Complete Summary

GUIDELINE TITLE

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 15: electrophysiological monitoring and lumbar 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 15: electrophysiological monitoring and lumbar fusion. J Neurosurg Spine 2005 Jun;2(6):725-32. [46 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
Evaluation
Management

CLINICAL SPECIALTY

Internal Medicine
Neurological Surgery
Neurology
Physical Medicine and Rehabilitation

INTENDED USERS

Health Plans
Managed Care Organizations
Physicians

GUIDELINE OBJECTIVE(S)

To examine the medical evidence concerning intraoperative monitoring to answer the following questions:

1. Does intraoperative electrophysiological monitoring of the nerve roots or spinal cord increase the safety of lumbar or lumbosacral instrumentation?
2. Does the use of intraoperative electrophysiological monitoring of the spinal cord and nerve roots influence patient outcomes following lumbar spinal surgery for degenerative disease?

TARGET POPULATION

Patients with degenerative disease of the lumbar spine undergoing lumbosacral fusion

INTERVENTIONS AND PRACTICES CONSIDERED

Use of somatosensory evoked potential (SSEP), dermatomal sensory evoked potential (DSEP), and electromyography (EMG) as adjuncts during instrumented lumbosacral fusion procedure for monitoring of spinal cord and nerve root injuries

MAJOR OUTCOMES CONSIDERED

Sensitivity, specificity, and positive and negative predictive value of intraoperative electrophysiological tests

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 "electrophysiology and

spinal surgery," or "EMG and spinal surgery," or "evoked potentials and spinal surgery." The search was restricted to the English language and yielded a total of 1068 citations. The titles and abstracts of each of these references were reviewed and papers not concerned with the use of monitoring for lumbosacral fusion were discarded. References were identified that provided either direct or supporting evidence relevant to the use of monitoring for lumbar or lumbosacral fusion procedures. These papers were obtained and reviewed, and relevant references from the bibliographies of these papers were also identified. All papers providing Class III or better medical evidence regarding the use of electrophysiological monitoring for lumbar or lumbosacral fusion procedures are summarized in Table 1 of the original guideline document. Additional information is provided by other references listed in the bibliography of the original guideline.

NUMBER OF SOURCE DOCUMENTS

26 papers providing Class III or better medical evidence regarding the use of electrophysiological monitoring for lumbar or lumbosacral fusion procedures 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

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

Diagnostic Recommendations

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

Guidelines. Use of intraoperative somatosensory evoked potential (SSEP) or dermatomal sensory evoked potential (DSEP) monitoring is recommended as an adjunct in those circumstances during instrumented lumbar spinal fusion procedures in which the surgeon desires immediate intraoperative information regarding the potential of a neurological injury. The occurrence of a postoperative neurological deficit is highly correlated with intraoperative changes in these monitoring modalities. An abnormal SSEP or DSEP during surgery, however, often does not correlate with a postoperative neurological injury because of a high false-positive rate.

Use of intraoperative evoked electromyography (EMG) recordings is recommended in those circumstances in which the operating surgeon wishes to confirm the lack of a neurological injury during pedicle screw placement. A normal evoked EMG response is highly predictive of the lack of a neurological injury. An abnormal EMG response during the surgical procedure may or may not be associated with a clinically significant injury.

Options. Intraoperative evoked EMG recording is recommended as an option during lumbar spinal fusion surgery in those situations in which the operating surgeon desires immediate information regarding the integrity of the pedicle wall, as a normal evoked EMG response is correlated with an intact pedicle wall.

Therapeutic Recommendations

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

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

Options. Intraoperative SSEP, DSEP, EMG, and/or evoked EMG monitoring are recommended only as adjunctive options during instrumented lumbosacral fusion procedures for degenerative spinal disease. The use of any of these modalities has not been convincingly demonstrated to influence patient outcome favorably.

Summary

Based on the medical evidence provided by the literature reviewed, there does not appear to be support for the hypothesis that any form of intraoperative monitoring improves patient outcomes following lumbar decompression or fusion procedures for degenerative spinal disease. Evidence does indicate that a normal evoked EMG response is predictive for intrapedicular screw placement (high negative predictive value [NPV] for breakout). The presence of an abnormal EMG response does not, however, exclude intrapedicular screw placement (low positive predictive value [PPV]). The majority of clinically apparent postoperative nerve injuries are associated with intraoperative changes in SSEP and/or DSEP monitoring. For this reason, changes in DSEP/SSEP monitoring appear to be sensitive to nerve root injury. There is a high-false positive rate, however, and changes in DSEP and SSEP recordings are frequently not related to nerve injury. A normal study has been shown to correlate with the lack of a significant postoperative nerve injury. There is no substantial evidence to indicate that the use of intraoperative monitoring of any kind provides useful information to the surgeon in terms of assessing the adequacy of nerve root decompression at the time of surgery.

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

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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 electrophysiological monitoring during instrumented lumbosacral fusion procedure

POTENTIAL HARMS

Somatosensory evoked potential (SSEP) and dermatomal sensory evoked potential (DSEP) are associated with false-positive and false-negative results.

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 15: electrophysiological monitoring and lumbar fusion. J Neurosurg Spine 2005 Jun;2(6):725-32. [46 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

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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.

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 8, 2007. The information was verified by the guideline developer on January 29, 2007.

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