



**CONGRESS OF NEUROLOGICAL SURGEONS SYSTEMATIC REVIEW AND
EVIDENCE-BASED GUIDELINES ON THE EVALUATION AND TREATMENT OF
PATIENTS WITH THORACOLUMBAR SPINE TRAUMA:
NOVEL SURGICAL STRATEGIES**

Sponsored by: Congress of Neurological Surgeons and the Section on Disorders of the Spine and Peripheral Nerves in collaboration with the Section on Neurotrauma and Critical Care

Endorsed by: Joint Guidelines Committee of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS)

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Keywords: Arthrodesis, burst fracture, fusion, minimally invasive surgery, thoracolumbar fracture

Abbreviations

AO - AO/Magerl Spine Injury Classification

ASIA - American Spinal Injury Association

CT - Computed Tomography

LBOS - Low Back Outcome Score

ODI - Oswestry Disability Index

SF-36 - Short Form-36 Health Survey

VAS - Visual Analog Scale

XR - X-ray

No part of this article has been published or submitted for publication elsewhere.

ABSTRACT

Background: Treatment of thoracolumbar burst fractures have traditionally involved spinal instrumentation with fusion performed with standard open surgical techniques. Novel surgical strategies, including instrumentation without fusion and percutaneous instrumentation alone, have been considered less invasive and more efficient treatments.

Objective: Review the current literature and determine the role of fusion in instrumented fixation, as well as the role of percutaneous instrumentation, in the treatment of patients with thoracolumbar burst fractures.

Methods: The task force members identified search terms/parameters and a medical librarian implemented the literature search, consistent with the literature search protocol (see Appendix I), using the National Library of Medicine PubMed database and the Cochrane Library for the period from January 1, 1946, to March 31, 2015.

Results: A total of 906 articles were identified and 38 were selected for full-text review. Of these articles, 12 articles met criteria for inclusion in this systematic review.

Conclusion: There is grade A evidence for the omission of fusion in instrumented fixation for thoracolumbar burst fractures. There is grade B evidence that percutaneous instrumentation is as effective as open instrumentation for thoracolumbar burst fractures.

RECOMMENDATIONS

Question

Does the addition of arthrodesis to instrumented fixation improve outcomes in patients with thoracic and lumbar burst fractures?

Recommendation

It is recommended that in the surgical treatment of patients with thoracolumbar burst fractures, surgeons should understand that the addition of arthrodesis to instrumented stabilization has NOT been shown to impact clinical or radiologic outcomes, and adds to increased blood loss and operative time.

Strength of Recommendation: Grade A

Question

How does the use of minimally invasive techniques (including percutaneous instrumentation) affect outcomes in patients undergoing surgery for thoracic and lumbar fractures compared to conventional open techniques?

Recommendation

Stabilization using both open and percutaneous pedicle screws may be considered in the treatment of thoracolumbar burst fractures as the evidence suggests equivalent clinical outcomes.

Strength of Recommendation: Grade B

INTRODUCTION

Goals and Rationale

This clinical guideline was created to improve patient care by outlining the appropriate information gathering and decision-making processes involved in the evaluation and treatment of patients with thoracolumbar spine trauma. The surgical management of these patients often takes place under a variety of circumstances and by various clinicians. This guideline was created as an educational tool to guide qualified physicians through a series of diagnostic and treatment decisions to improve the quality and efficiency of care.

Thoracolumbar fractures are injuries that may result in instability of the spinal column. Burst fractures account for approximately 50% of thoracolumbar fractures and may be treated both operatively and nonoperatively. Though predominantly occurring in younger patients, burst fractures occur in all age groups. The mechanism of burst fractures involves axial loading with or without flexion. The hallmark of the burst fracture is involvement of the anterior and middle

columns that can lead to spinal canal compromise with or without neurologic deficit or kyphotic deformity.

The goal of treatment for thoracolumbar burst fractures entails stabilization with or without decompression to prevent progressive deformity and neurologic compromise. Although some burst fractures may be treated nonoperatively, a certain percentage will require operative intervention. Formal open surgery for stabilization with instrumentation and arthrodesis, as well as decompression, as needed, has been the primary mode of surgical treatment. However, more specific surgical strategies, such as instrumentation without arthrodesis and percutaneous instrumentation alone, have all been offered as faster, safer, and more efficient alternatives to traditional open fusion surgery.

This guideline focuses on 2 questions: 1) Does the addition of arthrodesis to instrumented fixation improve outcomes in patients with thoracic and lumbar fractures? and 2) Does the use of minimally invasive techniques (including percutaneous instrumentation) affect outcomes in patients undergoing surgery for thoracic and lumbar fractures compared to conventional open techniques?

METHODS

The guidelines task force initiated a systematic review of the literature relevant to the diagnosis and treatment of patients with thoracolumbar trauma. Through objective evaluation of the evidence and transparency in the process of making recommendations, this evidence-based clinical practice guideline was developed for the diagnosis and treatment of adult patients with

thoracolumbar injury. These guidelines were developed for educational purposes to assist practitioners in their clinical decision-making processes. Additional information about the methods used in this systematic review can be found in the [introduction and methodology chapter](#).

Literature Search

The task force members identified search terms and parameters and a medical librarian implemented the literature search, consistent with the literature search protocol (see Appendix I), using the National Library of Medicine PubMed database and the Cochrane Library (which included the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effect, the Cochrane Central Register of Controlled Trials, the Health Technology Assessment Database, and the National Health Service Economic Evaluation Database) for the period from January 1, 1946, to March 31, 2015, using the search strategies provided in Appendix I.

RESULTS

The literature search yielded 906 abstracts relevant to this guideline. Task force members reviewed all abstracts yielded from the literature search and identified the literature for full-text review and extraction, addressing the clinical questions in accordance with the literature search protocol (Appendix I). Task force members identified the best research evidence available to answer the targeted clinical questions. When level I, II, or III literature was available to answer specific questions, the task force did not review level IV studies.

The task force selected 38 full-text articles for review. Of these, 26 were rejected for not meeting inclusion criteria or for being off topic. Twelve articles were selected for inclusion in the systematic review (Appendix II).

Inclusion/Exclusion Criteria

Articles were retrieved and included only if they met specific inclusion/exclusion criteria. These criteria were also applied to articles provided by guideline task force members who supplemented the electronic database searches with articles from their own files. To reduce bias, these criteria were specified before conducting the literature searches.

Articles that do not meet the following criteria were, for the purposes of this evidence-based clinical practice guideline, excluded. To be included as evidence in the guideline, an article had to be a report of a study that:

- Investigated patients with thoracolumbar injuries;
- Included patients ≥ 18 years of age;
- Enrolled $\geq 80\%$ of thoracolumbar injuries (studies with mixed patient populations were included if they reported results separately for each group/patient population);
- Was a full article report of a clinical study;
- Was not an internal medical records review, meeting abstract, historical article, editorial, letter, or commentary;
- Appeared in a peer-reviewed publication or a registry report;
- Enrolled ≥ 10 patients per arm per intervention (20 total) for each outcome;
- Included only human subjects;

- Was published in or after 1946 through March 31, 2015;
- Quantitatively presented results;
- Was not an in vitro study;
- Was not a biomechanical study;
- Was not performed on cadavers;
- Was published in English;
- Was not a systematic review, meta-analysis, or guideline developed by others*;
- Was a case series (therapeutic study) where higher level evidence exists.

The guideline task force used a modified version of the North American Spine Society's evidence-based guideline development methodology. The North American Spine Society methodology uses standardized levels of evidence (Appendix III) and grades of recommendation (Appendix IV) to assist practitioners in easily understanding the strength of the evidence and recommendations within the guidelines. The levels of evidence range from level I (high quality randomized controlled trial) to level IV (case series). Grades of recommendation indicate the strength of the recommendations made in the guideline based on the quality of the literature. Levels of evidence have specific criteria and are assigned to studies before developing recommendations. Recommendations are then graded based upon the level of evidence. To better understand how levels of evidence inform the grades of recommendation and the standard nomenclature used within the recommendations, see Appendix IV.

*The guideline task force did not include systematic reviews, guidelines, or meta-analyses conducted by others. These documents are developed using different inclusion criteria than those specified in this guideline; therefore, they may include studies that do not meet the inclusion criteria specific in this guideline. In cases where these types of documents' abstract suggested relevance to the guideline's recommendations, the task force searched their bibliographies for additional studies.

Guideline recommendations were written using a standard language that indicates the strength of the recommendation. “A” recommendations indicate a test or intervention is “recommended”; “B” recommendations “suggest” a test or intervention; “C” recommendations indicate a test or intervention or “is an option.” “Insufficient evidence” statements clearly indicate that “there is insufficient evidence to make a recommendation for or against” a test or intervention. Task force consensus statements clearly state that “in the absence of reliable evidence, it is the task force’s opinion that” a test or intervention may be considered. Both the levels of evidence assigned to each study and the grades of each recommendation were arrived at by consensus of the workgroup employing up to three rounds of voting when necessary.

In evaluating studies as to levels of evidence for this guideline, the study design was interpreted as establishing only a potential level of evidence. As an example, a therapeutic study designed as a randomized controlled trial would be considered a potential level I study. The study would then be further analyzed as to how well the study design was implemented and significant shortcomings in the execution of the study would be used to downgrade the levels of evidence for the study’s conclusions (see Appendix V for additional information and criteria).

Revision Plans

In accordance with the Institute of Medicine’s standards for developing clinical practice guidelines and criteria specified by the National Guideline Clearinghouse, the task force will monitor related publications after the release of this document and will revise the entire document and/or specific sections “if new evidence shows that a recommended intervention causes previously unknown substantial harm; that a new intervention is significantly superior to

a previously recommended intervention from an efficacy or harms perspective; or that a recommendation can be applied to new populations.”¹ In addition, the task force will confirm within 5 years from the date of publication that the content reflects current clinical practice and the available technologies for the evaluation and treatment for patients with thoracolumbar trauma.

DISCUSSION

Question 1

Does the addition of arthrodesis to instrumented fixation improve outcomes in patients with thoracic and lumbar burst fractures?

Dai et al² performed a randomized clinical trial of 73 consecutive patients with a single level Denis-type burst fracture between T11 and L2, who were assigned to treatment with short segment pedicle instrumentation with posterior lateral fusion (n = 37) or without posterior lateral fusion (n = 36). A total of 91 patients were screened with 18 patients being excluded. Patients were followed for 5 years and assessed with Frankel score, American Spinal Injury Association (ASIA) score, visual analog scale (VAS) score, Short Form (SF)-36 score, and radiographic images for kyphosis. There was no significant difference in clinical or radiographic outcomes between patients managed with or without fusion. The nonfusion group had shorter operative times and lower blood loss ($P < .05$), while donor site pain appeared to be a prevalent issue in the fusion group. Of note, the type B fractures included in this study had a load sharing score of ≤ 6 . This paper offers level I evidence, having fulfilled the criteria without exception, that there is no difference in clinical and radiographic outcome between fusion and nonfusion strategies. Jindal

et al³ reported on 47 patients with thoracolumbar burst fractures in a prospective randomized trial treated with short segment instrumentation with posterior spinal fusion (n = 23) and without posterior spinal fusion (n = 24). Average follow-up was a minimum of 15 months with a mean of 24 months for the study. Outcomes that were measured included the Greenough low back outcomes score and ASIA score, as well as radiographic images for angle of kyphosis. A total of 70 patients were screened and 20 patients were excluded for randomization. During the trial, an additional 3 patients were excluded because of noncompliance with the protocol. Patients were treated with short segment open pedicle instrumentation with or without arthrodesis using iliac crest autograft. No decompression was performed. All patients were also treated with an external brace for 3 months. The results showed no difference in clinical and radiographic outcomes between the groups. Blood transfusion requirements and length of surgery were significantly higher in the fusion group. This study provides level I evidence, having fulfilled the criteria without exception, that there is no difference in clinical and radiographic outcomes between fusion and nonfusion stabilization.

Chou et al⁴ reported 46 adult patients <65 years of age with Denis type A and B burst fractures between T12 and L2, who were randomly assigned to treatment with short segment pedicle instrumentation with posterior lateral arthrodesis (n = 24) and without (n = 22). Included patients had at least 10 years of follow-up. Outcomes included the Greenough low back outcome score and VAS, as well as radiographic images. Clinical and radiographic outcomes were similar between the 2 groups at all time points without significant differences. Though regional motion was preserved in the nonfusion group, the nonfusion group also underwent additional surgery more often to remove the spinal implants. Although this paper was designed as a randomized

trial, it was downgraded because of the lack of power analysis and blinding. Therefore, this paper provides level II evidence that there is no difference in clinical and radiographic outcomes with or without the addition of arthrodesis to short segment instrumentation for thoracolumbar burst fractures.

Tezeren et al⁵ reported on 42 consecutive patients in a prospective randomized trial of thoracolumbar burst fractures treated with long segment spinal fixation with fusion (n = 21) versus without fusion (n = 21). Median follow-up was 35 months. Outcome measures included Greenough low back outcome score and radiographic parameters for angulation and vertebral body height. Long segment fusion surgery was performed with hook and claw constructs 2 levels above and below the injury site. In the fusion group, bone graft was harvested from the iliac crest, as well as spinous process and lamina in the area of surgery, mixed with bone chips, and applied as a short arthrodesis just 1 level above and below the injury. Both groups had a similar outcome regarding radiographic parameters, as well as low back outcome score. The fusion group also had longer operative time, increased blood loss, and increased pain from the bone donor site. Although this paper was designed as a randomized trial demonstrating that fusion is not necessary with long segment fixation, it was downgraded from level I to level II evidence because the method of randomization was not reported. There was also a lack of blinding and power analysis. This study provides level II evidence that there is similar clinical and radiographic outcome between surgery with and without fusion.

Wang et al⁶ reported on 58 patients in a prospective randomized trial treated with open short segment fixation with or without fusion. Patients were included if they were: 1) neurologically

intact with a kyphotic angle of $\geq 20^\circ$, $\geq 50\%$ vertebral body height loss, or canal compromise of $>50\%$, or 2) had incomplete neurologic deficit with canal compromise $<50\%$. The authors also included complete neurologic deficit and multilevel spinal injury as inclusion criteria. Patients were excluded if they required a subsequent anterior procedure. Surgery was performed as an open short segment fixation with a “lordosing” screw placed at the level of injury. Intraoperative distraction was applied. Iliac crest, as well as lamina and spinous process, were harvested as autograft. It is unclear whether patients underwent a decompression. Follow-up was 41 months on average (range 24–71 months). Clinical outcomes were no different between the 2 groups. Radiographic parameters were better in the nonfusion group regarding angulation and loss of vertebral body height. At final follow-up, the average kyphotic angle was 11.5° with fusion and 9.8° without fusion, which was not significantly different. Nonfusion patients also had less blood loss and experienced shorter surgery times and less donor site pain. Although this study was designed as a randomized trial demonstrating that fusion is not necessary in the treatment of thoracolumbar burst fractures, it was downgraded from level I to level II evidence because of poor randomization methods, a lack of blinding, and a lack of power analysis. This paper provides level II evidence that there are no clinical differences between surgery with and without fusion.

In 2009, Hwang, et al⁷ performed a retrospective study of 74 patients with unstable burst fractures from T11 to L2 with 3 years of follow-up. Short segment pedicle screw fixation with fusion (n = 35) and without fusion (n = 39) were followed with radiographic images (XR and CT), VAS, and clinical/hospital metrics. Fusion patients had better maintenance of kyphosis correction during follow-up compared to nonfusion patients, who seemed to do well initially but

who could not maintain the correction of kyphosis. Screw loosening was also observed more often in nonfusion patients. However, fusion patients also had longer surgeries and increased blood loss. This paper is a retrospective review and offers level III evidence that fusion provides better maintenance of deformity correction and less hardware loosening compared to non-fusion.

Question 2

How does the use of minimally invasive techniques (including percutaneous instrumentation) affect outcomes in patients undergoing surgery for thoracic and lumbar fractures compared to conventional open techniques?

Jiang et al⁸ presented a prospective, randomized trial of 61 patients with single level burst fractures from T11 to L2 without neurologic deficit, who were treated with percutaneous stabilization (n = 31) or open paraspinal pedicle stabilization (n = 30). All patients had ≥ 3 years of follow-up. Outcome measures included radiographic metrics, VAS score, and Oswestry Disability Index (ODI) score. Power analysis determined a sample size of 28 patients per group for the expected differences. Paraspinal surgery resulted in significantly better vertebral body height (13% vs 2% correction, $P < .001$) and kyphosis correction (9° vs 0.4° corrected, $P < .001$) compared with percutaneous fixation. Three-month postoperative ODI and pain scores favored percutaneous fixation, but they were not different at any other time point. Although this study was designed as a randomized trial, the paper was downgraded to level II evidence favoring open

surgery over percutaneous surgery because of a lack of randomization method, a lack of blinding, and possible heterogeneity of fracture types (mixture of stable and unstable fractures).

Vanek et al's 2014 study⁹ reported on 37 consecutive patients with single level thoracolumbar AO A3.1–3.3 fractures without neurologic deficits treated prospectively with short segment pedicle instrumentation performed either in standard open surgery (n = 19) or with percutaneous minimally invasive surgery (n = 18). Outcomes included VAS score, daily activity scale, return to work, and radiographic images for angulation and height. Patients had a minimum of 2 years of follow-up. External bracing was not used. Patients treated with fusion had local bone mixed with bone substitute. Results showed that the percutaneous screw group had shorter surgery with lower blood loss. Postoperative pain at 7 days was lower in the percutaneous screw group. Radiographic outcomes were no different for angulation and vertebral body height during follow-up. There was no significant difference in the patient's satisfaction or return to work at 2 years. This paper is a prospective observational cohort study and provides level II evidence that percutaneous fixation is as effective as open fixation, although it had relatively small groups, and selection bias may be present.

In 2013, Grossbach et al¹⁰ published a retrospective cohort study of 39 patients with flexion-distraction injuries (not burst fractures) between T4 and L2 that were treated with open stabilization (n = 27) or percutaneous stabilization (n = 11). The average follow-up was 18.5 months for the open group and 9 months for the percutaneous group. Outcome measures included radiographic and operative metrics. No difference in radiographic measurements were observed between the groups, although patients with percutaneous fixation had shorter surgery

and less blood loss. This paper provides level III evidence that there is little difference in radiographic between percutaneous and open fixation for treating flexion-distraction injuries.

Lee et al¹¹ reported on a retrospective cohort study of 59 patients with Denis burst fractures without neurologic injury treated with percutaneous fixation (n = 32) versus open fixation (n = 27). Follow-up was an average of 30 months for the percutaneous group and 40 months for the open fixation group. Outcome measures included radiographic metrics, VAS, Low Back Outcome score (LBOS), and Frankel score. Percutaneous stabilization resulted in less blood loss, a shorter surgery time, and significantly improved 3- and 6-month VAS and LBOS scores. There were no differences between cohorts regarding radiographic results or final long-term clinical outcomes. This paper provides level III evidence that percutaneous stabilization is similar to open stabilization but also leads to improved short-term clinical outcomes and improved perioperative metrics.

In 2013, Dong et al¹² published a cohort study of 39 patients with single level thoracolumbar fractures without neurologic deficits treated with percutaneous fixation (n = 18) or intermuscular short segment pedicle instrumentation (n = 21). The average follow-up was 17.3 months (range 5–35 months). Outcome measures included ODI and radiographic metrics. No differences were observed between the 2 groups, except that percutaneous fixation increased operative time and cost. Drawbacks to this study include unclear methods, small cohorts, and short follow-up. This

paper is a retrospective cohort study providing level III evidence that there is no significant difference between percutaneous and open fixation.

In 2010, Wang et al¹³ published a retrospective study of 38 patients with AO A1–3 fractures from T12 to L2 treated with open stabilization (n = 21) or percutaneous stabilization (n = 17). The average follow-up was 11.6 months (range 8–24 months), and outcome measures included radiographic metrics and VAS. Open fixation resulted in better anterior vertebral body height reduction compared to percutaneous fixation (28% vs 21% improvement, $P = .155$), but no differences in Cobb angle or overall height were observed. Open fixation was associated with more complications, including wound issues and malposition of screws. Although this paper was designed as a retrospective cohort study, it was downgraded from level III to level IV because of unclear methods and short follow-up. This paper provides level IV evidence that open fixation results in better radiographic results, but also has more wound and hardware complications compared to percutaneous fixation.

Summary

Question 1

Does the addition of arthrodesis to instrumented fixation improve outcomes in patients with thoracic and lumbar burst fractures?

Recommendation 1

It is recommended that in the surgical treatment of patients with thoracolumbar burst fractures, surgeons should understand that the addition of arthrodesis to instrumented stabilization has

NOT been shown to impact clinical or radiologic outcomes and adds to increased blood loss and operative time.

Strength of Recommendation: Grade A

The literature provides 2 high-quality randomized clinical trials (level I), as well as 3 prospective studies (level II) that show no difference between fusion and nonfusion groups. There is only 1 retrospective study (level III) showing that fusion helps to maintain kyphotic correction and prevents screw loosening. All studies show less blood loss, shorter surgery times, and no donor site–related issues in the nonfusion group.

Question 2

How does the use of minimally invasive techniques (including percutaneous instrumentation) affect outcomes in patients undergoing surgery for thoracic and lumbar fractures compared to conventional open techniques?

Recommendation 2

Stabilization using both open and percutaneous pedicle screws may be considered in the treatment of thoracolumbar burst fractures as the evidence suggests equivalent clinical outcomes.

Strength of Recommendation: Grade B

The literature provides 3 level III studies showing no difference in outcome with percutaneous fixation versus open fixation. There are 2 level II studies that show open fixation is better at correcting a deformity and maintaining the deformity correction compared to percutaneous fixation. There is 1 level IV paper that shows added time and cost with percutaneous fixation, but

no other difference. Because of the comparable level of competing evidence, both percutaneous and open fixation may be considered in treating burst fractures.

Future Research

Further research is needed to clarify the role of fusion in patients who require a decompression in addition to stabilization or in the setting of neurologic injury, as well as to identify potential risk factors for screw loosening in nonfusion patients. It is unclear whether removal of instrumentation has any role in patients treated without arthrodesis. Additional randomized trials are needed to determine the effectiveness of percutaneous fixation alone compared to open fixation without fusion.

Conclusions

The medical literature provides compelling reasons to recognize that there is little difference when instrumenting thoracolumbar burst fractures with or without fusion. This does not necessarily apply for more complex fracture patterns, and the papers used in this guideline generally did not include patients with neurologic injury and need for direct decompression. Harvesting autograft for fusion predictably led to longer surgery times, increased blood loss, and more donor site issues. The medical literature provides comparable and competing evidence for percutaneous fixation. Percutaneous fixation may be effective at reducing blood loss and operative time. However, there is no conclusive evidence that percutaneous fixation is any better or worse than open fixation.

Potential Conflicts of Interest

The task force members were required to report all possible conflicts of interest (COIs) prior to beginning work on the guideline, using the COI disclosure form of the AANS/CNS Joint Guidelines Committee, including potential COIs that are unrelated to the topic of the guideline. The CNS Guidelines Committee and Guideline Task Force Chairs reviewed the disclosures and either approved or disapproved the nomination. The CNS Guidelines Committee and Guideline Task Force Chairs are given latitude to approve nominations of Task Force members with possible conflicts and address this by restricting the writing and reviewing privileges of that person to topics unrelated to the possible COIs. The conflict of interest findings are provided in detail in the companion [introduction and methods manuscript](#).

Disclaimer of Liability

This clinical systematic review and evidence-based guideline was developed by a multidisciplinary physician volunteer task force and serves as an educational tool designed to provide an accurate review of the subject matter covered. These guidelines are disseminated with the understanding that the recommendations by the authors and consultants who have collaborated in their development are not meant to replace the individualized care and treatment advice from a patient's physician(s). If medical advice or assistance is required, the services of a competent physician should be sought. The proposals contained in these guidelines may not be suitable for use in all circumstances. The choice to implement any particular recommendation contained in these guidelines must be made by a managing physician in light of the situation in each particular patient and on the basis of existing resources.

Disclosures

These evidence-based clinical practice guidelines were funded exclusively by the Congress of Neurological Surgeons and the Section on Disorders of the Spine and Peripheral Nerves in collaboration with the Section on Neurotrauma and Critical Care, which received no funding from outside commercial sources to support the development of this document.

Acknowledgments

The guidelines task force would like to acknowledge the CNS Guidelines Committee for their contributions throughout the development of the guideline and the AANS/CNS Joint Guidelines Committee for their review, comments, and suggestions throughout peer review, as well as the contributions of Trish Rehring, MPH, CHES, Senior Manager of Clinical Practice Guidelines for the CNS, and Mary Bodach, MLIS, Guidelines Specialist and Medical Librarian for assistance with the literature searches. Throughout the review process the reviewers and authors were blinded from one another. At this time, the guidelines task force would like to acknowledge the following individual peer reviewers for their contributions: Maya Babu, MD, MBA, Greg Hawryluk, MD, PhD, Steven Kalkanis, MD, Yi Lu, MD, PhD, Jeffrey J. Olson, MD, Martina Stippler, MD, Cheerag Upadhyaya, MD, MSc, and Robert Whitmore, MD.

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Appendix I. Literature Searches

Search Strategies

PubMed

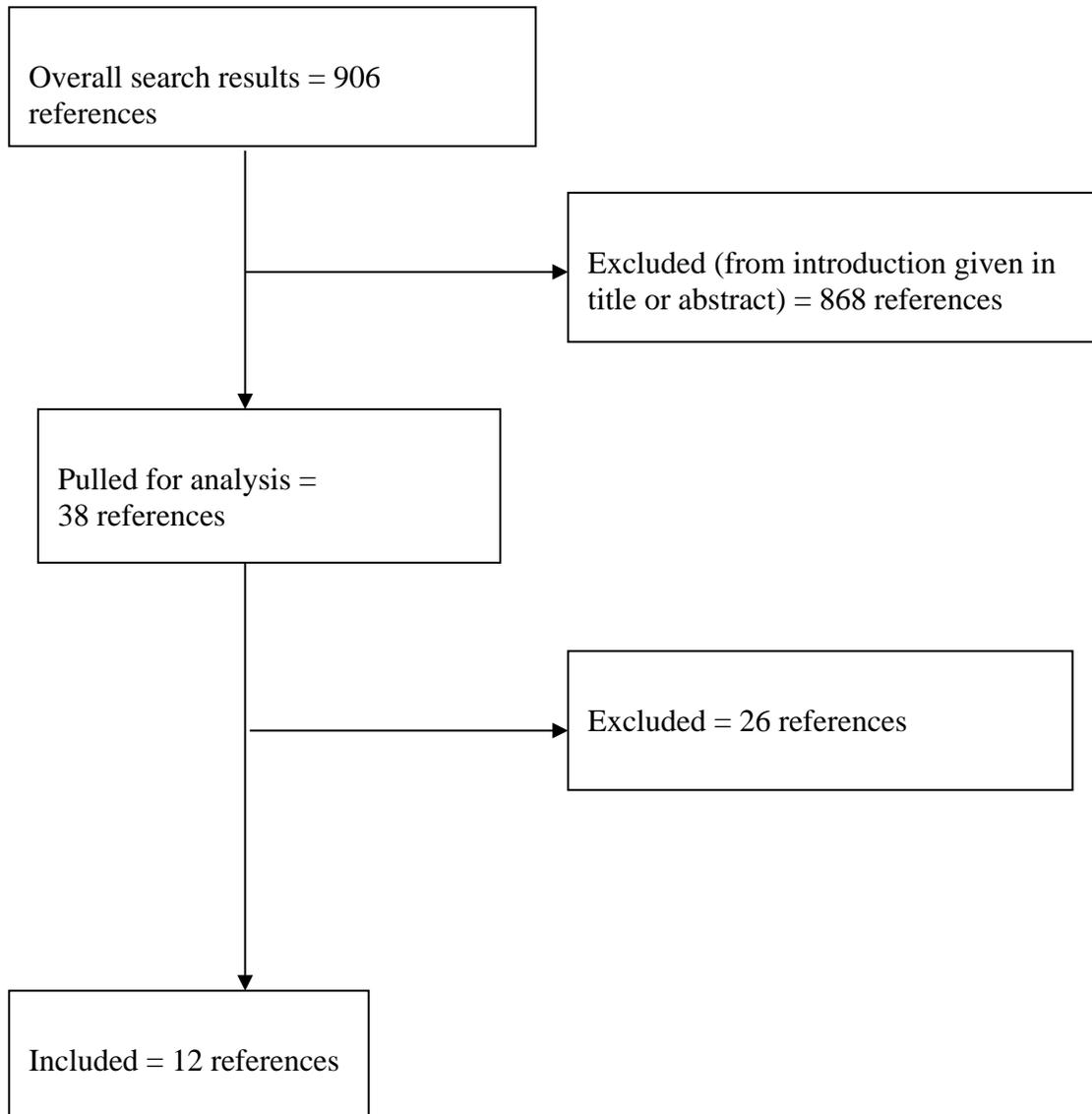
1. Lumbar vertebrae [MeSH] OR Thoracic vertebrae [MeSH]
2. Spinal Injuries [MeSH] OR Spinal Cord Injuries [MeSH]
3. #1 AND #2
4. Thoracolumbar [TIAB] OR thoraco-lumbar [TIAB] OR thoraco lumbar [TIAB] OR burst [Title]
5. Injur* [TIAB] OR trauma* [TIAB] OR fractur* [TIAB] OR dislocation* [TIAB]
6. #4 AND #5
7. Lumbar vertebrae/injuries [MeSH] OR Thoracic vertebrae/injuries [MeSH] (3150 results)
8. #3 OR #6 OR #7
9. Minimally Invasive surgical Procedures [MeSH]
10. minimal* invasive OR percutaneous or “minimal access”[TIAB]
11. Fusion [title] OR spondylodes*[title] OR spondylosyndes*[title] OR arthrodes*[title] OR fixation[title]
12. #9 OR #10 OR #11
13. #8 AND #12
14. (animal [MeSH] NOT human [MeSH]) OR cadaver [MeSH] OR cadaver* [Titl] OR comment [PT] OR letter [PT] OR editorial [PT] OR addresses [PT] OR news [PT] OR “newspaper article” [PT] OR case reports [PT]
15. #13 NOT #14
16. osteoporosis [MH] OR osteoporotic fractures [MH] OR osteoporo* [TITLE] OR spinal neoplasms [MH] OR tumor* [TITLE] OR tumour* [TITLE] OR malignan* [TITLE]
17. #15 NOT #16
18. #16 AND English [Lang]
19. 11 AND ("1946/01/01"[PDAT] : "2015/03/31"[PDAT])

Cochrane Library

1. Lumbar vertebrae: MeSH descriptor, explode all trees
2. Thoracic vertebrae: MeSH descriptor, explode all trees
3. #1 OR #2
4. Spinal Injuries: MeSH descriptor
5. Spinal Cord Injuries: MeSH descriptor
6. #4 OR #5
7. #3 AND #6
8. (Thoracolumbar OR thoraco-lumbar OR thoraco lumbar OR burst) NEAR/4 (Injur* OR trauma* OR fractur* OR dislocation*):ti,ab,kw
9. Lumbar vertebrae/injuries: MeSH descriptor, explode all trees
10. Thoracic vertebrae/injuries: MeSH descriptor, explode all trees
11. #9 OR #10
12. #7 OR #8 OR #11
13. mh osteoporosis or mh osteoporotic fractures or mh spinal neoplasms
14. osteoporo* or tumor* or malignan*:ti
15. #13 OR #14
16. #12 NOT #15

Appendix II. Article Inclusions and Exclusions

Included and Excluded Articles Flowchart



Appendix III. Rating Evidence Quality

Levels of Evidence for Primary Research Question^a

Types of studies				
	Therapeutic studies – Investigating the results of treatment	Prognostic studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic studies – Investigating a diagnostic test	Economic and decision analyses – Developing an economic or decision model
Level I	<ul style="list-style-type: none"> • High-quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic review^b of level I RCTs (and study results were homogenous^c) 	<ul style="list-style-type: none"> • High-quality prospective study^d (all patients were enrolled at the same point in their disease with $\geq 80\%$ follow-up of enrolled patients) • Systematic review^b of level I studies 	<ul style="list-style-type: none"> • Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) • Systematic review^b of level I studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review^b of level I studies
Level II	<ul style="list-style-type: none"> • Lesser quality RCT (e.g., $\leq 80\%$ follow-up, no blinding, or improper randomization) • Prospective^d comparative study^e • Systematic review^b of level II studies or level I studies with inconsistent results 	<ul style="list-style-type: none"> • Retrospective^f study • Untreated controls from an RCT • Lesser quality prospective study (e.g., patients enrolled at different points in their disease or $\leq 80\%$ follow-up) • Systematic review^b of level II studies 	<ul style="list-style-type: none"> • Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) • Systematic review^b of level II studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review^b of level II studies

Level III	<ul style="list-style-type: none"> • Case control study^g • Retrospective comparative study^e • Systematic review^b of level III studies 	<ul style="list-style-type: none"> • Case control study^g 	<ul style="list-style-type: none"> • Study of non consecutive patients; without consistently applied reference “gold” standard • Systematic review^b of level III studies 	<ul style="list-style-type: none"> • Analyses based on limited alternatives and costs; and poor estimates • Systematic review^b of level III studies
Level IV	Case series ^h	Case series	<ul style="list-style-type: none"> • Case-control study • Poor reference standard 	<ul style="list-style-type: none"> • Analyses with no sensitivity analyses

RCT, Randomized controlled trial.

^aA complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

^bA combination of results from ≥ 2 previous studies.

^cStudies provided consistent results.

^dStudy was started before the first patient enrolled.

^ePatients treated one way (e.g., instrumented arthrodesis) compared with a group of patients treated in another way (e.g., unsinstrumented arthrodesis) at the same institution.

^fThe study was started after the first patient enrolled.

^gPatients identified for the study based on their outcome, called “cases” (e.g., pseudoarthrosis) are compared to those who did not have outcome, called “controls” (e.g., successful fusion).

^hPatients treated one way with no comparison group of patients treated in another way.

Appendix IV. Linking Levels of Evidence to Grades of Recommendation

Grade of Recommendation	Standard Language	Levels of Evidence	
A	Recommended	Two or more consistent level I studies	
B	Suggested	One level I study with additional supporting level II or III studies	Two or more consistent level II or III studies
C	Is an option	One level I, II, or III study with supporting level IV studies	Two or more consistent level IV studies
Insufficient (insufficient or conflicting evidence)	Insufficient evidence to make recommendation for or against	A single level I, II, III, or IV study without other supporting evidence	>1 study with inconsistent findings ^a

^aNote that in the presence of multiple consistent studies, and a single outlying, inconsistent study, the Grade of Recommendation will be based on the level of the consistent studies.

Appendix V. Criteria Grading the Evidence

The task force used the criteria provided below to identify the strengths and weaknesses of the studies included in this guideline. Studies containing deficiencies were downgraded one level (no further downgrading allowed, unless so severe that study had to be excluded). Studies with no deficiencies based on study design and contained clinical information that dramatically altered current medical perceptions of topic were upgraded.

1. Baseline study design (i.e., therapeutic, diagnostic, prognostic) determined to assign initial level of evidence.
2. Therapeutic studies reviewed for following deficiencies:
 - Failure to provide a power calculation for an RCT;
 - High degree of variance or heterogeneity in patient populations with respect to presenting diagnosis/demographics or treatments applied;
 - <80% of patient follow-up;
 - Failure to utilize validated outcomes instrument;
 - No statistical analysis of results;
 - Cross over rate between treatment groups of >20%;
 - Inadequate reporting of baseline demographic data;
 - Small patient cohorts (relative to observed effects);
 - Failure to describe method of randomization;
 - Failure to provide flowchart following patients through course of study (RCT);
 - Failure to account for patients lost to follow-up;
 - Lack of independent post-treatment assessment (e.g., clinical, fusion status, etc.);
 - Utilization of inferior control group:
 - Historical controls;
 - Simultaneous application of intervention and control within same patient.
 - Failure to standardize surgical/intervention technique;
 - Inadequate radiographic technique to determine fusion status (e.g., static radiographs for instrumented fusion).
3. Methodology of diagnostic studies reviewed for following deficiencies:
 - Failure to determine specificity and sensitivity;
 - Failure to determine inter- and intraobserver reliability;
 - Failure to provide correlation coefficient in the form of kappa values.
4. Methodology of prognostic studies reviewed for following deficiencies:
 - High degree of variance or heterogeneity in patient populations with respect to presenting diagnosis/demographics or treatments applied;
 - Failure to appropriately define and assess independent and dependent variables (e.g., failure to use validated outcome measures when available).

Appendix VI. Evidence Tables

Author, Year	Level of Evidence	Task Force Conclusions Relative to Question and Rationale for Evidence Grading
Chou et al, ⁴ 2014	II	This paper provides evidence that there is no difference in outcome between fusion and nonfusion groups. Regional motion preserved in nonfusion group. Hardware removal surgery higher in nonfusion group
Dai et al, ² 2009	I	This paper provides evidence that there is no difference between fusion and nonfusion. Nonfusion patients had shorter OR times, less blood loss, and less donor site pain
Dong et al, ¹² 2013	III	This paper provides evidence that there are no differences between percutaneous and open fixation with respect to operating time. Percutaneous fixation was associated with longer hospitalization times and increased cost
Grossbach et al, ¹⁰ 2013	III	This paper provides evidence that there is little difference between percutaneous and open fixation
Hwang et al, ⁷ 2009	III	This paper provides evidence that fusion patients had better maintenance of kyphosis, although with longer surgery times and more blood loss
Jiang et al, ⁸ 2012	II	This paper provides evidence that open (paraspinal) fixation resulted in better vertebral body height and kyphosis correction over percutaneous fixation
Jindal et al, ³ 2012	I	This paper provides evidence that there is no difference between fusion and nonfusion groups. Nonfusion patients had shorter OR times and fewer blood transfusions
Lee et al, ¹¹ 2013	III	This paper provides evidence that there is no clinical or long-term clinical difference between percutaneous and open fixation. Percutaneous fixation had shorter OR times and less blood loss
Tezeren et al, ⁵ 2009	II	This paper provides evidence that radiographic parameters and low back pain scores are the same at follow-up between fusion and nonfusion groups. Fusion patients had longer surgeries, increased blood loss, and more donor site pain
Vanek et al, ⁹ 2014	II	This paper provides evidence that percutaneous fixation is as effective as open fixation. Percutaneous fixation had shorter OR times, less blood loss, and lower postoperative pain at 7 days

Author, Year	Level of Evidence	Task Force Conclusions Relative to Question and Rationale for Evidence Grading
Wang et al, ⁶ 2006	II	This paper provides evidence that clinical outcomes are similar between fusion and nonfusion patients. Nonfusion patients had less blood loss, shorter OR times, and less donor site pain
Wang et al, ¹³ 2010	IV	This paper provides evidence that open fixation results in a nonsignificant improvement of vertebral body height reduction compared to percutaneous, but was also associated with more complications