Complete Summary

GUIDELINE TITLE

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 9: fusion in patients with stenosis and spondylolisthesis.

BIBLIOGRAPHIC SOURCE(S)

Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, Mummaneni P, Watters WC 3rd, Wang J, Walters BC, Hadley MN, American Association of Neurological Surgeons/Congress of Neurological Surgeons. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 9: fusion in patients with stenosis and spondylolisthesis. J Neurosura Spine 2005 Jun;2(6):679-85. [34 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS **QUALIFYING STATEMENTS** IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT **CATEGORIES**

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Degenerative disease of the lumbar spine: stenosis and spondylolisthesis

GUIDELINE CATEGORY

Management Treatment

CLINICAL SPECIALTY

Internal Medicine Neurological Surgery Neurology Orthopedic Surgery Physical Medicine and Rehabilitation

INTENDED USERS

Health Plans Managed Care Organizations Physicians

GUIDELINE OBJECTIVE(S)

To examine the literature concerning the role of fusion after decompression surgery in patients with degenerative spondylolisthesis and stenosis

TARGET POPULATION

Patients with stenosis and spondylolisthesis

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Lumbar posterolateral fusion (PLF) in addition to decompression
- 2. Pedicle screw fixation as an adjunct to lumbar fusion

MAJOR OUTCOMES CONSIDERED

Effectiveness of treatment in terms of pain relief, walking tolerance, functional improvement, medication usage, activities of daily living, and patient satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A computerized search of the database of the National Library of Medicine from 1966 to August 2003 was conducted using the search terms "fusion and degenerative spondylolisthesis." The search was restricted to the English language and yielded 217 references. The titles and abstracts of each of these references were reviewed, and papers not concerned with the use of fusion with degenerative spondylolisthesis were discarded. Eighty-five references were identified that provided either direct or supporting evidence relevant to the use of fusion for degenerative lumbar spondylolisthesis. These papers were reviewed, and relevant references from the bibliographies were identified. All papers providing Class III or

better medical evidence are summarized in Table 1 of the original guideline document. Additional supportive data are provided in references listed in the bibliography of the original guideline.

NUMBER OF SOURCE DOCUMENTS

32 papers providing Class III or better medical evidence are summarized in Table 1 of the original guideline document.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Classes of Evidence

Class I Evidence from one or more well-designed, randomized controlled clinical trials, including overviews of such trials

Class II Evidence from one or more well-designed comparative clinical studies, such as nonrandomized cohort studies, case-control studies, and other comparable studies, including less well-designed randomized controlled trials

Class III Evidence from case series, comparative studies with historical controls, case reports, and expert opinion as well as significantly flawed randomized controlled trials

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The group culled through literally thousands of references to identify the most scientifically robust citations available concerning each individual topic. Not every reference identified is cited. In general, if high-quality (Class I or II) medical evidence was available on a particular topic, poorer-quality evidence was only briefly summarized and rarely included in the evidentiary tables. If no high-quality evidence existed, or if there was significant disagreement between similarly classified evidence sources, then the Class III and supporting medical evidence were discussed in greater detail. If multiple reports were available that provided similar information, a few were chosen as illustrative examples.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In January 2003, a group was formed at the request of the leadership of the Congress of Neurological Surgeons (CNS) by the executive committee of the American Association of Neurological Surgeons/CNS Joint Section on Disorders of the Spine and Peripheral Nerves to perform an evidence-based review of the literature on lumbar fusion procedures for degenerative disease of the lumbar spine and to formulate treatment recommendations based on this review. In March 2003, this group was convened. Invitations were extended to approximately 12 orthopedic and neurosurgical spine surgeons active in the Joint Section or in the North American Spine Society to ensure participation of nonneurosurgical spine surgeons. The recommendations that were developed represent the product of the work of the group, with input from the Guidelines Committee of the American Association of Neurological Surgeons/CNS and the Clinical Guidelines Committee of North American Spine Society.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

Standards Recommendations of the strongest type, based on Class I evidence reflecting a high degree of clinical certainty

Guidelines Recommendations based on Class II evidence reflecting a moderate degree of clinical certainty

Options Recommendations based on Class III evidence reflecting unclear clinical certainty

COST ANALYSIS

Lumbar fusion may be associated with a high short-term cost, especially if instrumentation is placed; however, there appear to be long-term economic benefits associated with lumbar fusion including resumption of employment. To describe the economic impact of lumbar fusion for degenerative disease adequately, it is important to define the patient population treated with fusion and to compare efficacy as well as the costs of other treatment alternatives. Any such analysis should include both short- and long-term costs and benefits.

See "Part 3: assessment of economic outcome" in the "Availability of Companions Documents" field for the complete analysis.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The committee presents data that have been reviewed by the major organizations representing neurological surgery and orthopedic surgery. The Board of Directors of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) Executive Committee have reviewed these Lumbar Fusion Guidelines and formally voted their approval. In addition, input and approval was received and greatly appreciated from the AANS/CNS Guidelines committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Congress of Neurological Surgeons: An addendum has been released for this guideline. See the <u>AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves</u> Web site for details.

The grades of recommendations (standards, guidelines, and options) and classes of evidence (I–III) are defined at the end of the "Major Recommendations" field.

Guidelines. There is insufficient evidence to recommend a treatment guideline.

Options. 1) The performance of a lumbar posterolateral fusion (PLF) is recommended for patients with lumbar stenosis and associated degenerative spondylolisthesis who require decompression. 2) Pedicle screw fixation as an adjunct to lumbar posterolateral fusion should be considered as a treatment option in patients with lumbar stenosis and spondylolisthesis in cases in which there is preoperative evidence of spinal instability or kyphosis at the level of the spondylolisthesis or when iatrogenic instability is anticipated.

Summary

The best medical evidence available in the literature confirms the utility of fusion for improving patient outcomes following decompression for stenosis associated with spondylolisthesis. The majority of evidence from other studies comparing outcomes after decompression alone or decompression combined with PLF in patients with stenosis and spondylolisthesis also favors the performance of PLF. The medical evidence regarding the use of pedicle screw fixation in this patient population is rated as Class III and is inconsistent. A consistent benefit associated with the use of pedicle screw fixation has been reported in patients with preoperative instability or kyphosis. Iatrogenic instability following decompression is associated with poor outcomes and may also be treated with PLF involving supplemental instrumentation. The precise definition of instability or kyphosis has varied among researchers and requires further study.

Definitions:

Grades of Recommendation

Standards Recommendations of the strongest type, based on Class I evidence reflecting a high degree of clinical certainty

Guidelines Recommendations based on Class II evidence reflecting a moderate degree of clinical certainty

Options Recommendations based on Class III evidence reflecting unclear clinical certainty

Classes of Evidence

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of lumbar posterolateral fusion (PLF) and pedicle screw fixation in patients with stenosis and spondylolisthesis

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The precise definition of instability or kyphosis has varied among researchers and requires further study.
- The strength of an evidence-based document is only as strong as the foundation on which it is built. This comprehensive document chronicles the

state of scientific information in 2005. Many of the published reviews presented flawed results due to poorly defined outcome measures, inadequate numbers of patients, and comparison of dissimilar treatment groups. These studies of "apples and oranges" gleaned little scientific information; therefore, for the purpose of this review, the authors have discarded Class III studies whenever stronger scientific evidence was available. The result is that most of the published studies on lumbar fusion were not included on this document. When Class I or II scientific evidence was available, standards and guidelines were formulated; however, in most cases, the scientific data were only adequate to support recommendations for treatment options. The aforementioned results do not detract from the importance of this document; rather, the need for the neurosurgical community to design and complete prospective randomized controlled studies to answer the many lingering clinical questions with rigorous scientific power can clearly be seen. As more data continue to be accumulated, revisions of this document will be needed.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, Mummaneni P, Watters WC 3rd, Wang J, Walters BC, Hadley MN, American Association of Neurological Surgeons/Congress of Neurological Surgeons. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 9: fusion in patients with stenosis and spondylolisthesis. J Neurosurg Spine 2005 Jun;2(6):679-85. [34 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Jun

GUIDELINE DEVELOPER(S)

American Association of Neurological Surgeons - Medical Specialty Society Congress of Neurological Surgeons - Professional Association

SOURCE(S) OF FUNDING

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GUIDELINE COMMITTEE

Guidelines Committee of the American Association of Neurological Surgeons/Congress of Neurological Surgeons (CNS)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Daniel K. Resnick, MD; Tanvir F. Choudhri, MD; Andrew T. Dailey, MD; Michael W. Groff, MD; Larry Khoo, MD; Paul G. Matz, MD; Praveen Mummaneni, MD; William C. Watters III, MD; Jeffery Wang, MD; Beverly C. Walters, MD, MPH; Mark N. Hadley, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

North American Spine Society - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site.

Print copies: Available from Daniel K. Resnick, M.D., Department of Neurological Surgery, University of Wisconsin Medical School, K4/834 Clinical Science Center, 600 Highland Avenue, Madison, Wisconsin 53792; Email: Resnick@neurosurg.wisc.edu.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Introduction to the guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. 2005 Jun. 1 p. Available in Portable Document Format (PDF) from the <u>AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site.</u>
- Guidelines for the performance of fusion procedures for degenerative disease
 of the lumbar spine. Part 1: introduction and methodology. 2005 Jun. 2 p.
 Available in Portable Document Format (PDF) from the <u>AANS/CNS Joint</u>
 Section on Disorders of the Spine and Peripheral Nerves Web site.
- Guidelines for the performance of fusion procedures for degenerative disease
 of the lumbar spine. Part 3: assessment of economic outcome. 2005 Jun. 6 p.
 Available in Portable Document Format (PDF) from the <u>AANS/CNS Joint</u>
 <u>Section on Disorders of the Spine and Peripheral Nerves Web site</u>.
- Addendum for Guideline #9. Electronic copies: Available from the <u>AANS/CNS</u>
 <u>Joint Section on Disorders of the Spine and Peripheral Nerves Web site.</u>

Print copies: Available from Daniel K. Resnick, M.D., Department of Neurological Surgery, University of Wisconsin Medical School, K4/834 Clinical Science Center, 600 Highland Avenue, Madison, Wisconsin 53792; Email: Resnick@neurosurg.wisc.edu.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 5, 2007. The information was verified by the guideline developer on January 29, 2007.

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