Complete Summary

GUIDELINE TITLE

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 10: fusion following decompression in patients with stenosis without 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 10: fusion following decompression in patients with stenosis without spondylolisthesis. J Neurosurg Spine 2005 Jun;2(6):686-91. [32 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 without spondylolisthesis

GUIDELINE CATEGORY

Management Treatment

CLINICAL SPECIALTY

Internal Medicine Neurological Surgery Neurology Orthopedic Surgery Physical Medicine and Rehabilitation

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To examine the literature concerning the use of posterolateral fusion (PLF) after decompression in patients with lumbar stenosis without deformity
- To examine the following two key guestions:
 - 1. Is there evidence that the addition of PLF improves outcome compared with decompression alone in patients with lumbar stenosis without deformity? If so, which patients with lumbar stenosis are likely to benefit from the use of adjunctive spinal fusion?
 - 2. Is there evidence that the application of spinal instrumentation, in addition to PLF, improves outcome compared with fusion without instrumentation in this patient population?

TARGET POPULATION

Patients with stenosis without spondylolisthesis

INTERVENTIONS AND PRACTICES CONSIDERED

1. In situ lumbar posterolateral fusion (PLF) in addition to decompression in selected patients

Note: The addition of pedicle screw instrumentation is considered but not recommended.

MAJOR OUTCOMES CONSIDERED

Effectiveness of treatment in terms of pain relief, walking tolerance, 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 March 2003 was conducted using the search terms "lumbar stenosis and fusion and spinal surgery" or "lumbar stenosis and arthrodesis." The search was restricted to the English language and yielded 204 references. The titles and abstracts of each reference were reviewed, and papers not concerned with decompression and fusion for lumbar stenosis were discarded. Thirty-two references were identified that provided either direct or supporting evidence relevant to the use of spinal fusion in the treatment of lumbar stenosis without spondylolisthesis. These papers were reviewed, and relevant references from their bibliographies were identified. All papers providing Class III medical evidence or better regarding the use of fusion and decompression for nondeformity-based lumbar stenosis are summarized in Table 1 of the original guideline document. Additional supportive data are provided by references listed in the bibliography of the original guideline.

NUMBER OF SOURCE DOCUMENTS

26 papers providing Class III medical evidence or better regarding the use of fusion and decompression for nondeformity-based lumbar stenosis 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

Review of Published Meta-Analyses 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

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

Standards. There is insufficient evidence to recommend a treatment standard.

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

Options. 1) In situ posterolateral lumbar fusion is not recommended as a treatment option in patients with lumbar stenosis in whom there is no evidence of preexisting spinal instability or likely iatrogenic instability due to facetectomy. 2) In situ lumbar PLF is recommended as a treatment option in addition to decompression in patients with lumbar stenosis without deformity in whom there is evidence of spinal instability. 3) The addition of pedicle screw instrumentation is not recommended in conjunction with PLF following decompression for lumbar stenosis in patients without spinal deformity or instability.

Summary

Based on the medical evidence derived from the scientific literature on this topic, there does not appear to be evidence to support the hypothesis that fusion (with or without instrumentation) provides any benefit over decompression alone in the treatment of lumbar stenosis in patients in whom there is no evidence of preoperative deformity or instability. A single report provides Class II medical evidence and several papers provide Class III medical evidence suggesting that the addition of fusion to decompression in patients with lumbar stenosis and

instability evidenced by movement on preoperative flexion–extension radiographs does improve outcome. There are also reports (Class III medical evidence) indicating that patients with lumbar stenosis, without deformity or instability, treated with wide decompression or facetectomy may suffer iatrogenic lumbar instability. Fusion in these patients may improve outcome. There is conflicting Class III medical evidence regarding the application of instrumentation in addition to PLF in patients treated for lumbar stenosis without deformity or preoperative instability.

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

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

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) in patients with stenosis without spondylolisthesis

POTENTIAL HARMS

Lumbar fusion following discectomy is associated with increased blood loss and operative duration.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

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 quidelines 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 10: fusion following decompression in patients with stenosis without spondylolisthesis. J Neurosurg Spine 2005 Jun;2(6):686-91. [32 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

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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 8 of 10

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web</u> 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>
 <u>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 3: assessment of economic outcome. 2005 Jun. 6 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.

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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