinical outcome for the treatment of infectious spondylodiskitis in lumbar and thoracic spine.^{13,21,29,30} Under this basis, PEIDF provides the same qualification for spinal fusion and stability, alongside the preservation of back erector muscles, facet joints, and posterior bony structures. In summary, our PEIDF procedure would be composed of anterior radical debridement of infectious foci and restabilization via anterior bone-grafting reconstruction and posterior percutaneous instrumentation, with only five 1-cm skin incisions.

Percutaneous endoscopic lumbar discectomy and interbody fusion had been described in recent years, with good outcomes in patients without infections.³¹⁻³⁷ In our review of the literature, we found no reports about the application of endoscopic technique for infectious spine debridement, reconstruction, and fusion. In our preliminary results of PEIDF group, the infection control and fusion rates were satisfactory. Only 1 patient required revision surgery due to recurrent infection and implant loosening

2 months after discharge. However, this patient had end-stage renal failure and right septic knee. Three patients achieved solid fusion, and 7 partial union at 1 year after surgery, with an overall fusion rate of 83.3%. Spine sagittal alignment was also improved after surgery, and postoperative kyphosis angle and correction at 1 year were significantly better in PEIDF group. Late kyphosis is often observed to some degree after spine infection, especially in patients treated conservatively. Chronic back pain, muscle fatigue, and disability are related to spine malalignment, including pathologic kyphosis.³⁸ Loss of lordosis causes a predisposition to adjacent disc degeneration and physiological discomfort. Rajnics et al.³⁹ showed that people with predisposing disc degeneration and low back pain had a relatively kyphotic spine in the sagittal plane.

Antibiotic treatment guided by culture results remains the mainstay treatment of pyogenic spondylodiskitis.⁴⁰ Microbiological diagnosis is essential to enable targeted antibiotic treatment, and could be obtained through blood samples or deep necrotic tissue from CT-guided biopsy or surgery. In all patients of this study, abscess and necrotic tissue from the infected disc were sent for histopathological and microbiological studies. We performed this procedure as the first step, prior to any normal saline irrigation during both PEIDF and PEDD. Then, positive pathogen identification was 10 in PEIDF group (83.3%) and 12 in PEDD group (80%) and the main pathogen identified in our study was *S. aureus* (11 of 22, 50%), which were similar with other studies.⁴¹

The innovative surgical procedure, PEIDF is composed of the advantage of minimally invasive approach for infectious foci debridement in PEDD, and the spinal restabilization through bone-grafting reconstruction and percutaneous posterior instrumentation. This procedure supports minimally invasive surgical treatment for infected patients with multiple comorbidities, mechanical back pain, spinal instability, large bone defect, and kyphosis. There are some limitations of this study. The study was performed at one single medical center, and the number of patients was small. The retrospective nature of the study makes control of bias and confounders difficult. Some selection bias would result from our narrow inclusion criteria and exclusion criteria. Lastly, the follow-up period was short; longer follow-up time is necessary to determine the long-term outcomes of the PEIDF procedure.

CONCLUSION

PEIDF is an effective procedure for the treatment of pyogenic

lumbar spondylodiskitis, especially in patients with an unstable spine and medical comorbidities. It is minimally invasive, allows rapid ambulation, and is associated with good clinical and functional outcomes. Based on the results of this study, future studies with larger numbers of patients and longer follow-up to further evaluate the procedure are warranted.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Case Report

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INTRODUCTION

The retro-odontoid pseudotumor around the atlantodental joint is often concurrent with non-traumatic atlantoaxial subluxation (AAS).¹ Therefore, pannus formation by atlantoaxial instability is a relatively common complication in patients with rheumatoid arthritis (RA), a chronic, systemic inflammatory disease.² The cervical spine is a popular focus of ligamentous

Upper Cervical Compression Myelopathy Caused by the Retro-Odontoid Pseudotumor With Degenerative Osteoarthritis and Calcium Pyrophosphate Dihydrate Disease: A Case Report and Literature Review

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The retro-odontoid pseudotumor is often concurrent with atlantoaxial subluxation (AAS). Therefore, the pseudotumor is relatively common in rheumatoid arthritis (RA) but rare in primary osteoarthritis (OA). This is a case report of an elderly male patient suffering from neck pain and compression myelopathy caused by the craniocervical pseudotumor with OA but without atlantoaxial instability. He had long-lasting peripheral and spinal pain treated by nonsteroidal anti-inflammatory drugs. Imaging found upper cervical spondylosis without AAS or dynamic instability but with periodontoid calcifications and ossifications, suggesting calcium pyrophosphate dihydrate (CPPD) crystal deposition. Based on a comprehensive literature search and review, CPPD disease around the atlantodental joint is a possible contributor to secondary OA development and retro-odontoid pannus formation through chronic inflammation, which can be enough severe to induce compression myelopathy in non-RA patients without AAS. The global increase in the aged population advises caution regarding more prevalent upper cervical spine disorders associated with OA and CPPD.

Keywords: Retro-odontoid atlantodental pseudotumor, Osteoarthritis, Calcium pyrophosphate dihydrate, Compression myelopathy, Neck pain, Cervical spine

laxity and joint destruction by RA, and AAS is the most frequently observed involvement.³⁻⁵ The pseudotumor can occur even in patients without RA,⁶ which is however a rare condition in upper cervical osteoarthritis (OA).^{1,7} Although the development of OA is multifactorial, altered mechanical properties arising from degenerative instability^{8,9} with calcification and/or ossification^{10,11} are the primary cause.¹² Then, OA can secondarily be developed often more severely by other factors includ-

ing trauma, inflammation, e.g., gout, and metabolic disorders, e.g., diabetes.¹³ Because of less involvement of AAS in OA,¹⁴ there is only limited evidence regarding the link between the cranio-cervical pseudotumor, atlantoaxial instability, and OA.¹⁵

We experienced an elderly male patient case of the retro-odontoid atlantodental pseudotumor with upper cervical OA including the occipitocervical region, thereby causing compression myelopathy. The patient did not have marked AAS but periodontoid calcifications and ossifications, suggesting the involvement of calcium pyrophosphate dihydrate (CPPD) crystal deposition disease, also known as pseudogout and pyrophosphate arthropathy. In this case, CPPD-induced chronic inflammation may be a causative factor of secondary OA and the atlantoaxial pseudotumor. We thus performed a comprehensive literature search and review. We discussed a possible contribution of CPPD to the retro-odontoid pseudotumor in non-RA but OA patients without AAS and also the selection of treatment options.

CASE REPORT

This study was approved by the Institutional Review Board (IRB) at Kobe University Graduate School of Medicine (IRB



Fig. 1. Midsagittal T2-weighted magnetic resonance imaging of the cervical spine in the male patient at 62 years old. Atlanto-dental joint swelling without spinal cord compression was observed.

No. B190002). Written informed consent was obtained from the patient. Further, this patient was informed that data from the case would be submitted for publication, and gave his consent. This study was conducted in accordance with the principles of the Declaration of Helsinki and with the laws and regulations of Japan.

A 55-year-old Japanese man was referred to the authors' hospital due to complaints of low back, neck, shoulder, elbow, and hip pain. His symptoms lasted long before visiting, but relieved conservatively by nonsteroidal anti-inflammatory drugs (NSAIDs). His low back pain resulted from lumbar spinal canal stenosis with disc herniation as shown by magnetic resonance imaging (MRI). Then, his visiting continued 1 to 3 times a year complaining joint pain without any abnormality reflected on the blood test. Radiographic peripheral joint findings were normal except for hip joint effusion detected by MRI when he was 57 years old.

At 62 years old, neck pain worsened with a limited range of motion. Cervical spine flexion–extension radiographs revealed no apparent atlantoaxial instability but structural changes were obscure because of bony overlapping. Then, MRIs showed slight cervical disc bulging in lower vertebrae and granulomatous soft-tissue swelling around the atlantodental joint that resembled the pseudotumor associated with AAS in RA (Fig. 1). Based on no spinal cord compression and rapid pain relief by NSAIDs, further examinations were not performed. He had medical history of hypertension but not diabetes mellitus, rheumatic dis-

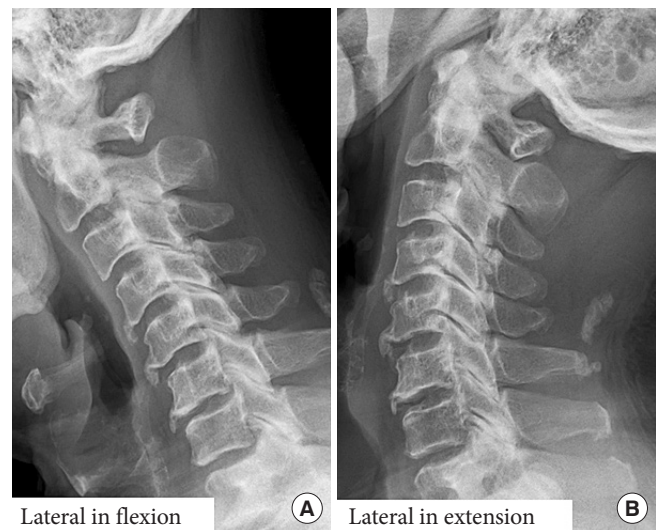


Fig. 2. Lateral radiographs in flexion (A) and extension (B) positions of the cervical spine in the male patient at 68 years old. No apparent development of atlantoaxial subluxation but with upper cervical degenerative spondylosis was observed.

eases, allergic diseases, or metabolic disorders. However, as low back and leg pain by lumbar spinal stenosis had worsened, decompression surgery was performed at 66 years old, facilitating successful postoperative relief of symptoms.

At 68 years old, he felt severe neck and occipital pain with limited motion in extension with rotation, shooting pain in both upper extremities with hand clumsiness and numbness, and walking disturbance. Four days after the onset, he visited our hospital. Neurological examination revealed modest muscle weakness in left extremities; however, sensory sensation and deep tendon reflexes were normal except for elevated left ankle jerk. Laboratory blood and urine data were within normal limits including white blood cell count and C-reactive protein. Cervical spine radiographs demonstrated subaxial spondylosis including vertebral osteophytes with disc height narrowing and Barsony's sign; however, no marked development of AAS or dynamic atlantoaxial instability was observed in flexion and extension positions (Fig. 2). Spinal cord compression by the enlarged retro-odontoid pseudotumor and C1 posterior arch with an intramedullary high signal-intensity lesion was detected on T2-weighted MRIs (Fig. 3). Computed tomography (CT) scan

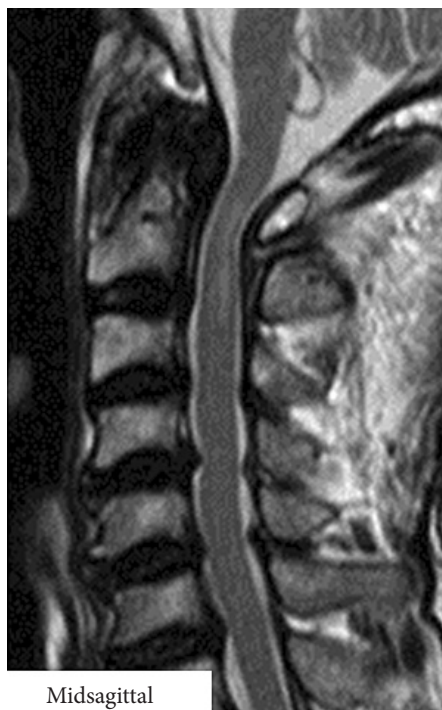


Fig. 3. Midsagittal T2-weighted magnetic resonance imaging of the cervical spine in the male patient at 68 years old. Marked spinal cord compression with an intramedullary high-signal intensity lesion between the enlarged retro-odontoid pseudotumor and C1 posterior arch was observed.

showed degenerative changes with calcifications and osteophytes around the occipitocervical junction but no ossification of the anterior longitudinal ligament (OALL) (Fig. 4). According to neurological and radiological findings with previous disease episodes, this patient was diagnosed with compression myelopathy due to the retro-odontoid pseudotumor associated with OA and CPPD but without RA or AAS.

Because of the presented long tract sign and difficulty of daily activities, surgical resection of the posterior arch of the atlas was performed. No apparent atlantoaxial instability indicated decompression alone. His symptoms immediately disappeared after C1 laminectomy. No remarkable AAS progression in radiographs, maintained spinal cord decompression with a decreased intramedullary abnormal signal at C1–2 level on T2-weighted MRIs, although the size of the retro-odontoid pseudotumor remained relatively unchanged, and increased periodontoid calcifications and osteophytes in CT images, suggest-

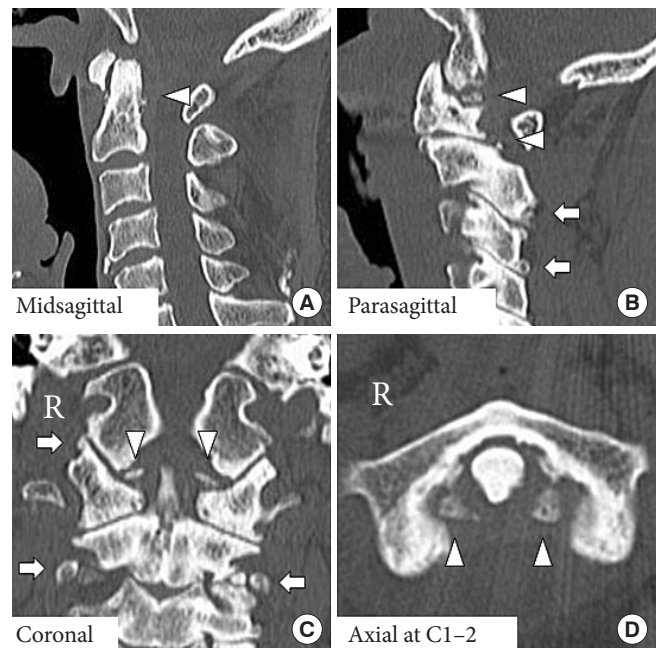


Fig. 4. Computed tomography images of the occipitocervical joint in the male patient at 68 years old. (A) In a midsagittal image, small but multiple calcifications (arrowhead) and osteophytes around the atlantodental joint were observed. (B) In a parasagittal image, calcifications (arrowheads), and narrowed joints with osteophytes (arrows) in the upper cervical spine were observed. (C) In a coronal image, ossifications of the transverse ligament (arrowheads) and degenerative joints (arrows) were observed. (D) In an axial image at C1–2, osteophytes and ossifications along with the transverse ligament (arrowheads) were observed. R indicates the right side of the body.

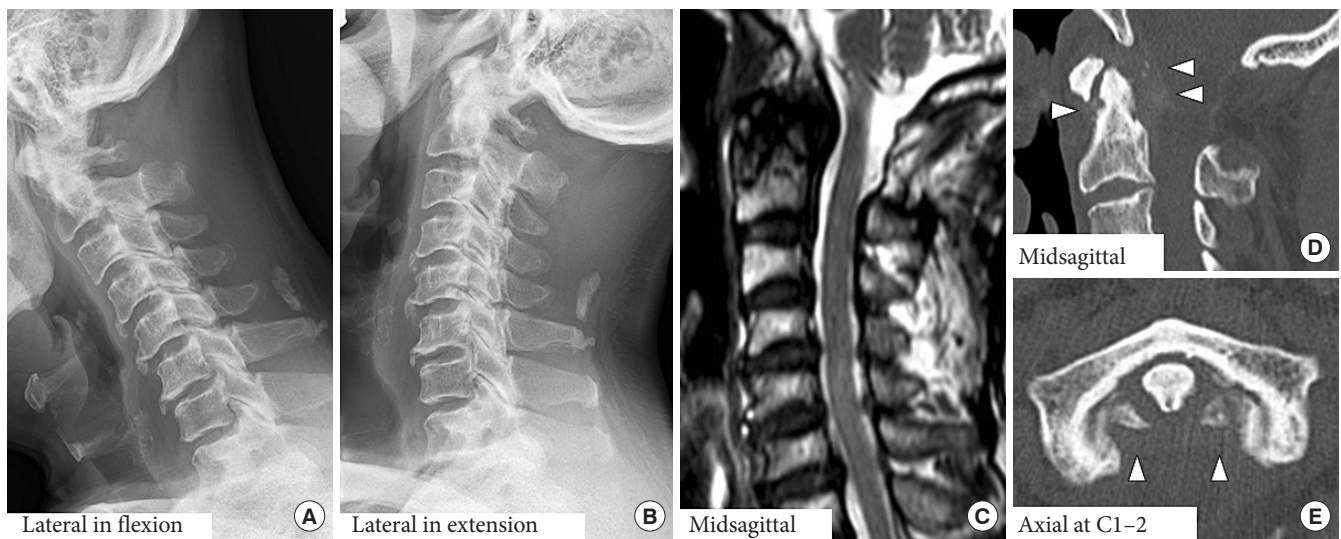


Fig. 5. Lateral radiographs in flexion (A) and extension (B) positions, midsagittal T2-weighted magnetic resonance imaging (C), and midsagittal (D) and axial at C1–2 (E) computed tomography images of the cervical spine in the male patient at 70 years old. No remarkable progression of atlantoaxial subluxation was observed 2 years after laminectomy of the C1 posterior arch. Surgical decompression of the spinal cord at C1–2 level with an improved intramedullary high-signal intensity lesion was obtained. Meanwhile, elevated levels of periodontoid calcifications (D, arrowheads) and ossifications (E, arrowheads) were found, indicating calcium pyrophosphate dihydrate crystal deposition.

ing sustained CPPD inflammation, were monitored at postoperative 2-year follow-up (Fig. 5).

LITERATURE SEARCH

Literature search of scientific articles published between 1977 and 2019 was performed in PubMed (<https://pubmed.ncbi.nlm.nih.gov/>). Three primary keywords of “pseudotumor” (107), “OA” (531), and “CPPD” including “pseudogout” and “chondrocalcinosis” (372) were examined with the combination of “retro-odontoid,” “atlantoaxial,” “atlantodontal,” “atlanto-odontoid,” “atlantodens,” and “cervical spine.” Numbers in the parenthesis showed in-relevant articles. Important articles regarding RA, AAS, and diffuse idiopathic skeletal hyperostosis (DISH) were additionally obtained by hand search. The abstract was evaluated and discussed by 2 authors (TY and TI), and 96 articles were selected eligible for the inclusion in this literature review. Based on 4 major topics of craniocervical “pseudotumor,” “OA,” “CPPD,” and “treatment” related to the presented patient case, 70 articles were finally referenced.

DISCUSSION

This is a case report of an older male patient suffering from neck pain and compression myelopathy due to chronic CPPD

inflammation-induced secondary upper cervical OA and atlantodontal pseudotumor even without AAS. Few prior papers reviewing the retro-odontoid “pseudotumor” with “OA” and “CPPD” have been published. The “treatment” is also undetermined. Therefore, we performed an in-depth literature review and discussed this patient case based on these 4 issues.

1. Non-RA Retro-Odontoid Pseudotumor

The retro-odontoid pseudotumor and/or AAS can be developed in patients with autoimmune diseases including RA,^{1–5} ankylosing spondylitis (AS),¹⁶ systemic lupus erythematosus (SLE),^{17,18} and Sjögren syndrome,¹⁸ which is also observed in non-RA patients with gout, pseudogout, hemodialysis, pigmented villonodular synovitis, and odontoid fracture nonunion.¹ Factors related to cervical spinal cord compression are synovial cyst, epidural lipoma and hematoma, and ossification of the posterior longitudinal ligament.¹ Although the generalized incidence of the retro-odontoid pseudotumor is unknown because of its rarity, the pseudotumor was detected by MRI in 23.2% of 164 patients with AAS surgically treated.¹⁹ In more recent registry data from a consecutive MRI study of 105 patients with the pseudotumor, RA diagnosis was only 27.6%,⁷ indicating a common involvement of non-RA disease. It is noteworthy that 44.7% of non-RA patients, who were older and male-dominant, had clinical CPPD or imaging evidence for tissue calcification.⁷ Then, the

pathomechanism of the pseudotumor development in non-RA is considered as transverse ligament degeneration^{6,20} due to the altered biomechanics of the craniocervical junction from congenital atlantooccipital assimilation anomaly²¹ as well as subaxial ankylosis in severe spondylosis,²² OALL,²³ Forestier disease,²⁴ DISH,^{25,26} and AS.¹⁶ A systematic review of the pseudotumor without radiographic instability failed due to the limited number of cases available, which although had different etiologies including atlantoaxial hypermobility, deposition of substances, and probably disc herniation.¹⁵ Reported causes of AAS and the retro-odontoid pseudotumor are summarized in Table 1.

Here we reported a non-RA male patient with the atlanto-dental pseudotumor and upper cervical compression myelopathy. He complained neck pain and arthralgia, showing craniocervical OA and periodontoid calcifications and ossifications without AAS. Based on our literature review, CPPD crystal deposition is suggested to be involved.

2. Upper Cervical OA

In 31 patients with atlantoaxial OA, both the atlantodontoid and lateral mass joints, only the atlantodontoid joint, and only lateral mass joints were radiologically involved in 71.0%, 16.1%, and 12.9%, respectively.²⁷ The importance of CT evaluation, identifying atlantodontoid OA and transverse ligament calcification, was later emphasized in middle-aged and older patients with occipitalgia and limited neck motion because of the difficulty in radiographically assessing overlapping craniocervical bony structures.²⁸ Upper cervical CT examination of 700 patients without trauma clarified an age-dependent increase in the prevalence of atlantodontoid OA: 16% in 18–25 years, 23% in 25–30 years, 33% in 30–40 years, 54% in 40–50 years, 70% in 50–60 years, 87% in 60–70 years, and 93% in >70 years.²⁹ A CT study of 1,543 patients at a trauma center showed an age-dependent decrease in the atlantodontoid interval and increase in bone cyst formation and synovitis with calcium deposition around the dens in >40 years old.³⁰ Consecutive 700 patients undergoing brain or paranasal sinus CT exhibited increased transverse ligament calcification with age and advanced atlantodontoid degeneration.³¹ Furthermore, mean 32.6-year-old male porters carrying loads on the head radiologically presented joint space narrowing with osteophytes, interspinous and transverse ligament calcifications, and occipito-atlantoaxial joint ankylosis, indicating primary OA, but did not all develop AAS or pseudotumor.³² Based on these findings, OA is common with age in the atlantodontoid and lateral mass joints. Then, age-related increase in retro-odontoid soft-tissue thick-

Table 1. Reported causes of atlantoaxial subluxation and the retro-odontoid pseudotumor

Cause	Reference
Atlantoaxial and/or atlantooccipital pathology	
OA	6, 8, 11, 14, 31, 32, 35-37, 60, 61
Primary OA	
Secondary OA	
Inflammation	1-5, 7, 16-18, 33, 43, 44, 53-55
Infection	
Autoimmune diseases (RA, AS, SLE, Sjögren syndrome, and reactive arthritis)	
Pseudogout/CPPD crystal deposition	
Gout	
Hemodialysis	38, 39
Trauma	37
Fracture of the dens	
Congenital anomaly	9, 21
Os odontoideum	
Craniocervical assimilation	
Developmental disease	37
Down syndrome	
Cerebral palsy	
Mucopolysaccharidosis	
Others	
Subaxial pathology (to develop atlantoaxial instability by limiting subaxial motion)	
OALL	20, 22-26
OPLL	
DISH	
Spondylosis (multilevel OA)	
Others	

OA, osteoarthritis; RA, rheumatoid arthritis; AS, ankylosing spondylitis; SLE, systemic lupus erythematosus; CPPD, calcium pyrophosphate dihydrate; OALL, ossification of the anterior longitudinal ligament; OPLL, ossification of the posterior longitudinal ligament; DISH, diffuse idiopathic skeletal hyperostosis.

ness was found on CT³³ and MRI,³⁴ particularly in male patients with OA and/or undergoing dialysis.³⁴ Cervical compression myelopathy also resulted from degenerative AAS¹⁴ and/or dens hypertrophy.^{11,35,36} The periodontoid soft-tissue mass resembling to the pseudotumor was detected in 90% of 108 surgically treated patients with degenerative atlantoaxial instability resulting from trauma and congenital anomaly without RA or CPPD.³⁷ The pseudotumor with amyloid deposition can be caused by atlantoaxial instability due to secondary OA in hemo-

dialysis patients.^{38,39} Consequently, secondary OA is often associated with the development of atlantoaxial instability and the retro-odontoid pseudotumor.

The presented patient had long-term episodes of neck pain without episodes of chronic mechanical stress in the upper cervical spine. Imaging examination displayed no OALL, DISH, or abnormal biomechanics but spondylosis with periodontoid calcifications and ossifications, suggesting CPPD as a cause of secondary OA.

3. CPPD Disease

The CPPD disease comprises a variety of clinical phenotypes including OA-like and RA-like.⁴⁰ Crystals of CPPD are known

to induce joint inflammation, bony erosion, and cartilage destruction, possibly resulting in degenerative OA.⁴⁰ The prevalence of the chronic polyarticular type of CPPD is roughly 50% while the acute type is approximately 25%.⁴¹ A national study of United States veterans also showed the chronic progression in more than half of cases.⁴² While the crowned dens syndrome is a common acute-type CPPD disease in the craniocervical junction,^{43,44} Chronic CPPD crystal deposition of the ligamentum flavum occurs frequently in the cervical spine.^{45,46} On craniocervical CT for acute trauma, a prevalence of atlantoaxial CPPD was 12.5% of 513 patients, increasing with age.³³ Another study detected a similar CT-based prevalence of periodontoid CPPD as 13.5% of 296 patients suspected of brain disease, showing an

Table 2. Reported radiological characteristics of primary causes of the retro-odontoid pseudotumor

Cause	Atlantoaxial pathology	Atlantooccipital pathology	Subaxial pathology	General/other joint pathology	Reference
Primary OA	Sclerosis, osteophyte formation, and decreased joint space	Sclerosis, osteophyte formation, and decreased joint space	Spondylosis	Not affected	27, 29-32
	Less involvement of ligament calcification and/or ossification (18.7%) ³²	Ankylosis			
	Early involvement from younger ages No AAS	Atlantoaxial calcification			
Secondary OA	Sclerosis, osteophyte formation, and decreased joint space with or without AAS	Congenital anomaly	AS	Usually not affected	8, 14, 16, 21, 23, 24, 26, 35-37
	Infection	Basilar invagination	OALL		
	AS		OPLL		
	Hemodialysis		DISH		
	Trauma		Spondylosis		
	Congenital anomaly Hypertrophic dens				
RA	AAS	VS	SAS	Affected	1-5
	VS	Basilar invagination			
Pseudogout/CPPD crystal deposition	Calcification of the transverse ligament in older ages	Little evidence in the occipitocervical region and predominantly involved in the spine	Calcification of the yellow ligament in the chronic type	Affected (OA-like and RA-like) ⁴⁰	40, 41, 43-46, 49, 50, 56
	Sclerosis, osteophyte formation, and decreased joint space	Sclerosis, osteophyte formation, and decreased joint space		Affected (Acute type, 25%; chronic type, 50%) ^{40,41} Long disease history	

OA, osteoarthritis; AAS, atlantoaxial subluxation; AS, ankylosing spondylitis; OALL, ossification of the anterior longitudinal ligament; OPLL, ossification of the posterior longitudinal ligament; DISH, diffuse idiopathic skeletal hyperostosis; RA, rheumatoid arthritis; VS, vertical subluxation of the atlas; SAS, subaxial subluxation; CPPD, calcium pyrophosphate dihydrate.

age-dependent increase.⁴⁷ Although calcification of the transverse and alar ligaments around the atlantodontoid joint was observed in 60%–70% of patients with pseudogout, the majority were asymptomatic with normal serological findings while only a small percentage of those exhibited neck pain and fever.⁴⁸⁻⁵¹ Recurrent sterile spondylodiscitis and epidural abscess by atlantoaxial CPPD were also observed.⁵² The retro-odontoid pseudotumor in patients with CPPD often displays iso-signal intensity on T1-weighted MRIs and iso-signal to high-signal intensity on T2-weighted MRIs.^{53,54} Histopathologically, CPPD crystal deposition can be confirmed from surgical specimens through transoral resection.^{44,53,55} The CPPD disease causes inflammatory responses more predominantly in the craniocervical junction than in the subaxial spine, demonstrating occipital pain, numbness, and paresthesias as well as lower cranial nerve deficits.^{43,44} Due to CPPD inflammation, atlantodontoid and occipitocervical OA changes with narrowed joint spaces, osteo-

phytes, and transverse and alar ligament calcifications and/or ossifications were observed.^{49,50,56} Despite no reports comparing the severity between primary and secondary OA, CPPD-induced secondary OA should manifest more extensive degeneration than primary OA because of persistent inflammation. Reported radiological characteristics of primary causes of the retro-odontoid pseudotumor are summarized in Table 2.

The current patient with long-standing periodical neck pain without serological inflammation would suffer from chronic CPPD with OA progression in the craniovertebral region. The identified retro-odontoid pseudotumor had iso-signal intensity on T1-weighted MRIs and low-signal intensity on T2-weighted MRIs, showing a similar pattern to OA rather than to CPPD.^{24,37} Therefore, this pseudotumor can be developed by secondary OA-mediated biomechanical alteration rather compared to CPPD inflammation.

Table 3. Reported advantages and disadvantages of treatment for the retro-odontoid pseudotumor

Treatment	Patient condition	Advantage	Disadvantage	Reference
Conservative management with a cervical collar	Rejected surgery Serious morbidity	No risk of surgery	Poor compliance Unpredictable results Prolonged treatment	57, 58
C1 decompression alone	No atlantoaxial instability Mild myelopathy	Good neurological recovery Less surgical invasion Expected tumor size reduction	Potential risk of perioperative neurological damage Less tumor size reduction Possible recurrence of the pseudotumor with the increase in instability	8, 20, 35, 63-66
C1–2 fusion without decompression	Mild atlantoaxial instability Moderate to severe myelopathy	Better neurological recovery Earlier, more reliable tumor size reduction	Potential risk of perioperative neurological damage Complications associated with instrumentation	19, 35, 61, 62, 66-70
C1–2 or occipitocervical fusion with decompression	Severe atlantoaxial instability Severe myelopathy Larger pseudotumor	Best neurological recovery in posterior surgery Earlier, more reliable tumor size reduction	Higher potential risk of perioperative neurological damage Complications associated with instrumentation	
Anterior decompression with fusion	Severe myelopathy Larger pseudotumor without posterior pathology	Optimal neurological recovery through direct tumor resection or decompression	Oral complications Requirement of additional posterior fixation depending on the anterior stability	6, 24, 25, 60
	Currently less common			

4. Treatment

Conservative treatment by neck collar was adapted for patients who had the difficulty in undergoing surgery due to serious complications and/or who rejected surgery, as the size reduction in the retro-odontoid pseudotumor and recovery of symptoms have been reported.^{57,58} Nevertheless, surgery is the first selection for patients suffering from pseudotumor-induced compression myelopathy.⁵⁹ Anterior decompression by transoral odontoid process and pseudotumor resection (combined with C1–2 posterior fusion) achieved good clinical and neurological outcomes.^{6,24,25,60} More recent papers presented a remarkable pseudotumor size reduction even with the disappearance by C1–2 posterior fusion only.^{19,61,62} Currently, posterior approach is the primary strategy based on pseudotumor pathologies of soft-tissue swelling and atlantoaxial instability. Then, spinal cord compression by the anterior pseudotumor or posterior C1 arch even after manual AAS reduction may require decompression with fusion. Moreover, C1 laminectomy alone is an acceptable option with good clinical results including pseudotumor size reduction, similar to decompression and fusion, and nonworsened AAS.^{63–65} In a comparative study between the retro-odontoid pseudotumor between posterior fusion and decompression alone, recovery rate at the mean 54-month final follow-up did not differ but pseudotumor regression was more frequent in the fusion group (100% vs. 42%), resulting in the recommendation of fusion irrespective of atlantoaxial instability.⁶⁶ Further comparative studies regarding the need for stabilization and decompression are required. Reported advantages and disadvantages of treatment for the retro-odontoid pseudotumor are summarized in Table 3.

In our patient, posterior C1 laminectomy was selected because of mild myelopathy without marked AAS. Advantages of decompression alone are less invasive and avoidable from complications according to bone grafting and/or fusion surgery.^{67–70} Disadvantages would be residual neck pain and nonexclusive future atlantoaxial instability and also pseudotumor progression.²⁰ Careful follow-up is necessary.

CONCLUSION

This is a case report of an elderly male patient suffering from neck pain and compression myelopathy caused by the retro-odontoid pseudotumor without RA or AAS. Although prior articles described the atlanto-odontoid pseudotumor with upper cervical spondylosis, most cases were associated not with primary OA but with secondary OA.³² Based on periodontoid cal-

cifications and ossifications, the pseudotumor would occur with chronic inflammatory CPPD crystal deposition. Subclinical CPPD progression around the atlantoaxial joint facilitates secondary OA development and retro-odontoid pannus formation, which can be enough severe to induce compression myelopathy in non-RA patients without AAS. The elderly population rapidly increases in the world; therefore, more careful attention around the craniocervical region should be paid to identify compression myelopathy associated with OA and CPPD.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Instructions for Contributors

Revised: July 10, 2018

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- 1) Objective, Methods, Results, and Conclusion sections should be included in abstract of clinical or laboratory research, but are not necessary in other types of studies.
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Discussions about the findings of the research and interpretations in relation to other studies are made. It is necessary to emphasize the new and critical findings of the study, not to repeat the results of the study presented in the previous sections. The meaning and limitation of observed facts should be described, and the conclusion should be related to the objective of the study only when it is supported by the results of the research.

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The conclusion section should include a concise statement of the major findings of the study in accordance with the study purpose.

9. References

The authors are responsible for the accuracy of the references. Key the references (double-spaced) at the end of the manuscript. End-Note users can access a direct download of the updated *Neurospine* Publications style at <https://www.e-neurospine.org>. References should be numbered consecutively in the order in which they are first mentioned in the text. All references cited in the text must be both listed and cited by the reference number (footnotes are not accepted). Use superscript numerals outside periods and commas, inside colons and semicolons. When more than 2 references are cited at a given place in the manuscript, use hyphens to join the first and last numbers of a closed series; use commas without space to separate other parts of a multiple citation (e.g., As reported previously,^{1,3-8,19} ...The derived data were as follows^{3,4,12}.)

Do not link the references to the text. Cite unpublished data, such as papers submitted but not yet accepted for publication or personal communications, in parentheses in the text. If there are more than three authors, name only the first three authors and then use et al. Refer to the List of Journals Indexed in Index Medicus for abbreviations of journal names, or access the list at <https://www.nlm.nih.gov/archive/20130415/tsd/serials/lji.html>. Sample references are given below:

• Journal article

1. Sakai K, Okawa A, Takahashi M, et al. Five-year follow-up evaluation of surgical treatment for cervical myelopathy caused by ossification of the posterior longitudinal ligament. *Spine (Phila Pa 1976)* 2012;37:367-76.

• Book chapter

2. Sweitzer S, Arruda J, DeLeo J. The cytokine challenge: Methods for the detection of central cytokines in rodent models of persistent pain. In: Kruger L, editor. *Methods in pain research*. Boca Raton, FL: CRC Press; 2001:109-32.

• Entire book

3. Atlas SW. *Magnetic resonance imaging of the brain and spine*. Philadelphia: Lippincott Williams & Wilkins; 2001.

• Software

4. Epi Info [computer program]. Version 6. Atlanta: Centers for Disease Control and Prevention; 1994.

• Online journals

5. Friedman SA. Preeclampsia: A review of the role of prostaglan-

dins. *Obstet Gynecol* [serial online]. January 1988;71:22-37. Available at: BRS Information Technologies; McLean, VA. Accessed December 15, 1990.

• Database

6. CANCERNET-PDQ [database online]. Bethesda (MD): National Cancer Institute; 1996. Updated March 29, 1996.

• World Wide Web

7. Gostin LO. Drug use and HIV/AIDS [Internet]. June 1, 1996. Available at: <http://www.ama-assn.org/special/hiv/ethics>. Accessed June 26, 1997.

10. Tables

- 1) Tables should be created using the table formatting and editing feature of Microsoft Word. The title of the table must be noted. Tables cannot be submitted in a picture format.
- 2) Tables should be prepared in detail, in order to understand the contents of the manuscript without further reference.
- 3) Tables should be submitted separately from manuscript. Do not include vertical lines in table, and refer to the table formats in formal papers in *Neurospine*.

11. Figures and Illustrations

- 1) Figures should have resolution of 300 dpi or above and should be submitted individually (Namely, if Figure 1 is divided into A, B, C, and D, do not combine them into one, but submit each of them separately). Allowable file format for figures are JPG or TIF (TIFF) only.
- 2) Figures should be named according to figure name (example: Fig-1A.tif). If the quality of the photographs is considered as inappropriate for printing, resubmission of them can be requested by the journal.
- 3) Authors should submit figures in black and white if they want them to be printed in black and white. Authors are responsible for any additional costs of producing color figures (Additional cost for color printing is determined by the editorial board).
- 4) Line art should have resolution of 1,200 dpi or more in JPG or TIF format.

12. Author Check List

- 1) Before submitting the manuscript, authors should double-check all requirements noted in the agreement form regarding the registration and copyrights of their manuscript. A manuscript that does not fit the author instructions of the journal regarding format and references will be returned to the authors for further correction.
- 2) The page numbers in the manuscript should be counted from the page with the abstract, and the name and affiliation of the

authors should not appear thereafter.

- 3) Author check list should be prepared, signed by corresponding author, submitted with manuscripts, and then registered online. Relevant forms can be downloaded at manuscript submission site.

IV. Peer Review Process

All manuscripts are considered confidential. They are peer-reviewed by at least 2 anonymous reviewers selected by the Editor. The corresponding author is notified as soon as possible of the Editor's decision to accept, reject, or ask for revisions. The average time interval for an initial review process that involves both editorial and peer reviews is approximately 1 month; occasionally, there are unavoidable delays, usually because a manuscript needs multiple reviews or several revisions. When manuscripts are returned for revision, a cover letter from the Editor provides directions that should be followed carefully. When submitting the revised manuscript, authors should include a Response Letter, which describes how the manuscript has been revised. A point-by-point response to the Editor should be included with the revised manuscript. Authors who plan to resubmit but cannot meet this deadline should contact the Editorial Office. Manuscripts held for revision will be retained for a maximum of 90 days. The revised manuscript and the author's comments will be reviewed again. If a manuscript is completely acceptable, according to the criteria set forth in these instructions, it is scheduled for publication in the next available issue.

We neither guarantee the acceptance without review nor very short peer review times for unsolicited manuscripts. Commissioned manuscripts also are reviewed before publication.

We adopt double-blind peer review in which case, not only authors but also reviewers do not know each other.

V. Publication and Charges

- 1) Once a manuscript is accepted for publication by the journal, it will be sent to the press, and page proofs will be sent to authors. Authors must respond to the page proofs as soon as possible after making necessary corrections of misspellings, and the location of the photographs, figures or tables. Authors can make corrections for only typing errors, and are not allowed to make any author alteration or substantive changes of the text. Proofs must be returned to the press within 48 hours of receipt. No response from the authors within this time frame will lead the publication of the proof read without corrections, and the editorial board will not be responsible for any mistakes or errors occurring in this process.
- 2) There is no article processing charge (APC), also known as a publication fee including submission fee, for accepted articles.

VI. Ethical Guidelines

1. Research Ethics

- 1) All of the manuscripts should be prepared in strict observation of research and publication ethics guidelines recommended by the Council of Science Editors (CSE), International Committee of Medical Journal Editors (ICMJE), World Association of Medical Editors (WAME), and the Korean Association of Medical Journal Editors (KAMJE).
- 2) Any study including human subjects or human data must be reviewed and approved by a responsible institutional review board (IRB). Please refer to the principles embodied in the Declaration of Helsinki (<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>) for all investigations involving human materials.
- 3) Animal experiments also should be reviewed by an appropriate committee (Institutional Animal Care and Use Committee, IACUC) for the care and use of animals. Also studies with pathogens requiring a high degree of biosafety should pass review of a relevant committee (Institutional Biosafety Committee, IBC). The editor of *Neurospine* always request submission of copies of informed consents from human subjects in clinical studies or IRB approval documents.

2. Conflict of Interest

- 1) The corresponding author of an article is asked to inform the Editor of the authors' potential conflicts of interest possibly influencing their interpretation of data. A potential conflict of interest should be disclosed in the cover letter even when the authors are confident that their judgments have not been influenced in preparing the manuscript. Such conflicts may be financial support or private connections to pharmaceutical companies, political pressure from interest groups, or academic problems. Disclosure form shall be same with ICMJE Uniform Disclosure Form for Potential Conflicts of Interest (http://www.icmje.org/coi_disclosure.pdf).
- 2) The Editor will decide whether the information on the conflict should be included in the published paper. Before publishing such information, the Editor will consult with the corresponding author. In particular, all sources of funding for a study should be explicitly stated. The *Neurospine* asks referees to let its Editor know of any conflict of interest before reviewing a particular manuscript.

3. Journal Policies on Authorship and Contributorship

- 1) Authors are required to make clear of their contribution to their manuscript in cover letter. To be listed as an author one should have contributed substantially to all three categories established

by the International Committee of Medical Journal Editors (ICMJE): (1) conception and design, or acquisition, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published; and (4) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

- 2) When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the Acknowledgments. Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship. Authors are responsible for replying to all questions asked by reviewers or editors that relate to the accuracy or integrity of any part of the work. All persons who have made a substantial contribution, but who are not eligible as authors, should be named in the acknowledgments. Authors are expected to consider carefully the way authors should be listed and ordered before submitting their manuscripts, and to provide a definitive list of authors with their original submission. Any addition, deletion, or rearrangement of author names in the authorship list should be made before the manuscript has been accepted—and only if approved by the journal Editor. To request such a change, the Editor must receive the following from the corresponding author: (a) the reason for requesting a change in the list of authors; and (b) written confirmation (by e-mail or letter) from all authors to say that they agree with the addition, removal, or rearrangement.

4. Redundant Publication and Plagiarism

- 1) Redundant publication is defined as “reporting (publishing or attempting to publish) substantially the same work more than once, without attribution of the original source(s)”. Characteristics of reports that are substantially similar include the following: (a) “at least one of the authors must be common to all reports (if there are no common authors, it is more likely plagiarism than redundant publication);” (b) “the subject or study populations are often the same or similar;” (c) “the methodology is typically identical or nearly so;” and (d) “the results and their interpretation generally vary little, if at all.”
- 2) When submitting a manuscript, authors should include a letter informing the editor of any potential overlap with other already published material or material being evaluated for publication and should also state how the manuscript submitted to *Neurospine* differs substantially from this other material. If all or

part of your patient population was previously reported, this should be mentioned in the Materials and Methods, with citation of the appropriate reference(s).

- 3) The editorial committee checks the similarity by using the iThenticate (<http://www.ithenticate.com/>) program for all submitted articles to prevent plagiarism. The editorial committee rejects the article suspected of plagiarism and asks the author to check whether it is plagiarized and make a resubmission.

5. Readership

It is primarily for clinicians and researchers who care patients with spine and spinal cord diseases. They are able to obtain tailored information to adopt for their research and practice. Its readership can be expanded to other positions: • Researchers can get the recent topics of clinical research in spine and spinal cord field and detailed research methods; • Clinicians in the field can get the new information and recent development for care of patients; • Medical teacher can access and adopt a variety of data in medical education; • Allied health professionals including nurses are able to get the recent information for care of patients with spine and spinal cord diseases; • Medical health students can understand the recent trends of the field and interesting cases for their work; • Policy makers are able to reflect the results of the articles to the nation-wide health care policies for patients with spine and spinal cord diseases; • The public, especially family of patients with spine and spinal cord diseases are able to read the advancement in their family’s diseases so that they have a better knowledge on the diseases and a confidence in the clinicians’ devotion to their family.

6. Obligation to Register Clinical Trial

- 1) Clinical trial defined as “any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome” should be registered to the primary registry to be prior publication.
- 2) *Neurospine* accepts the registration in any of the primary registries that participate in the WHO International Clinical Trials Portal (<http://www.who.int/ictrp/about/details/en/index.html>) as well as <https://www.anzctr.org.au/>, www.clinicaltrials.gov, www.umin.ac.jp/ctr/index/htm and www.trialregister.nl. The clinical trial registration number shall be published at the end of the abstract.

7. Process for Identification of and Dealing With Allegations of Research Misconduct

When the Journal faces suspected cases of research and publication misconduct such as a redundant (duplicate) publication, plagiarism, fabricated data, changes in authorship, undisclosed conflicts of interest, an ethical problem discovered with the submitted manuscript, a

reviewer who has appropriated an author's idea or data, complaints against editors, and other issues, the resolving process will follow the flowchart provided by the Committee on Publication Ethics (<http://publicationethics.org/resources/flowcharts>). The Editorial Board will discuss the suspected cases and reach a decision. We will not hesitate to publish errata, corrigenda, clarifications, retractions, and apologies when needed.

Neurospine adheres to the research and publication ethics policies outlined in International Standards for Editors and Authors (<http://publicationethics.org>) and the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (<http://icmje.org>). Any studies involving human subject must comply with the principles of the World Medical Association Declaration of Helsinki. Clinical research should be approved by the Institutional Review Board, as well through patient consent. A patient's personal information cannot be published in any form. However, if it is absolutely necessary to use a patient's personal information, the consent of the patient or his/her guardian will be needed before publishing. Animal studies should be performed in compliance with all relevant guidelines, observing the standards described in the NIH Guide for the Care and Use of Laboratory Animals.

Cases that require editorial expressions of concern or retraction shall follow the COPE flowcharts available from: <http://publicationethics.org/resources/flowcharts>. If correction is needed, it will follow the ICMJE Recommendation for Corrections, Retractions, Republications and Version Control available from: <http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/corrections-and-version-control.html> as follows:

Honest errors are a part of science and publishing and require publication of a correction when they are detected. Corrections are needed for errors of fact. Minimum standards are as follows: First, it shall publish a correction notice as soon as possible, detailing changes from and citing the original publication on both an electronic and numbered print page that is included in an electronic or a print Table of Contents to ensure proper indexing; Second, it shall post a new article version with details of the changes from the original version and the date(s) on which the changes were made through CrossMark; Third, it shall archive all prior versions of the article. This archive can be either directly accessible to readers; and Fourth, previous electronic versions shall prominently note that there are more recent versions of the article via CrossMark.

8. Handling Complaints and Appeals

The policy of the journal is primarily aimed at protecting the authors, reviewers, editors, and the publisher of the journal. If not described below, the process of handling complaints and appeals follows the guidelines of the Committee of Publication Ethics available from:

<https://publicationethics.org/appeals>

Who complains or makes an appeal?

Submitters, authors, reviewers, and readers may register complaints and appeals in a variety of cases as follows: falsification, fabrication,

plagiarism, duplicate publication, authorship dispute, conflict of interest, ethical treatment of animals, informed consent, bias or unfair/inappropriate competitive acts, copyright, stolen data, defamation, and legal problem. If any individuals or institutions want to inform the cases, they can send a letter to editor through <https://www.e-neurospine.org/about/contact.php>. For the complaints or appeals, concrete data with answers to all factual questions (who, when, where, what, how, why) should be provided.

Who is responsible to resolve and handle complaints and appeals?

The Editor, Editorial Board, or Editorial Office is responsible for them.

What may be the consequence of remedy?

It depends on the type or degree of misconduct. The consequence of resolution will follow the guidelines of the Committee of Publication Ethics (COPE).

9. Postpublication Discussions and Corrections

The postpublication discussion is available through letter to the editor. If any readers have a concern on any articles published, they can submit letter to the editor on the articles. If there founds any errors or mistakes in the article, it can be corrected through errata, corrigenda, or retraction.

10. Policies on data sharing and reproducibility

Until 2020, authors will be encouraged to share their data openly, but starting in 2021, they will be mandated to do so. The related regulation follows the open data sharing policy outlined below.

1) Open data sharing policy

For clarification on result accuracy and reproducibility of the results, raw data or analysis data will be deposited to a public repository, for example, Harvard Dataverse (<https://dataverse.harvard.edu/>) after acceptance of the manuscript. Therefore, submission of the raw data or analysis data is mandatory. If the data is already a public one, its URL site or sources should be disclosed. If data cannot be publicized, it can be negotiated with the editor. If there are any inquiries on depositing data, authors should contact the editorial office.

2) Clinical data sharing policy

This journal follows the data sharing policy described in "Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors" (<https://doi.org/10.3346/jkms.2017.32.7.1051>). As of July 1, 2018 manuscripts submitted to ICMJE journals that report the results of interventional clinical trials must contain a data sharing statement as described below. Clinical trials that begin enrolling participants on or after January 1, 2019 must include a data sharing plan in the trial's registration. The ICMJE's policy regarding trial registration is explained at <http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html>. If the data sharing plan changes

Table. Examples of Data Sharing Statements That Fulfill These ICMJE Requirements*

	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes	Yes	Yes	No
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification.	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Not available
What other documents will be available?	Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code	Study Protocol, Statistical Analysis Plan, Analytic Code	Study Protocol	Not available
When will data be available (start and end dates)?	Immediately following publication. No end date.	Beginning 3 months and ending 5 years following article publication.	Beginning 9 months and ending 36 months following article publication.	Not applicable
With whom?	Anyone who wishes to access the data.	Researchers who provide a methodologically sound proposal.	Investigators whose proposed use of the data has been approved by an independent review committee (learned intermediary) identified for this purpose.	Not applicable
For what types of analyses?	Any purpose.	To achieve aims in the approved proposal.	For individual participant data meta-analysis.	Not applicable
By what mechanism will data be made available?	Data are available indefinitely at (<i>Link to be included</i>).	Proposals should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website (<i>Link to be included</i>).	Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University's data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at (<i>Link to be provided</i>).	Not applicable

* These examples are meant to illustrate a range of, but not all, data sharing options.

after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record. All of the authors of research articles that deal with interventional clinical trials must submit data sharing plan of example 1 to 4 in Table 1. Based on the degree of sharing plan, authors should deposit their data after deidentification and report the DOI of the data and the registered site.

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In case of experimenting on human, the author(s) have certified that the process of the research is in accordance with ethical standards of Helsinki declaration, domestic and foreign committees that preside over human experiment.

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6. References

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- 4) If there are more than 3 authors in end-reference list, name only the first 3 authors and then use et al. Yes / No
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