Complete Summary

GUIDELINE TITLE

Diagnosis and treatment of degenerative lumbar spondylolisthesis.

BIBLIOGRAPHIC SOURCE(S)

North American Spine Society (NASS). Diagnosis and treatment of degenerative lumbar spondylolisthesis. Burr Ridge (IL): North American Spine Society (NASS); 2008. 133 p. [191 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Degenerative lumbar spondylolisthesis

Note: Degenerative lumbar spondylolisthesis is an acquired anterior displacement of one vertebra over the subjacent vertebra, associated with degenerative changes, without an associated disruption or defect in the vertebral ring.

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Anesthesiology
Chiropractic
Family Practice
Internal Medicine
Neurological Surgery
Neurology
Orthopedic Surgery
Physical Medicine and Rehabilitation
Psychology
Radiology
Rheumatology

INTENDED USERS

Allied Health Personnel
Health Care Providers
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide a tool that assists practitioners in improving the quality and efficiency of care delivered to patients with degenerative lumbar spondylolisthesis
- To provide evidence-based recommendations to address key clinical questions surrounding the diagnosis and treatment of degenerative lumbar spondylolisthesis
- To reflect contemporary treatment concepts for symptomatic degenerative lumbar spondylolisthesis as reflected in the highest quality clinical literature available on this subject as of June 2007

TARGET POPULATION

Adults (18 years or older) with a chief complaint of low back pain and/or lower extremity symptoms related to spinal stenosis

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. History and physical examination
2. Imaging studies
    - Lateral radiograph
    - Magnetic resonance imaging (MRI)
    - Plain and computed tomography (CT) myelography
    - Computed tomography (CT) scan
3. Outcome tools

- Zurich Claudication Questionnaire (ZCQ)/Swiss Spinal Stenosis Questionnaire (SSS), Oswestry Disability Index (ODI), Likert Five-Point Pain Scale and 36-Item Short Form Health Survey
- Japanese Orthopedic Association (JOA) Score and the calculated Recovery Rate
- Shuttle Walking Test (SWT), Oxford Claudication Score (OCS), Low Back Pain Bothersome Index and the Stenosis Bothersome Index)

Treatment

1. Medical and interventional treatments
2. Surgical Treatments
    - Direct surgical decompression
    - Indirect surgical decompression
    - Surgical decompression with fusion
    - Instrumentation in addition to decompression and fusion

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Quality of life
- Symptom relief
- Patient satisfaction
- Complication rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Identification of Clinical Questions

Trained guideline participants were asked to submit a list of clinical questions that the guideline should address. The lists were compiled into a master list, which was then circulated to each member with a request that they independently rank the questions in order of importance for consideration in the guideline. The most highly ranked questions, as determined by the participants, served to focus the guideline.

Identification of Search Terms and Parameters

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence and the formulation of evidence-based recommendations. In order to ensure a thorough literature search, North American Spine Society (NASS) has instituted a Literature Search Protocol (*Appendix D* in the original guideline document) which has been followed to identify literature for evaluation

in guideline development. In keeping with the Literature Search Protocol, work group members have identified appropriate search terms and parameters to direct the literature search.

Specific search strategies, including search terms, parameters and databases searched, are documented in the appendices (See *Appendix E* in the original guideline document).

Completion of the Literature Search

Once each work group identified search terms/parameters, the literature search was implemented by a medical/research librarian, consistent with the Literature Search Protocol.

Following these protocols ensures that NASS recommendations (1) are based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. NASS maintains a search history for future use or reference.

Review of Search Results/Identification of Literature to Review

Work group members reviewed all abstracts yielded from the literature search and identified the literature they will review in order to address the clinical questions, in accordance with the Literature Search Protocol. Members have identified the *best research evidence available* to answer the targeted clinical questions. That is, if Level I, II and or III literature is available to answer specific questions, the work group was not required to review Level IV or V studies.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)
Subjective Review
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for Primary Research Question[1]

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analy Developing an economic or de model

	Types of Studies			
Level I	• High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic review[2] of Level I RCTs (and study results were homogenous[3])	• High quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥80% follow-up of enrolled patients) • Systematic review[2] of Level I studies	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level I studies	• Sensible and alternat values obtaine many st with mu sensitiv analyse • System review[2] Level I
Level II	• Lesser quality RCT (e.g., <80% follow-up, no blinding, or improper randomization) • Prospective[4] comparative study[5] • Systematic review[2] of Level II studies or Level 1 studies with inconsistent results	• Retrospective[6] study • Untreated controls from an RCT • Lesser quality prospective study (e.g., patients enrolled at different points in their disease or <80% follow-up) • Systematic review[2] of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level II studies	• Sensible and alternat values obtaine limited studies; multiwa sensitiv analyse • System review[2] Level II studies
Level III	• Case control study[7] • Retrospective[6] comparative study[5] • Systematic review[2] of Level III studies	• Case control study[7]	• Study of nonconsecutive patients; without consistently applied reference "gold" standard • Systematic review[2] of Level III studies	• Analyse based o limited alternat and cos and poo estimat • System review[2] Level II studies
Level IV	Case Series[8]	Case Series	• Case-control study	• Analyse no sens

	Types of Studies			
			• Poor reference standard	analyse
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

RCT = randomized controlled trial

[1] A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

[2] A combination of results from two or more prior studies.

[3] Studies provided consistent results.

[4] Study was started before the first patient enrolled.

[5] Patients treated one way (e.g., cemented hip arthroplasty) compared with a group of patients treated in another way (e.g., uncemented hip arthroplasty) at the same institution.

[6] The study was started after the first patient enrolled.

[7] Patients identified for the study based on their outcome, called "cases" (e.g., failed total arthroplasty) are compared to those who did not have outcome, called "controls" (e.g., successful total hip arthroplasty).

[8] Patients treated one way with no comparison group of patients treated in another way.

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

Evidence Analysis

Members have independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses and assigning levels of evidence. In order to systematically control for potential biases, at least two work group members have reviewed each article selected and independently assigned levels of evidence to the literature using the North American Spine Society (NASS) levels of evidence. Any discrepancies in scoring have been addressed by two or more reviewers. The consensus level (the level upon which two-thirds of reviewers were in agreement) was then assigned to the article.

As a final step in the evidence analysis process, members have identified and documented gaps in the evidence to educate guideline readers about where

evidence is lacking and help guide further needed research by NASS and other societies.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Nominal Group Technique)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Identification of Work Groups

Multidisciplinary teams were assigned to work groups and assigned specific clinical questions to address. Because North American Spine Society (NASS) is comprised of surgical, medical and interventional specialists, it is imperative to the guideline development process that a cross-section of NASS membership is represented on each group. This also helps to ensure that the potential for inadvertent biases in evaluating the literature and formulating recommendations is minimized.

Formulation of Evidence-Based Recommendations and Incorporation of Expert Consensus

Work groups held face-to-face meetings to discuss the evidence-based answers to the clinical questions, the grades of recommendations and the incorporation of expert consensus. Expert consensus has been incorporated only where Level I-IV evidence is insufficient and the work group has deemed that a recommendation is warranted. Transparency in the incorporation of consensus is crucial, and all consensus-based recommendations made in this guideline very clearly indicate that Level I-IV evidence is insufficient to support a recommendation and that the recommendation is based only on expert consensus.

Consensus Development Process

Voting on guideline recommendations was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 ("extremely inappropriate") to 9 ("extremely appropriate").

Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8 or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted.

After the recommendations were established, work group members developed the guideline content, addressing the literature which supports the recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation for Summaries or Reviews of Studies

A. Good evidence (Level I Studies with consistent finding) for or against recommending intervention.

B. Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention.

C. Poor quality evidence (Level IV or V Studies) for or against recommending intervention.

I. Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Submission of the Draft Guidelines for Review/Comment

Guidelines were submitted to the full Evidence- Based Guideline Development Committee, the Clinical Care Council Director and the Advisory Panel for review and comment. The Advisory Panel is comprised of representatives from physical medicine and rehab, pain medicine/management, orthopedic surgery, neurosurgery, anesthesiology, rheumatology, psychology/psychiatry and family practice. Revisions to recommendations were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

Submission for Board Approval

Once any evidence-based revisions were incorporated, the drafts were prepared for North American Spine Society (NASS) Board review and approval. Edits and revisions to recommendations and any other content were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of recommendations (A-C, I) and levels of evidence (I-V) are defined at the end of the Major Recommendations field.

Recommendations for Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis

A. Diagnosis and Imaging

What are the most appropriate historical and physical examination findings consistent with the diagnosis of degenerative lumbar spondylolisthesis?

Obtaining an accurate history and physical examination is essential to the formulation of the appropriate clinical questions to guide the physician in developing a plan for the treatment of patients with degenerative lumbar spondylolisthesis.

In older patients presenting with radiculopathy and neurogenic intermittent claudication, with or without back pain, a diagnosis of degenerative lumbar spondylolisthesis should be considered.

Grade of Recommendation: B

Diagnosing Spondylolisthesis with Imaging

What are the most appropriate diagnostic tests for degenerative lumbar spondylolisthesis?

The most appropriate, noninvasive test for detecting degenerative lumbar spondylolisthesis is the lateral radiograph.

Grade of Recommendation: B

The most appropriate, noninvasive test for imaging the stenosis accompanying degenerative lumbar spondylolisthesis is the magnetic resonance imaging (MRI).

Plain myelography or computed tomography (CT) myelography are useful studies to assess spinal stenosis in patients with degenerative lumbar spondylolisthesis.

Grade of Recommendation: B

CT is a useful noninvasive study in patients who have a contraindication to MRI, for whom MRI findings are inconclusive or for whom there is a poor correlation between symptoms and MRI findings, and in whom CT myelogram is deemed inappropriate.

B. Outcome Measures for Medical/Interventional and Surgical Treatment

What are the appropriate outcome measures for the treatment of degenerative lumbar spondylolisthesis?

The Zurich Claudication Questionnaire (ZCQ)/Swiss Spinal Stenosis Questionnaire (SSS), Oswestry Disability Index (ODI), Likert Five-Point Pain Scale and 36-Item Short Form Health Survey (SF-36) are appropriate measures for assessing treatment of degenerative lumbar spondylolisthesis.

Grade of Recommendation: A

Note: The Zurich Claudication Questionnaire (ZCQ) represents an evolution of Swiss Spinal Stenosis Questionnaire (SSS). Conclusions made about either questionnaire have a high likelihood of being applicable to the other.

The Japanese Orthopedic Association (JOA) Score and the calculated Recovery Rate may be useful in assessing outcome in degenerative lumbar spondylolisthesis.

Grade of Recommendation: B

The Shuttle Walking Test (SWT), Oxford Claudication Score (OCS), Low Back Pain Bothersome Index and Stenosis Bothersome Index are potential outcome measures in studying degenerative lumbar spondylolisthesis.

Grade of Recommendation: I (Insufficient Evidence)

C. Medical and Interventional Treatment

Medical/interventional treatment for degenerative lumbar spondylolisthesis when the radicular symptoms of stenosis predominate, most logically should be similar to treatment for symptomatic degenerative lumbar spinal stenosis.

D. Surgical Treatment

Do surgical treatments improve outcomes in the treatment of degenerative lumbar spondylolisthesis compared to the natural history of the disease?

Surgery is recommended for treatment of patients with symptomatic spinal stenosis associated with low grade degenerative spondylolisthesis whose symptoms have been recalcitrant to a trial of medical/interventional treatment.

Grade of Recommendation: B

Does surgical decompression alone improve surgical outcomes in the treatment of degenerative lumbar spondylolisthesis compared to medical/interventional treatment alone or the natural history of the disease?

Direct surgical decompression is recommended for treatment of patients with symptomatic spinal stenosis associated with low grade degenerative lumbar spondylolisthesis whose symptoms have been recalcitrant to a trial of medical/interventional treatment.

Grade of Recommendation: I (Insufficient Evidence)

Indirect surgical decompression is recommended for treatment of patients with symptomatic spinal stenosis associated with low grade degenerative lumbar spondylolisthesis whose symptoms have been recalcitrant to a trial of medical/interventional treatment.

Grade of Recommendation: I (Insufficient Evidence)

Does the addition of lumbar fusion, with or without instrumentation, to surgical decompression improve surgical outcomes in the treatment of degenerative lumbar spondylolisthesis compared to treatment by decompression alone?

Surgical decompression with fusion is recommended for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis to improve clinical outcomes compared with decompression alone.

Grade of Recommendation: B

Does the addition of instrumentation to decompression and fusion for degenerative lumbar spondylolisthesis improve surgical outcomes compared with decompression and fusion alone?

The addition of instrumentation is recommended to improve fusion rates in patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

Grade of Recommendation: B

The addition of instrumentation is not recommended to improve clinical outcomes for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

Grade of Recommendation: B

How do outcomes of decompression with posterolateral fusion compare with those for 360° fusion in the treatment of degenerative lumbar spondylolisthesis?

Because of the paucity of literature addressing this question, the work group was unable to generate a recommendation to answer this question.

What is the role of reduction (deliberate attempt to reduce via surgical technique) with fusion in the treatment of degenerative lumbar spondylolisthesis?

Reduction with fusion and internal fixation of patients with low grade degenerative lumbar spondylolisthesis is not recommended to improve clinical outcomes.

Grade of Recommendation: I (Insufficient Evidence)

What is the long-term result (four+ years) of surgical management of degenerative lumbar spondylolisthesis?

Decompression and fusion is recommended as a means to provide satisfactory long-term results for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

Grade of Recommendation: C

Definitions:

Grades of Recommendation for Summaries or Reviews of Studies

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Levels of Evidence for Primary Research Question[1]

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	Types of Studies			
	RCTs (and study results were homogenous[3])	studies	I studies	
Level II	• Lesser quality RCT (e.g., <80% follow-up, no blinding, or improper randomization) • Prospective[4] comparative study[5] • Systematic review[2] of Level II studies or Level 1 studies with inconsistent results	• Retrospective[6] study • Untreated controls from an RCT • Lesser quality prospective study (e.g., patients enrolled at different points in their disease or <80% follow-up) • Systematic review[2] of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level II studies	• Sensible and alternat values obtaine limited studies; multiwa sensitiv analyse • System review[2] Level II studies
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Level IV	Case Series[8]	Case Series	• Case-control study • Poor reference standard	• Analyse no sens analyse
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

RCT = randomized controlled trial

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[7] Patients identified for the study based on their outcome, called "cases" (e.g., failed total arthroplasty) are compared to those who did not have outcome, called "controls" (e.g., successful total hip arthroplasty).

[8] Patients treated one way with no comparison group of patients treated in another way.

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 most of the recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate diagnosis and effective treatment of degenerative lumbar spondylolisthesis

POTENTIAL HARMS

- Although reduction and fusion can be performed, it may increase the risk of neurological complications.
- Bilateral foraminotomies with reduction and instrumented fusion has a 7% major complication rate.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guideline does not represent a "standard of care," nor is it intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside this guideline will sometimes be necessary. This guideline should not be seen as prescribing the type, frequency or duration of intervention. Treatment should be based on the individual patient's need and physician's professional judgment. This

document is designed to function as a guideline and should not be used as the sole reason for denial of treatment and services. This guideline is not intended to expand or restrict a health care provider's scope of practice or to supersede applicable ethical standards or provisions of law.

- The clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The recommendations will be reviewed by a group experienced in performance measure development (e.g., the AMA Physician's Consortium for Performance Improvement) to identify those recommendations rigorous enough for measure development.

This guideline will be pilot tested among spine care specialists and primary care physicians for one year following publication. Findings of the pilot test will be considered to inform future guideline development.

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)

North American Spine Society (NASS). Diagnosis and treatment of degenerative lumbar spondylolisthesis. Burr Ridge (IL): North American Spine Society (NASS); 2008. 133 p. [191 references]

ADAPTATION

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

DATE RELEASED

2008

GUIDELINE DEVELOPER(S)

North American Spine Society - Medical Specialty Society

SOURCE(S) OF FUNDING

North American Spine Society (NASS)

GUIDELINE COMMITTEE

North American Spine Society (NASS) Evidence-Based Guideline Development Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: William C. Watters III, MD, Committee Chair; Christopher Bono, MD, Surgical Treatment Chair; Thomas Gilbert, MD, Diagnosis/Imaging Chair; D. Scott Kreiner, MD, Natural History Chair; Daniel Mazanec, MD, Medical/Interventional Treatment Chair; William O. Shaffer, MD, Outcome Measures Chair; Jamie Baisden, MD; John Easa, MD; Robert Fernand, MD; Gary Ghiselli, MD; Michael Heggeness, MD, PhD; Richard Mendel, MD; Conor O'Neill, MD; Charles Reitman, MD; Daniel Resnick, MD; Jeffrey Summers, MD; Reuben Timmons, MD; John Toton, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All participants involved in guideline development have disclosed potential conflicts of interest to their colleagues, and their potential conflicts have been documented for future reference. They will not be published in any guideline, but kept on file at North American Spine Society (NASS) for reference, if needed. Participants have been asked to update their disclosures regularly throughout the guideline development process.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the North American Spine Society (NASS) Web site.

Print copies: Available from the North American Spine Society (NASS), 7075 Veterans Boulevard, Burr Ridge, IL 60527; Toll-free: (866) 960-6277. An order form is available from the North American Spine Society Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on September 5, 2008. The information was verified by the guideline developer on September 8, 2008.

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