

Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 1: Introduction and methodology

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Fusion procedures are an accepted and successful management strategy to alleviate pain and/or neurological symptoms associated with degenerative disease of the lumbar spine. In 2005, the first version of the “Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine” was published in the *Journal of Neurosurgery: Spine*. In an effort to incorporate evidence obtained since the original publication of these guidelines, an expert panel of neurosurgical and orthopedic spine specialists was convened in 2009. Topics reviewed were essentially identical to the original publication. Selected manuscripts from the first iteration of these guidelines as well as relevant publications between 2005 through 2011 were reviewed. Several modifications to the methodology of guideline development were adopted for the current update. In contrast to the 2005 guidelines, a 5-tiered level of evidence strategy was employed, primarily allowing a distinction between lower levels of evidence. The qualitative descriptors (standards/guidelines/options) used in the 2005 recommendations were abandoned and replaced with grades to reflect the strength of medical evidence supporting the recommendation. Recommendations that conflicted with the original publication, if present, were highlighted at the beginning of each chapter. As with the original guideline publication, the intent of this update is to provide a foundation from which an appropriate treatment strategy can be formulated. (<http://thejns.org/doi/abs/10.3171/2014.4.SPINE14257>)

KEY WORDS • lumbar spine • lumbar fusion • practice guidelines

FUSION procedures have become a necessary element of the surgeon's armamentarium in the treatment of lumbar degenerative disease. The application of these surgical procedures continues to expand as technological advances facilitate our ability to achieve a solid arthrodesis and our understanding of the pathological and biomechanical aspects of degenerative spine disease improves.

Utilizing national Medicare data from the Dartmouth Atlas Project, Weinstein et al. have identified a steady increase in lumbar fusion surgeries between 1992 and 2003 in patients over the age of 65, from 0.3/1000 to 1.1/1000

enrollees.⁶ A 20-fold variation in regional rates among enrollees was also identified, representing the largest regional variation for any surgical procedure. During this interval the annual amount spent for lumbar fusion surgeries rose 500%, to 482 million dollars in 2003.⁶ Although Deyo et al. identified a slight decline in the number of lumbar fusion procedures performed among Medicare beneficiaries between 2002 and 2007, the number of complex fusion procedures increased 15-fold, from 1.3 to 19.9 procedures for every 100,000 beneficiaries.¹ With this increase in the complexity of surgery performed, an increase in costs, morbidity, and resource utilization has also been observed. Utilizing the Nationwide Inpatient Sample database, Kalanithi et al. demonstrated a 70% increase in the rate of complications following lumbar fusion in patients over

Abbreviation used in this paper: NASS = North American Spine Society.

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65 years of age when compared with patients between 45 and 64 years of age.⁴ As a result of this increasing rate of lumbar fusions, expansion of indications, and complexity of surgery, the socioeconomic impact has become more closely scrutinized, requiring that medical evidence justify the application of these procedures.

In 2005, the first iteration of the “Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine” was published in the *Journal of Neurosurgery: Spine*.⁵ This comprehensive compendium outlined 16 topics pertaining to the performance of lumbar fusion surgery for degenerative spinal disease, providing 50 recommendations based on a review of the medical literature published between 1966 and 2003. Given the time dependency of a literature review, clinical practice guidelines are evolving documents that require periodic updating as new information and knowledge accumulates. The purpose of the current series, “Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine,” is to incorporate the more recent medical evidence that has been published since the original publication and establish new recommendations.

In 2009, an expert panel of neurosurgical and orthopedic spine surgeons was convened, many having participated in the original guidelines effort. All members had experience with clinical guideline development and had completed the evidence-based medicine course developed by the North American Spine Society (NASS). As the current document is to serve as an update, identical topics and search terms were selected from the original guideline publication.

Methodology

The development of evidence-based clinical guidelines is a multistep process, the basis of which has been well described.³ The current update was constructed through a series of steps, similar to the previous guideline efforts:

1. Selection of topics to study
 - a. As this is an update, the same topics from the original guidelines were chosen.
2. Performing a literature search
 - a. Searches were limited to English studies investigating human subjects.
3. Collecting relevant studies for review
 - a. Searches were reviewed and studies specifically investigating the topic under consideration were chosen.
4. Assessing the quality and strength of the evidence
 - a. Modified NASS strategy
5. Formulation of recommendations based on the evidence
 - a. Modified NASS strategy
6. Panel review of the evidentiary tables
 - a. Consensus method used to establish uniformity of response
7. Submission of guidelines for peer review

As previously stated, the first two steps were based on the topics and search terms used in the original guideline submission.

The literature searches were conducted with the assistance of a librarian who had extensive experience formulating and conducting evidence-based literature searches. Search terms from the original guidelines were used and altered as deemed necessary. Searches of the National Library of Medicine and Cochrane database were conducted from the termination of the original searches, in 2003, through December of 2011. The abstracts were reviewed and all relevant publications were selected for formal assessment. Bibliographies were reviewed from selected publications and appropriate studies selected. The specifics of each search, including the MeSH terms, are described in each chapter.

Topics were assigned to individual panel members, with the primary assignee intended to perform the assessment of evidence and a second panel member intended to review the evidentiary table prior to presentation to the entire panel. Each assignee formulated preliminary recommendations based on their review of the literature. The expert panel completed final determination of the levels of evidence and recommendation grades after reviewing the evidentiary tables.

In an effort to conform to spine guidelines published from other clinical societies, as well as maintain an objective assessment of the evidence, the current panel elected to deviate from the methodology employed in the original guidelines and use the NASS strategy for evidence assessment and recommendation grading (see Tables 1 and 2). As there are no uniformly accepted methods for downgrading evidence, the panel decided to limit downgrading of evidence by no more than one level to avoid excessive subjectivity.

As the current publication is intended to serve as an update of the previous guidelines, the decision was made to include all Level I and II evidence from the original guidelines. A reevaluation of these studies utilizing the NASS strategy was necessary. The panel agreed not to include lower levels of evidence, as these studies were not likely to enhance the updated recommendations.

Quality of Medical Evidence

The foundation for any evidence-based practice guidelines rests on the assessment of medical evidence. The NASS assessment of medical evidence is a 5-tiered strategy that assigns separate levels to “case series” and “expert opinion” (see Table 1). This highlights the major difference between the 3-tiered approach used in the original guideline publication, where the decision was made to combine all lower levels of evidence. This distinction becomes relevant when grading recommendations.

Each study was categorized according to the underlying objective—therapeutic, diagnostic, or prognostic. The initial level of evidence was determined by defining the overall study design. For example, a randomized control trial would start as Level I evidence while a retrospective review could start no higher than Level III. The study’s methodology was then analyzed to determine if the nec-

TABLE 1: Levels of medical evidence for primary research topic

Level	Therapeutic Study— Investigating the Effectiveness of Treatment	Diagnostic Study— Investigating the Accuracy of a Diagnostic Test	Prognostic Study— Investigating the Impact That a Baseline Characteristic Has on Disease Outcome	Economic Analysis— Formulating an Economic Model to Determine the Cost Effectiveness of Treatment
I	1. Well-designed RCT w/ appropriate statistical analysis/ reporting a. No major limitations* b. No more than 1 minor limitation* 2. Systematic review of well- designed RCTs w/ consistent findings	1. Evaluation of previously established diagnostic test/ criteria a. Consecutively enrolled patients b. Application of reference “gold” standard 2. Systematic review of Level I studies	1. Well-designed prospective study w/ patient enrollment occurring at same time point in disease process a. At least 80% follow-up at study end point 2. Systematic review of Level I studies	1. Inclusion of sensible/realistic costs & treatment alternatives a. Data derived from multitude of sources b. Multi-way sensitivity analysis performed 2. Systematic review of Level I studies
II	1. Prospective comparative study 2. Systematic review of Level II studies or review of Level I studies w/ inconsistent findings	1. Formulation of diagnostic criteria/test a. Consecutively enrolled patients b. Application of reference “gold” standard 2. Systematic review of Level II studies	1. Retrospective review 2. Study population derived from untreated controls of an RCT 3. Inferior prospective study a. Patient enrolled at different time points b. Less than 80% follow-up 4. Systematic review of Level II studies	1. Inclusion of sensible/realistic costs & treatment alternatives a. Data derived from limited studies b. Multi-way sensitivity analysis performed 2. Systematic review of Level II studies
III	1. Case control studies 2. Retrospective comparative studies 3. Systematic review of Level III studies	1. Study of nonconsecutive patients a. Failure to consistently apply reference “gold” standard	1. Case control study	1. Study analysis based on incomplete costs & failure to consider alternative treatments 2. Systematic review of Level III studies
IV	1. Case series	1. Case control study 2. Utilization of poor reference standard	1. Case series	1. Failure to include sensitivity analysis
V	1. Expert opinion	1. Expert opinion	1. Expert opinion	1. Expert opinion

* See Table 3 for listing of major and minor limitations of study design utilized to determine level of medical evidence. RCT = randomized controlled trial.

essary criteria were fulfilled to maintain the initial level of evidence. These criteria were in part based on the NASS strategy as well as the panel’s scientific and clinical experience and are listed in Table 3. Downgrading of therapeutic studies occurred if at least 1 major or 2 minor limitations were identified. For the other study categories, these criteria were considered as well as those specifically outlined in Table 3.

Studies that met all criteria and contained data that would significantly alter current medical practice would be upgraded; however, no study met these criteria. During the panel review of the evidentiary tables, consensus method was used to resolve any disagreement.² Ultimately, the panel achieved unanimous agreement for every study evaluated in the evidentiary tables.

Formulation of Treatment Recommendations

The primary investigator for a given topic, prior to the consensus development process, formulated preliminary recommendations. During panel discussions the decision was made as to which studies would serve as the basis for the final recommendations, and these studies were includ-

ed within the “Scientific Foundation” for a given topic. In general, if high-quality evidence (Level I and II data) was available to formulate a recommendation, lesser-quality evidence was not included. Studies of low quality that conflicted with high-quality evidence were not included in the evidentiary tables, but this discrepancy was mentioned in the “Scientific Foundation.”

The expert panel assigned a grade to each recom-

TABLE 2: Recommendation grades

Grade	Definition
A	Good evidence—2 or more Level I studies w/ consistent findings
B	Fair evidence—single Level I study or multiple Level II or III studies w/ consistent findings
C	Poor evidence—single Level II study or multiple Level IV or V studies
I	Insufficient evidence for recommendation—single Level III, IV, or V study; studies of equivalent strength w/ conflicting findings/conclusions

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TABLE 3: Classification of study limitations

Major limitations
Failure to provide a power calculation for an RCT
Failure to utilize validated outcomes measures
Heterogeneous patient population
More than 20% patients lost to follow-up
Failure to perform statistical analysis
Crossover rate >20% btwn cohorts
Minor limitations
Inadequate reporting of baseline demographics
Small sample size (<50 patients per treatment group for comparative studies or <50 total enrolled patients for noncomparative studies)
Failure to describe method of randomization
Lack of flow chart following patients' course through study
Failure to account for patients lost to follow-up
Failure to perform independent clinical or radiographic analysis
Utilization of inferior control cohort (e.g., historical control group)
Treatment & control simultaneously applied to same patient
Failure to standardize surgical technique
Inferior radiographic analysis of fusion (e.g., static radiographs)
Clinical &/or radiographic follow-up <1 year

mentation based on the strength of the supporting evidence. Instead of a qualitative description of recommendation grade, as performed in the original guidelines, the expert panel chose to use recommendation grades modified from NASS (see Table 2). The baseline NASS strategy was used, but modifications were included to address instances in which a single study provided evidence for a specific recommendation. The highest-quality recommendation, Grade “A,” required 2 or more Level I studies with consistent findings. Fair evidence, either a single Level I study or consistent findings from multiple Level II or III studies, was given a Grade “B” recommendation. Poor-quality evidence would support a Grade “C” recommendation, including either a single Level II study or consistent findings from Level IV or V studies. Recommendations based on a single Level III or lower-level study or studies of equal strength that demonstrated conflicting results were given a Grade “I” designation.

Summary

As greater emphasis is placed on validating the surgical treatments for our patients, particularly with regard to spine surgery, the necessity for evidence-based clinical guidelines is becoming increasingly apparent. Given the time dependency of a literature review, all clinical practice guidelines are evolving documents that require periodic updating. As an update, the current publication was intended to build on the foundation established by the original lumbar fusion guidelines. After careful evaluation, the current expert panel felt it necessary to reconsider the methodology of previous guidelines. These changes were incorporated in an effort to perform a more

objective evaluation and allow for easier communication among clinicians from other subspecialty organizations.

Although emphasis has recently been placed on evidence-based clinical practice and improving the method of scientific investigation, the panel frequently encountered studies of inferior quality. Despite this limitation, one objective of the current update is to identify areas of future research and stimulate more objective clinical investigation. It is the hope that the well-informed reader will carefully evaluate the “Scientific Foundation” to understand the justification for a given recommendation. As with previous guideline efforts, there is a risk of specialty bias as no nonsurgical stakeholders were involved in the development of this update. Although the potential for this bias exists, considerable effort was taken to try and objectively evaluate the current literature.

These guidelines are not intended to provide rigid treatment algorithms. Instead, it is hoped that this update will serve as a comprehensive review of the current state of the literature and provide the reader with a foundation to formulate an appropriate individualized treatment plan for a given patient. Furthermore it is the intent of any guideline to identify current limitations of the literature and stimulate further investigational research.

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