Complete Summary

GUIDELINE TITLE

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 4: radiographic assessment of fusion.

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 4: radiographic assessment of fusion. J Neurosurg Spine 2005 Jun;2(6):653-7. [21 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

GUIDELINE CATEGORY

Diagnosis
Technology Assessment

CLINICAL SPECIALTY

Internal Medicine
Neurological Surgery
Neurology
Orthopedic Surgery
Physical Medicine and Rehabilitation
Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To examine the literature regarding the ability of various diagnostic techniques to assess fusion status after lumbar fusion is performed to treat degenerative disease

TARGET POPULATION

Patients with degenerative disease of the lumbar spine treated with lumbar fusion

INTERVENTIONS AND PRACTICES CONSIDERED

Radiographic assessment of fusion status using combination of noninvasive modalities such as static plain radiography, lateral flexion-extension radiography, and computerized tomography (CT)

Note: The following radiographic tests were considered but not recommended due either to unreliability of the tests or lack of scientific evidence: static lumbar radiography as a stand-alone test, technetium-99 bone scanning, Roentgen stereophotogrammetric analysis (RSA), polytomography, magnetic resonance imaging, and ultrasonography.

MAJOR OUTCOMES CONSIDERED

Accuracy, sensitivity, specificity, and positive and negative predictive value of radiographic studies

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 between 1966 and July 2003 was conducted using the search terms "lumbar spine

fusion assessment," "lumbar spine pseudoarthrosis," or "lumbar spine fusion outcome." The search was restricted to references in the English language involving humans. This yielded a total of 1076 references. The titles and abstracts of each of these references were reviewed. Only papers concerned with the assessment of fusion status following arthrodesis procedures for degenerative lumbar disease were included. Additional articles were obtained from the bibliographies of the selected articles. Forty-five references were identified that provided either direct or supporting evidence relevant to the radiographic assessment of lumbar fusion status. Reports involving Class III or better medical evidence are listed in Table 1 in the original guideline document. Supportive data are provided by additional references listed in the bibliography of the original guideline.

NUMBER OF SOURCE DOCUMENTS

7 reports involving Class III or better medical evidence are listed in Table 1 in 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

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. Static lumbar radiographs are not recommended as a stand-alone means to assess fusion status following lumbar arthrodesis surgery.

Guidelines. 1) Lateral flexion and extension radiography is recommended as an adjunct to determine the presence of lumbar fusion postoperatively. The lack of motion between vertebrae, in the absence of rigid instrumentation, is highly suggestive of successful fusion. 2) Technetium- 99 bone scanning is not recommended as a means to assess lumbar fusion.

Options. Several radiographic techniques, including static radiography, lateral flexion–extension radiography, and/or computed tomography (CT) scanning, often in combination, are recommended as assessment modality options for the noninvasive evaluation of symptomatic patients in whom failed lumbar fusion is suspected.

Summary

The assessment of fusion status with static plain radiography is accurate in approximately two thirds of patients treated with lumbar fusion when the radiographic results are compared with surgical exploration findings. Therefore, static plain radiography is not recommended as a stand-alone modality following lumbar fusion procedures. The addition of lateral flexion–extension radiography may improve accuracy because the lack of motion between fused lumbar segments on lateral views is highly suggestive of a solid fusion. Some degree of motion between segments may be present even when the spine has fused. The amount of motion allowable across fused segments is not clear, and the role of internal fixation in limiting motion has also not been adequately addressed. The addition of multiplanar CT scanning results in the detection of pseudarthrosis in some patients in whom fusion has been deemed successful based on plain radiographic criteria. Therefore, CT scanning may be more accurate in the determination of fusion status than plain radiography; however, a rigorous

comparison of modern CT scanning and surgical exploration has not been performed. It appears that Roentgen stereophotogrammetric analysis (RSA) is exquisitely sensitive for the detection of motion between vertebral bodies, and the loss of motion between treated vertebral segments does appear to indicate the presence of fusion. The modality, however, is invasive and not widely available. Furthermore, the only comparison of RSA with surgical exploration provided only Class III medical evidence supporting the accuracy of RSA. It is recommended that multiple modalities be used for the noninvasive evaluation of symptomatic patients with suspected fusion failure because no radiographic gold standard exists.

Definitions:

Grades of Recommendation

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

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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

Use of appropriate radiographic modalities for assessment of fusion status following lumbar fusion for degenerative disease of the lumbar spine

POTENTIAL HARMS

- Plain static radiography can render false-positive or false-negative results and is not recommended as a stand-alone test.
- The radiographic assessment of lumbar fusion status is imperfect, consumes healthcare resources, and exposes the patient to ionizing radiation.

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 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 4: radiographic assessment of fusion. J Neurosurg Spine 2005 Jun;2(6):653-7. [21 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

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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.
- Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 5: correlation between radiographic and functional outcome. 2005 Jun. 4 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 4, 2007. The information was verified by the guideline developer on January 29, 2007.

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