Complete Summary

GUIDELINE TITLE

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 7: intractable low-back pain without stenosis or 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 7: intractable low-back pain without stenosis or spondylolisthesis. J Neurosurg Spine 2005 Jun;2(6):670-2. [7 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Degenerative disease of the lumbar spine: intractable low-back pain without stenosis or 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
Physical Therapists
Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the published literature regarding the use of lumbar fusion in patients with low-back pain without stenosis or spondylolisthesis

TARGET POPULATION

Patients with low-back pain without stenosis or spondylolisthesis

INTERVENTIONS AND PRACTICES CONSIDERED

1. Lumbar fusion in carefully selected patients
2. Physical therapy and cognitive therapy in patients in whom conventional medical management has failed

MAJOR OUTCOMES CONSIDERED

Effectiveness of treatment in terms of pain relief, degree of disability as measured by the Oswestry Disability Index (ODI), daily use of medication, return-to-work status, and degree of patient and independent observer 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

The database of the National Library of Medicine was searched using the search terms "spinal fusion and randomized clinical trial," "lumbar fusion and randomized clinical trial," "spinal fusion and outcomes," "lumbar fusion and outcomes," and "lumbar fusion and physical therapy." The Cochrane Central Register of Controlled Trials was searched using the search term "spinal fusion." Reference lists from relevant papers as well as from the Cochrane Review were reviewed, and all

randomized clinical trials comparing lumbar fusion with nonoperative management were identified. Both of these trials are identified in Table 1 of the original guideline document. A number of case series, cohort studies, and studies evaluating different fusion techniques were also identified and provide supportive scientific evidence.

NUMBER OF SOURCE DOCUMENTS

2 randomized clinical trials comparing lumbar fusion with nonoperative management were identified.

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

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. Lumbar fusion is recommended as a treatment for carefully selected patients with disabling low-back pain due to one- or two-level degenerative disease without stenosis or spondylolisthesis.

Guidelines. There is insufficient evidence available to support a treatment guideline.

Options. An intensive course of physical therapy and cognitive therapy is recommended as a treatment option for patients with low-back pain in whom conventional medical management has failed.

Summary

Class I medical evidence exists in support of the use of lumbar fusion as a treatment standard for carefully selected patients with low-back pain intractable to the best medical management. There is Class III medical evidence that suggests that a course of intensive cognitive and physical therapy may be an efficacious treatment option for the treatment of patients with chronic disabling low-back pain.

Definitions:

Grades of Recommendation

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Options Recommendations based on Class III evidence reflecting unclear clinical certainty

Classes of Evidence

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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 treatment of patients with degenerative disease of the lumbar spine with intractable low-back pain without stenosis or spondylolisthesis

POTENTIAL HARMS

Lumbar spinal fusion procedures are associated with significant cost and the potential for complications.

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 7: intractable low-back pain without stenosis or spondylolisthesis. J Neurosurg Spine 2005 Jun;2(6):670-2. [7 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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This project was funded entirely by a grant from AANS/CNS Section on Disorders of the Spine. No funding was received from any commercial entity to support the production or publication of these guidelines.

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 AANS/CNS Joint 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 1: introduction and methodology. 2005 Jun. 2 p. Available in Portable Document Format (PDF) from the AANS/CNS Joint 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 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.

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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