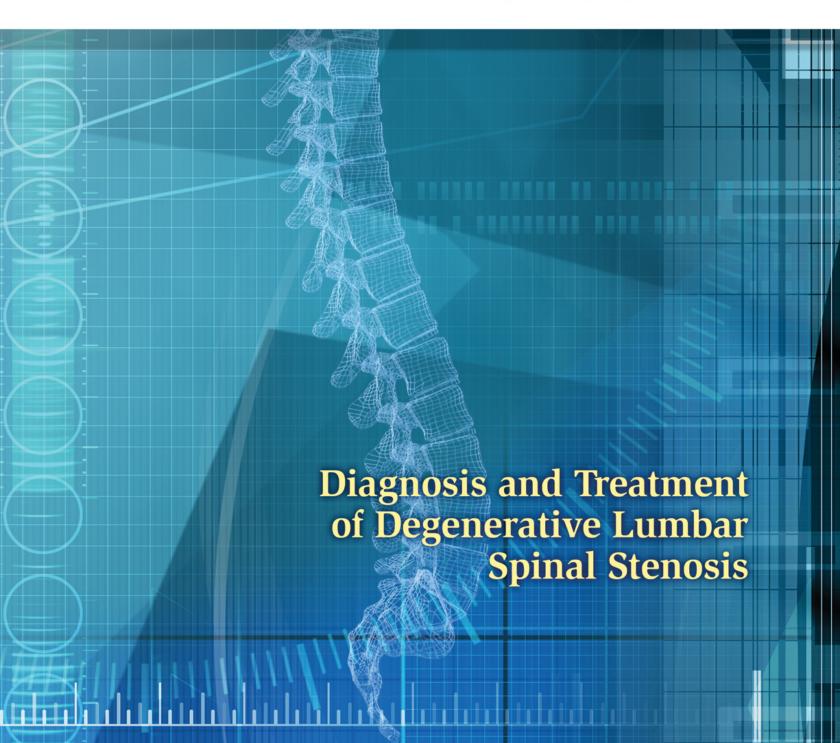
Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care



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Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis

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John F. Toton Nothing to disclose.

Range Key:

Level A. \$100 to \$1,000 Level B. \$1,001 to \$10,000 Level C. \$10,001 to \$25,000 Level D. \$25,001 to \$50,000 Level E. \$50,001 to \$100,000 Level F. \$100,001 to \$500,000 Level G. \$500,001 to \$1M Level H. \$1,000,001 to \$2.5M Level I. Greater than \$2.5M

Comments

Comments regarding the guideline may be submitted to the North American Spine Society and will be considered in development of future revisions of the work.

North American Spine Society Clinical Guidelines for Multidisciplinary Spine Care Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis

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A technical report, including the literature search parameters and evidentiary tables developed by the authors, can be accessed at http://www.spine.org/Documents/2011StenosisTechReport.pdf

I. Introduction

Objective

The objective of the North American Spine Society (NASS) Clinical Guideline for the Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis is to provide evidence-based recommendations to address key clinical questions surrounding the diagnosis and treatment of degenerative lumbar spinal stenosis. The guideline is intended to reflect contemporary treatment concepts for symptomatic degenerative lumbar spinal stenosis as reflected in the highest quality clinical literature available on this subject as of July 2010. The goals of the guideline recommendations are to assist in delivering optimum, efficacious treatment and functional recovery from this spinal disorder.

Scope, Purpose and Intended User

This document was developed by the North American Spine Society Evidence-based Guideline Development Committee as an educational tool to assist practitioners who treat patients with degenerative lumbar spinal stenosis. The goal is to provide a tool that assists practitioners in improving the quality and efficiency of care delivered to patients with degenerative lumbar spinal stenosis. The NASS Clinical Guideline for the Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis provides a definition and explanation of the natural history of degenerative lumbar spinal stenosis, outlines a reasonable evaluation of patients suspected to have degenerative lumbar spinal stenosis and

outlines treatment options for adult patients with a diagnosis of degenerative lumbar spinal stenosis.

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 doctor's professional judgment and experience. 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.

Patient Population

The patient population for this guideline encompasses adults (18 years or older) with a chief complaint of neurogenic claudication without associated spondylolisthesis. Furthermore, the nature of the pain and associated patient characteristics (eg, age) should be more typical of a diagnosis of spinal stenosis than herniated disc.

II. Guideline Development Methodology

Through objective evaluation of the evidence and transparency in the process of making recommendations, it is NASS' goal to develop evidence-based clinical practice guidelines for the diagnosis and treatment of adult patients with various spinal conditions. These guidelines are developed for educational purposes to assist practitioners in their clinical decision-making processes. It is anticipated that where evidence is very strong in support of recommendations, these recommendations will be operationalized into performance measures.

Multidisciplinary Collaboration

With the goal of ensuring the best possible care for adult patients suffering with spinal disorders, NASS is committed to multidisciplinary involvement in the process of guideline and performance measure development. To this end, NASS has ensured that representatives from medical, interventional and surgical spine specialties have participated in the development and review of all NASS guidelines. To ensure broad-based representation, NASS has invited and welcomes input from other societies and specialties

Evidence Analysis Training of All NASS Guideline Developers

NASS has initiated, in conjunction with the University of Alberta's Centre for Health Evidence, an online training program geared toward educating guideline developers about evidence analysis and guideline development. All participants in guideline development for NASS have completed the training prior to participating in the guideline development program at NASS. This training includes a series of readings and exercises, or interactivities, to prepare guideline developers for systematically evaluating literature and developing evidence-based guidelines. The online course takes approximately 15-30 hours to complete and participants have been awarded CME credit upon completion of the course.

Disclosure of Potential 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 in this guideline. Participants have been asked to update their disclosures regularly throughout the guideline development process.

Levels of Evidence and Grades of Recommendation

NASS has adopted standardized levels of evidence (*Appendix B*) and grades of recommendation (*Appendix C*) to assist practitioners in easily understanding the strength of the evidence and recommendations within the guidelines. The levels of evidence range from Level I (high quality randomized controlled trial) to Level V (expert consensus). Grades of recommendation indi-

cate the strength of the recommendations made in the guideline based on the quality of the literature.

Grades of Recommendation:

A: Good evidence (Level I studies with consistent findings) 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.

Levels of evidence have very specific criteria and are assigned to studies prior to developing rec-ommendations. Recommendations are then graded based upon the level of evidence. To better un-derstand how levels of evidence inform the grades of recommendation and the standard nomencla-ture used within the recommendations see *Appendix D*.

Guideline recommendations are written utilizing a standard language that indicates the strength of the recommendation. "A" recommendations indicate a test or intervention is "recommended"; "B" recommendations "suggest" a test or intervention and "C" recommendations indicate a test or in-tervention "may be considered" or "is an option." "I" or "Insufficient Evidence" statements clearly indicate that "there is insufficient evidence to make a recommendation for or against" a test or in-tervention. Work group consensus statements clearly state that "in the absence of reliable evidence, it is the work group's opinion that" a test or intervention may be appropriate.

The levels of evidence and grades of recommendation implemented in this guideline have also been adopted by the Journal of Bone and Joint Surgery, the American Academy of Orthopaedic Surgeons, Clinical Orthopaedics and Related Research, the journal Spine and the Pediatric Orthopaedic Society of North America.

In evaluating studies as to levels of evidence for this guideline, the study design was interpreted as establishing only a potential level of evidence. As an example, a therapeutic study designed as a randomized controlled trial would be considered a potential Level I study. The study would then be further analyzed as to how well the study design was implemented and significant short comings in the execution of the study would be used to downgrade the levels of evidence for the study's con-clusions. In the example cited previously, reasons to downgrade the results of a potential Level I randomized controlled trial to a Level II study would include, among other possibilities: an under-powered study (patient sample too small, variance too high), inadequate randomization or masking of the group assignments and lack of validated outcome measures.

In addition, a number of studies were reviewed several times in answering different questions within this guideline. How a given question was asked might influence how a study was evaluated and interpreted as to its level of evidence in answering that particular question. For example, a randomized control trial reviewed to evaluate the differences between the outcomes of surgically treated versus untreated patients with lumbar spinal stenosis might be a well designed and implemented Level I therapeutic study. This same study, however, might be classified as giving Level II prognostic evidence if the data for the untreated controls were extracted and evaluated prognostically.

Guideline Development Process

Step 1: 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.

Step 2: Identification of Work Groups

Multidisciplinary teams were assigned to work groups and assigned specific clinical questions to address. Because 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.

Step 3: 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, NASS has instituted a Literature Search Protocol (*Appendix E*) 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 technical report that accompanies this guideline.

Step 4: 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) rep-resent the current best research evidence available. NASS maintains a search history in Endnote, for future use or reference.

Step 5: 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.

Step 6: 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 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.

Step 7: Formulation of Evidence-Based Recommendations and Incorporation of Expert Consensus

Work groups held webcasts 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 evi-dence 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 rec-ommendation was adopted.

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

Step 8: Submission of the Draft Guidelines for Review/Comment

Guidelines were submitted to the full Evidence-Based Guideline Development Committee and the Research Council Director for review and comment. Revisions to recommendations were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

Step 9: Submission for Board Approval

Once any evidence-based revisions were incorporated, the drafts were prepared for 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.

Step 10: Submission for Publication and National Guideline Clearinghouse (NGC) Inclusion

Following NASS Board approval, the guidelines have been slated for publication and submitted for inclusion in the National Guidelines Clearinghouse (NGC). No revisions were made at this point in the process, but comments have been and will be saved for the next iteration.

Step 11: Identification and Development of Performance Measures

The recommendations will be reviewed by a group experienced

in performance measure develop-ment (eg, the AMA Physician's Consortium for Performance Improvement) to identify those rec-ommendations rigorous enough for measure development. All relevant medical specialties involved in the guideline development and at the Consortium will be invited to collaborate in the development of evidence-based performance measures related to spine care.

Step 12: Review and Revision Process

The guideline recommendations will be reviewed every three years by an EBM-trained multidiscipli-nary team and revised as appropriate based on a thorough review and assessment of relevant literature published since the development of this version of the guideline.

Use of Acronyms

Throughout the guideline, readers will see many acronyms with which they may not be familiar. A glossary of acronyms is available in *Appendix A*.

Nomenclature for Medical/Interventional Treatment

Throughout the guideline, readers will see that what has traditionally been referred to as "nonoper-ative," "nonsurgical" or "conservative" care is now referred to as "medical/interventional care." The term medical/interventional is meant to encompass pharmacological treatment, physical therapy, exercise therapy, manipulative therapy, modalities, various types of external stimulators and injections.

III. Definition and Natural History of Degenerative Lumbar Spinal Stenosis

What is the best working definition of degenerative lumbar spinal stenosis?

Degenerative lumbar spinal stenosis describes a condition in which there is diminished space available for the neural and vascular elements in the lumbar spine secondary to degenerative changes in the spinal canal. When symptomatic, this causes a variable clinical syndrome of gluteal and/or lower extremity pain and/or fatigue which may occur with or without back pain. Symptomatic lumbar spinal stenosis has certain characteristic provocative and palliative features. Provocative features include upright exercise such as walking or positionally-induced neurogenic claudication. Palliative features commonly include symptomatic relief with forward flexion, sitting and/or recumbency.

Work Group Consensus Statement

What is the natural history of degenerative lumbar spinal stenosis?

In order to perform a systematic review of the literature regarding the natural history of patients with lumbar stenosis, the above definition of lumbar stenosis was developed by consensus following a global review of the literature and definitive texts, and used as the standard for comparison of treatment groups. It is important to understand this is an anatomic definition that when symptomatic has characteristic clinical features. In order for a study to be considered relevant to the discussion, the patient population was required to be symptomatic, with characteristic clinical features described above, and to have confirmatory imaging demonstrating diminished space in the lumbar spinal canal. The Levels of Evidence for Primary Research Questions grading scale (*Appendix B*) was used to rate the level of evidence provided by each article with a relevant patient population. The diagnosis of lumbar stenosis was examined for its utility as a prognostic factor. The central question asked was: "What happens to patients with symptomatic lumbar stenosis who do not receive treatment?"

To address the natural history of symptomatic degenerative lumbar spinal stenosis, the work group performed a comprehensive literature search and analysis. The group reviewed the 2007 version of the guideline which included 33 references from 1966-2006, along with an additional 21 articles which were selected from a search of MEDLINE (PubMed), Cochrane Register of Controlled Trials, Web of Science and EMBASE Drugs &

Pharmacology for studies published between January 2006 and February 2010.

All identified studies failed to meet the guideline's inclusion criteria because they did not adequate-ly present data about the natural history of degenerative lumbar spinal stenosis. These studies did not report results of untreated control patients, thus limiting the validity of the papers' conclusions concerning natural history. This includes works that have been frequently cited as so-called natural history studies but are, in fact, reports of the results of one or more medical/interventional treat-ment measures.

The 2007 version of this guideline considered patients with minimal medical/interventional treat-ment as being representative of the natural course of the disease. It was the determination of the 2010 work group that any treatment may affect the natural history of the condition; therefore, the studies cited in 2007 supporting natural history of spinal stenosis would be more appropriately in-cluded in the medical/interventional treatment section of the guideline rather than be considered de facto controls.

Because of the limitations of the available literature, the work group was unable to definitively an-swer the question posed related to the natural history of degenerative lumbar spinal stenosis. In lieu of an evidence-based answer, the work group did reach consensus on the following statements addressing natural history.

In the absence of reliable evidence, it is the work group's opinion that the natural history of patients with clinically mild to moderately symptomatic degenerative lumbar stenosis can be favorable in about one-third to one-half of patients.

Work Group Consensus Statement

Based on evaluation of studies that contained varying and often relatively minimal or simple inter-ventions, it appears that the natural history of mild to moderate degenerative lumbar stenosis may be favorable for 33-50% of patients. It is the consensus of the work group that some of the medical treatments utilized in the studies reviewed likely did not significantly alter the symptomatic course of the disease.

In the absence of reliable evidence, it is the work group's opinion that in patients with mild or moderately symptomatic degenerative lumbar stenosis, rapid or catastrophic neurologic decline is rare.

Work Group Consensus Statement

The literature evaluated for the degenerative lumbar spinal stenosis guideline project included numerous reports describing the clinical course of patients with mild to moderate spinal stenosis. None of these reports described rapid or catastrophic neurologic decline in patients identified with mild or moderate lumbar spinal stenosis. While anecdotal experience may indicate the possibility of such a decline, evidence suggests that the occurrence of such a decline is exceedingly rare.

In the absence of reliable evidence, it is the work group's opinion that information in the literature is insufficient to define the natural history of clinically or radiographically severe degenerative lumbar stenosis.

Work Group Consensus Statement

It should be noted that all the series reviewed excluded patients with severe neurological compromise (or loss or dysfunction)

who were regarded as candidates for surgery; therefore, no concluions can be drawn about this patient population.

Future Directions for Research

The work group identified the following potential studies, which could generate meaningful evidence to assist in further defining the natural history of degenerative lumbar spinal stenosis.

Recommendation #1:

A prospective study of patients with symptomatic degenerative lumbar spinal stenosis without treatment, notwithstanding non-prescription analgesics, would provide Level I evidence regarding the natural history of this disorder. Unfortunately, at this time, following symptomatic patients long-term with no intervention is unlikely to occur.

Recommendation #2:

A systematic study reviewing patients with untreated symptomatic degenerative lumbar spinal stenosis would provide evidence regarding the natural history of the disease in this patient population.

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IV. Recommendations for Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis

A. Diagnosis and Imaging

Assessing Evidence for Diagnostic Tests

Assessing the evidence for diagnostic tests poses some difficulties that are not seen in therapeutic studies. In the assessment of diagnostic tests, both accuracy and the effect of testing on outcome should be considered. The accuracy of a diagnostic test refers to the ability of the examination to detect and characterize pathologic processes. Accuracy is typically expressed in terms of sensitivity and specificity — sensitivity referring to the proportion of patients with the target disorder who will have a positive test, and specificity to the number of people without the disease who have a negative test. With tests that have a high sensitivity, a negative test effectively rules out the disease. With tests that have a high specificity, a positive test effectively rules in the disease.

The performance of a test in a given population can also be stated in terms of positive and negative predictive value, which depends directly on the prevalence of disease in the tested population.1 In populations with a high prevalence of disease, a test with a high accuracy will accurately predict the presence of disease. Conversely, the same test result will yield a large percentage of false positives in patient populations with a low incidence of disease (such as an asymptomatic population). One of the purposes of a history and physical examination is to increase the prevalence of disease in patients sent for advanced testing. For this reason, in our systematic review, we have attempted to identify those symptoms or findings which have a high likelihood ratio for lumbar spinal stenosis — those symptoms or findings expected in patients diagnosed with lumbar spinal stenosis, but not in those who do not have lumbar spinal stenosis. The use of these criteria should increase the prevalence of this disease in the population sent for cross-sectional imaging.¹ Positive computed tomography (CT) or magnetic resonance imaging (MRI) findings in this population will have greater relevance relative to treatment and should lead to better outcomes.

Cross-sectional imaging exams have a low intrinsic specificity as evidenced by a significant incidence of stenosis and other pathologic findings in asymptomatic populations.^{2,3} The results of any cross-sectional examination need to be closely correlated with the clinical examination. As a result, the accuracy of a spine MRI or CT should incorporate the ability of the test to directly visualize neurologic structures and the effect of pathologic processes on these structures. Direct visualization of intrinsic neurologic processes and neural impingement is of obvious importance in determining the etiology of myelopathic and radicular symptoms.

The gold standard in the majority of the studies testing the ac-

curacy of a cross-sectional imaging exam is surgery. The validity of surgery as a gold standard for the assessment of stenosis can be questioned, however, as findings at surgery can be subjective. The degree or severity of central stenosis can also be difficult to quantify at surgery as decompression often precedes direct examination of the central canal. For these reasons, a case can be made to use the best available cross-sectional imaging exam as a gold standard; however, this too can be problematic.

Outcome can also be used as a gold standard in the assessment of a diagnostic exam. The assessment of a diagnostic exam in this manner is obviously confounded by the type of treatment applied, the skill of the treating physician and patient psychosocial variables among other factors. Outcome studies can be very useful, however, in assessing the appropriate utilization of cross-sectional imaging. For example, two Level I studies have recently been published concerning the use of Rapid MRI.^{4,5} In these studies, the value of obtaining an early MRI in the management of patients with low back pain was assessed using various outcome measures, including pain level, patient preference, patient satisfaction and cost of resource use. Each of these studies showed limited, if any, benefit in obtaining an MRI early in the course of a patient's treatment. Studies of this type were uncommon in our review, but are of obvious importance given rising health care costs.

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

The diagnosis of lumbar spinal stenosis may be considered in older patients presenting with a history of gluteal or lower extremity symptoms exacerbated by walking or standing which improves or resolves with sitting or bending forward. Patients whose pain is not made worse with walking have a low likelihood of stenosis.

Grade of Recommendation: C

Three recent diagnostic studies have been published by the same group of authors. 1-3 The initial study by Konno and Kikuchi et al1 included a retrospective sample followed by a collection of 250 prospective patients. Two subsequent studies, Konno and Hayashino et al2 and Sugioka et al3 utilized the same prospective group of 468 patients to evaluate the efficacy of two separate evaluation tools. It is not known whether some of the patients from the first study comprised a segment of the study groups for the other studies. All of these studies implemented methods intended to develop a simple clinical diagnostic tool that may help physicians diagnose lumbar spinal stenosis in patients with lower leg symptoms.

The first study was done in three phases.¹ The initial arm was retrospective on patients with proven lumbar spinal stenosis during surgery, second was prospective in a group of patients that were eventually confirmed surgically to have lumbar spinal stenosis, and third was a prospective validation study in a patient population of mixed diagnoses.

The first phase evaluated 234 patients retrospectively, 137 with lumbar spinal stenosis and 97 with lumbar disc herniation, who had successful surgery and pathology confirmed at surgery. They categorized the lumbar spinal stenosis group into radicular and cauda equina "types" based on history and physical exam as well as imaging. The radicular type was also further confirmed by temporary alleviation of symptoms with steroid injection. The radicular type of stenosis presented as unilateral radicular pain following a specific dermatome or dermatomes. The cauda equina type had symptoms often bilateral with less dermatomalspecific neurogenic claudication. To this initial group of 234 patients, several subjective and objective data were analyzed, and univariate analysis revealed key factors for predicting overlapping symptoms between the two types of lumbar spinal stenosis. Five historical findings had an odds ratio ≥ 2 or p < 0.05: age > 50, lower extremity pain or numbness, increased pain when walking, increased pain when standing, and improvement of symptoms on bending forward. No physical examination finding had an odds ratio ≥ 2 or p < 0.05. Another univariate analysis was done to differentiate those patients with cauda equina type lumbar spinal stenosis, and with this information a self-administered, self-reported history questionnaire (SSHQ) was developed consisting of 10 questions.

In the next phase, the investigators administered the questionnaire prospectively to 115 patients, 60 radicular type and 55 cauda equina type, whom were recruited from multiple facilities. These patients were also diagnosed with lumbar spinal stenosis by clinical exam and MRI, and later confirmed at surgery. A responsible nerve root was confirmed if intermittent claudication was abolished following single nerve root infiltration. The sensitivity of each question on the SSHQ was calculated and compared between the radicular and cauda equina types. To assess the cut-off point to distinguish between the types, one point was assigned to each question on the SSHQ, and the clinical prediction rule was defined based on the scores. Sensitivity of each question was calculated and a predictor role defined. A scoring system was assigned that could predict radicular type lumbar spinal stenosis, cauda equina type lumbar spinal stenosis, or neither. A score of 4 points on Q1-Q4 indicated the presence of lumbar spinal stenosis; a score of 4 on Q1-Q4 and < 1 on Q5–Q10 indicat-ed the radicular type of lumbar spinal stenosis; and a score of > 1 on Q1-Q4 and > 2 on Q5-Q10 in-dicated the cauda equina type of lumbar spinal stenosis.

In the last phase, 250 consecutively assigned patients with lower extremity pain and variable underlying diagnoses were prospectively enrolled, including 165 with lumbar spinal stenosis. Diagnosis was determined by a surgeon, then confirmed by a panel of six additional expert surgeons based on clinical exam and MRI. All patients completed the SSHQ. Of the 250 patients with persistent symptoms, 217 were given the SSHQ two weeks later for test-retest reliability. The validation studies for the SSHQ in this third phase showed an area under the ROC curve of 0.797 in the derivation set and 0.782 in the validation data set. These findings indicated that the SSHQ had both internal and external validity as a diagnostic tool for lumbar spinal stenosis. The difference between tests plotted against the mean of the tests indicated no obvious relationship or bias. The intraclass correlation coefficient of the SSHQ score for the first and second tests was 0.85, which indicated sufficient reproducibility. One item of the κ coefficient was found to be "fair" (question 8), and all other items were rated as having a conformity of moderate or above. They concluded that this was a simple clinical diagnostic support tool to help identify patients with lumbar spinal stenosis. By asking patients who presented with back and leg symptoms suggestive of lumbar spinal stenosis to fill out a simple questionnaire consisting of five questions on their medical history (age and history of diabetes) and symptoms (presence or absence of intermittent claudication, aggravation of symptoms by standing and relief of symptoms by forward bending) followed by a short clinical examination, the diagnosis of lumbar spinal stenosis could be determined with a sensitivity of 93% and specificity of 72%. A more detailed questionnaire, the SSHQ, was developed that provided a scoring system to diagnose patients with lumbar spinal stenosis and to further differentiate those patients with radicular type from cauda equina type lumbar spinal stenosis. They concluded that additional studies were needed to validate this tool in primary care settings.

In the next study by Konno et al², 468 patients with a primary complaint of pain or numbness in the legs were prospectively evaluated. All patients underwent extensive questioning and clinical exam. Presence of lumbar spinal stenosis was determined by two surgeons based on history, exam and MRI and any discrepancies reconciled by a consensus panel of additional 10 experts. Of the patients evaluated, 47% had lumbar spinal stenosis. A univariate analysis was conducted followed by multivariate regression. Multiple variables were included as independent predictors in the multivariable model with a P value less than 0.05. An integer score derived from the beta-coefficient was assigned to the identified risk factors with values as follows: age (60 to 70 - 1, > 70 - 2), absence of diabetes (1), intermittent claudication (3), exacerbation of symptoms when standing up (2), improvement of symptoms when bending forward (3), symptoms induced by having patients bend forward (minus 1), symptoms induced by having patients bend backward (1), good peripheral artery circulation (3), abnormal Achilles tendon reflex (1), and positive SLR test (minus 2). For each patient, all applicable risk score values were summed up to attain a total risk score for the patient. The sum of the risk scores for each patient ranged from -2 to 16. Performance modeling showed that the area under the ROC curve was 0.918; thus the model had good discriminatory power. The positivity cut-off point was defined as 7, since the sum of the sensitivity and the specificity was the highest at that cut-off point. Given that the positivity criterion for risk score was greater than 7, the clinical diagnostic support tool had a sensitivity of 92.8% and a specificity of 72.0%. The prevalence of lumbar spinal stenosis increased as the risk score increased. Lumbar spinal stenosis prevalences were 6.3% in the first quartile (-2 to 5), 39.3% in the second quartile (6 to 8), 72.4% in the third quartile (9 to 11), 99.0% in the fourth quartile (12 to 16). They concluded this tool could help improve the accuracy of the diagnosis of spinal stenosis.

The last study by Sugioka et al³ used the identical 468 patient population and similar methodology, but eliminated those variables that required a physical exam, thus investigating the efficacy of a self administered questionnaire. The patients were divided into derivation and validation sets. They found the key determinants with their risk scores to be age (60 to 70 - 2, >70 - 3), duration of symptoms longer than six months (1), symptom improvement with forward bending (2), symptomatic aggravation while standing up (2), symptoms improve with backward bending (minus 2), intermit-tent claudication (1), and urinary incontinence (1). These patients were categorized into risk score

quartiles defined by risk scores of 2 or less, 3-4, 5-6 and 7 or more, respectively. Of the 374 patients in the derivation set, Quartile #1 showed a 17.7% (9/51) probability of lumbar spinal stenosis, whereas the second, third and fourth quartiles showed 25.3% (25/99), 50.8% (62/122), and 77.5% (79/102), respectively. The likelihood ratio in Quartile #1 of the derivation set was 0.24. Perfor-mance modeling showed an area under the ROC curve of 0.77 (Figure 2). Sensitivity and specificity at the cut-off score point of 5 were 0.81 and 0.58, respectively. Of the 94 patients in the validation set, Quartile 1 showed a 13.3% (2/15) probability of lumbar spinal stenosis, whereas the second, third and fourth quartiles showed 47.6% (10/21), 55.2% (16/29) and 65.5% (19/29), respectively. Sensitivity and specificity at the cutoff score point of 5 were 0.75 and 0.51, respectively. The likeli-hood ratio in Quartile #1 of the validation set was 0.15. The authors concluded this self-administered questionnaire could be useful to improve the accuracy of the diagnosis of spinal ste-nosis, and in particular to rule out lumbar spinal stenosis.

In critique, criteria for the diagnosis of lumbar spinal stenosis could have been more clearly defined. In the first study, their retest validation was done in 217/250 patients. This series of studies provides Level II diagnostic evidence that a self-administered questionnaire can be useful to assist with providing clinical evidence of lumbar spinal stenosis. They also discovered several key predictors of lumbar spinal stenosis including age > 60, intermittent claudication, exacerbation of symptoms when standing up, improvement of symptoms when bending forward, symptoms induced by having patients bend backward and abnormal Achilles tendon reflexes. Diabetes, poor peripheral circulation, symptoms induced by having the patient bend forward and a positive straight leg raising test were negative predictors of lumbar spinal stenosis.

Katz et al⁴ conducted a study assessing the value of historical and physical findings in the diagnosis of lumbar spinal stenosis. The study included 93 consecutive patients evaluated in a spine center. All patients underwent a standardized history and physical examination. Lumbar spinal stenosis was diagnosed in 46% (43 of 93) of patients by expert physician assessment with at least 80% confidence. The remaining patients had diagnoses including nonspecific musculoskeletal pain, scoliosis, spondylolisthesis and fibromyalgia. Imaging was available in 88% of patients with lumbar spinal stenosis and confirmed the diagnosis.

Historical findings most strongly associated with lumbar spinal stenosis, with a likelihood ratio (LR) greater than two, were greater age (LR 2.5), severe lower extremity pain (LR 2.0), absence of pain when seated (LR 6.6), and improvement of pain with sitting (LR 3.1). Symptoms worse with walking had a negative likelihood ratio of 0.96. Physical findings most strongly associated with lumbar spinal stenosis were wide-based gait (LR 14.3), abnormal Romberg test (LR 4.3), thigh pain after 30 seconds of lumbar extension (LR 2.5) and neuromuscular deficits (LR 2.1). Independent correlates of lumbar spinal stenosis were advanced age, wide-based gait and thigh pain with lumbar extension. The authors concluded that the history and physical examination were useful in the diagnosis of lumbar spinal stenosis.

In critique, this study relies on expert opinion as the gold standard for the diagnosis of lumbar spinal stenosis with radiographic confirmation in just 88% of patients. These patients were compared to patients with other clinical diagnoses without imaging. This comparative patient population is not well described. This study provides Level IV evidence that the diagnosis of lumbar spinal stenosis is suggested by greater age, severe lower ex-

tremity pain, absence of extremity pain when seated and/or improvement of pain when seated as well as lower extremity pain with spinal extension greater than 30°, an abnormal Romberg test and wide-based gait.

There is insufficient evidence to make a recommendation for or against the use of selfadministered questionnaires to improve accuracy of the diagnosis of spinal stenosis.

Grade of Recommendation : I (Insufficient Evidence)

Konno et al¹ looked at the efficacy of a self-administered, selfreported history and questionnaire (SSHQ). Through multiple analyses, they developed a series of questions intended to improve the accuracy of the diagnosis of lumbar spinal stenosis, and also to differentiate between two types of lumbar spinal stenosis termed radicular type and cauda equine type. A scoring system was developed to predict the diagnostic categories. The validation studies for the SSHQ showed an area under the ROC curve of 0.797 in the derivation set and 0.782 in the validation data set. These findings indicated that the SSHQ had both internal and external validity as a diagnostic tool for lumbar spinal stenosis. The difference between tests plotted against the mean of the tests indicated no obvious relationship or bias. The intraclass correlation coefficient of the SSHQ score for the first and second tests was 0.85, which indicated sufficient reproducibility. One item of the κ coefficient was found to be "fair" (question 8), and all other items were rated as having a conformity of moderate or above.

A second study by the same group looked prospectively at 468 patients with lower extremity symptoms.3 It is not known if part of the sample included patients from the earlier study by Konno et al.1 The patients were divided into derivation and validation sets. Following regression analysis and beta-coefficient assignment, they found the key determinants with their risk scores to be age (60 to 70 - 2, > 70 - 3), duration of symptoms longer than six months (1), symptom improvement with forward bending (2), symptomatic aggravation while standing up (2), symptoms improve with backward bending (minus 2), intermittent claudication (1) and urinary incontinence (1). These pa-tients were categorized into risk score quartiles defined by risk scores of 2 or less, 3–4, 5–6 and 7 or more, respectively. Of the 374 patients in the derivation set, Quartile #1 showed a 17.7% (9/51) probability of lumbar spinal stenosis, whereas the second, third and fourth quartiles showed 25.3% (25/99), 50.8% (62/122), and 77.5% (79/102), respectively. The likelihood ratio in Quartile #1 of the derivation set was 0.24. Performance modeling showed an area under the ROC curve of 0.77 (Fig. 2). Sensitivity and specificity at the cut-off score point of 5 were 0.81 and 0.58, respectively. Of the 94 patients in the validation set, Quartile 1 showed a 13.3% (2/15) probability of lumbar spinal stenosis, whereas the second, third and fourth quartiles showed 47.6% (10/21), 55.2% (16/29) and 65.5% (19/29), respectively. Sensitivity and specificity at the cutoff score point of 5 were 0.75 and 0.51, respectively. The likelihood ratio in Quartile #1 of the validation set was 0.15. The authors concluded this self-administered questionnaire could be useful to improve the accuracy of the diagnosis of spinal stenosis, and in particular to rule out lumbar spinal stenosis.

In critique, criteria for the diagnosis of lumbar spinal stenosis could have been more clearly defined. In the first study, their retest validation was done in 217/250 patients. This series of studies provides Level II diagnostic evidence that a self-administered questionnaire can be useful to assist with providing clinical evidence of lumbar spinal stenosis.

Wai et al⁵ described a prospective comparative study assessing the test-retest reliability of a patient's ability to describe whether their lumbar spine pain was leg or back dominant using standardized questions. Eight questions to ascertain a patient's ability to report location of pain (back or leg dominant) were assessed in a self-administered questionnaire for one group of patients and by a trained interviewer in a second group. Of the 63 patients included in the study, 32 were consecutively assigned to self-assessment and 31 were assigned to trainer interview. All questions in the interviewer administered group were significantly more reliable (p<.001) than the self-administered group. Depending upon the specific question, between 0% and 32% of patients provided a com-pletely opposite response on test-retest. The authors concluded that A patient's ability to identify whether their pain is leg or back dominant may be unreliable and depends on which questions are asked, and also how they are asked. While the Percent question is the most reliable method to determine the dominant location of pain, given the variability of responses and the generally poorer reliability, it is recommended that multiple methods be used to assess a patient's dominant location of pain. They also found answers to be more consistent when questions were administered by an interview rather than selfadministered.

This small study provides Level II diagnostic evidence that questions during structured interview are more likely to result in consistent answers than self administered questions regarding dominance of location of leg vs. back pain. However, regardless of the question, this information can be unreliable from one point in time to another.

Konno and Kikuchi et al¹ and Konno and Hayashino et al² reported results from two studies suggesting that a constellation of variables could contribute to the diagnosis of lumbar spinal stenosis. After evaluating 468 patients, using univariate and multiple regression analysis, several key determinants scored

There is insufficient evidence to make a recommendation for or against certain physical findings for the diagnosis of degenerative lumbar spinal stenosis including an abnormal Romberg test, thigh pain exacerbated with extension, sensorimotor deficits, leg cramps and abnormal Achilles tendon reflexes.

Grade of Recommendation: I (Insufficient Evidence)

together were found to be predictive of lumbar spinal stenosis. Some of these determinants were physical findings, including good peripheral artery circulation, abnormal Achilles tendon reflex and positive SLR test.

In critique, criteria for the diagnosis of lumbar spinal stenosis could have been more clearly defined. In addition, these physical findings were never evaluated alone as predictors of lumbar spinal stenosis, only in the context of a combined scoring system using several other variables additionally related to patient history and demographics.

Katz et al⁴ conducted a study assessing the value of historical and physical findings in the diagnosis of lumbar spinal stenosis. The study included 93 consecutive patients evaluated in a spine center. All patients underwent a standardized history and physical examination. Lumbar spinal stenosis was diagnosed in 46% (43 of 93) of patients by expert physician assessment with at least 80% confidence. The remaining patients had diagnoses including nonspecific musculoskeletal pain, scoliosis, spondylolisthesis and fibromyalgia. Imaging was available in 88% of patients with lumbar spinal stenosis and confirmed the diagnosis.

Historical findings most strongly associated with lumbar spinal stenosis, with a likelihood ratio (LR) greater than two, were greater age (LR 2.5), severe lower extremity pain (LR 2.0), absence of pain when seated (LR 6.6), and improvement of pain with sitting (LR 3.1). Symptoms worse with walking had a negative likelihood ratio of 0.96. Physical findings most strongly associated with lumbar spinal stenosis were wide-based gait (LR 14.3), abnormal Romberg test (LR 4.3), thigh pain after 30 seconds of lumbar extension (LR 2.5) and neuromuscular deficits (LR 2.1). Independent correlates of lumbar spinal stenosis were advanced age, wide-based gait and thigh pain with lumbar extension. The authors concluded that the history and physical ex-

amination were useful in the diagnosis of lumbar spinal stenosis.

In critique, this study relies on expert opinion as the gold standard for the diagnosis of lumbar spinal stenosis with radiographic confirmation in just 88% of patients. These patients were compared to patients with other clinical diagnoses without imaging. This comparative patient population is not well described. This study provides Level IV evidence that the diagnosis of lumbar spinal stenosis is suggested by greater age, severe lower extremity pain, absence of extremity pain when seated and/or improvement of pain when seated as well as lower extremity pain with spinal extension greater than 30°, an abnormal Romberg test and wide-based gait.

Matsumoto et al⁶ described a retrospective case control study assessing the incidence of leg cramps in patients with lumbar spinal stenosis. Of the 271 patients with lumbar spinal stenosis, 120 completed the mailed survey. These findings were compared with 370 controls. The study found that 70.8% (85/120) of the stenosis patients and 37.2% (137/340) of the controls experienced leg cramps, with an odds radio of 4.87 after adjusting for differences in comorbidities. Leg cramps occurred once or twice per week in 34.9% of the stenosis group and once in several months in 44.5% of the control group. Leg cramps disturbed the quality of life and they rarely improved after decompression surgery. The authors concluded that leg cramps should be recognized as one of the symptoms of lumbar spinal stenosis which negatively affect the patients' quality of life. In critique, the low response rate may introduce bias, depending upon construct of the interview. Patients who had cramps may have been more likely to respond to the survey. Because of these limitations, this potential Level III study provides Level IV prognostic evidence that there is an increased prevalence of leg cramps in patients with spinal stenosis, and that these cramps are not alleviated by surgery.

There is insufficient evidence to make a recommendation for or against the diagnostic reliability of patient-reported dominance of lower extremity pain and low back pain.

Grade of Recommendation: I (Insufficient Evidence)

Wai et al5 described a prospective comparative study assessing the test-retest reliability of a patient's ability to describe whether their lumbar spine pain was leg or back dominant using standardized questions. Eight questions to ascertain a patient's ability to report location of pain (back or leg dominant) were assessed in a self-administered questionnaire for one group of patients and by a trained interviewer in a second group. Of the 63 patients included in the study, 32 were consecutively assigned to self-assessment and 31 were assigned to trainer interview. All questions in the interviewer administered group were signifi-

cantly more reliable (p<.001) than the self-administered group. Depending upon the specific question, between 0% and 32% of patients provided a completely opposite response on test-retest. The authors concluded that a patient's ability to identify whether their pain is leg or back dominant may be unreliable and depends on which questions are asked, and also how they are asked. While the percent question is the most reliable method to determine the dominant location of pain, given the variability of responses and the generally poorer reliability, it is recommended that multiple methods be used to assess a patient's dominant lo-

cation of pain. They also found answers to be more consistent when questions were administered by an interview rather than self-administered.

This small study provides Level II diagnostic evidence that questions during structured interview are more likely to result in consistent answers than self administered questions regarding dominance of location of leg versus back pain. However, regardless of the question, this information can be unreliable from one point in time to another.

Additional Diagnostic and Imaging Considerations

Diagnostic Papers on Clinical Diagnostic Testing

The work group for this guideline identified several reports on the use of clinical diagnostic testing in the diagnosis of lumbar spinal stenosis. These techniques generally utilize measures of walking tolerance, time for onset of pain with exercise and recovery time. Several studies utilized treadmill or bicycle testing and attempted to measure the effect of posture on exercise tolerance. The utility of these tests can be limited, however, by the ability of sometimes frail elderly patients to complete testing. The results of several studies, such as the study by Fritz et al described below, are promising. Testing protocols are heterogeneous, however, and many have not been critically studied.

Fritz et al⁷ reported on the initial experience with the twostage exercise treadmill test (ETT) in the differential diagnosis of patients with low back pain, lower extremity pain and selfreported deficits in walking tolerance. The authors hypothesized that the findings on ETT would discriminate between stenotic and nonstenotic patients. Forty-five patients with low back pain, lower extremity pain and self-reported limitations in walking tolerance were studied with MRI or CT, Oswestry Disability Index (ODI), Visual Analog Scale (VAS), three self-reported postural variables and two-stage ETT. Based on imaging, all patients were classified as stenotic or nonstenotic (HNP, etc).

The authors reported that a linear discriminant analysis using time to onset of symptoms and recovery time resulted in a likelihood ratio of 14.5. Likelihood ratios on self-reported variables were much lower (<2.0). The authors concluded that a two-stage treadmill test may be useful in the differential diagnosis of lumbar stenosis. In critique, it was not clearly stated whether the patients were consecutively selected and there was no consistently applied and agreed upon gold standard. This study provides Level III diagnostic evidence that a two-stage treadmill test may be useful in the differential diagnosis of lumbar stenosis.

The work group concluded that while studies are limited, clinical diagnostic testing may be useful in selected patients to differentiate neurogenic from vascular causes of claudication.

Future Directions for Research

The work group identified the following potential studies that might generate meaningful evidence to assist in further defining the appropriate historical and physical findings consistent with the diagnosis of lumbar spinal stenosis.

Recommendation #1:

A sufficiently powered observational study of the predictive value of historical and physical findings in patients with the lumbar spinal stenosis, as defined by this guideline, is proposed. The study should allow for a subgroup analysis of the subsets of patients with neurogenic claudication and radiculopathy.

Recommendation #2:

A prognostic study with long-term follow-up of up to 10 years could be performed on the cohort of spinal stenosis patients defined in Study #1.

Recommendation #3:

Recommend further research to clarify the association of gait abnormalities, posture, balance and fall risk in patients with lumbar spinal stenosis.

Recommendation #4:

Recommend further research on the reliability of patient-reported dominance of lower extremity pain and low back pain.

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Diagnosing Spinal Stenosis with Imaging

Limitations and Assumptions in Magnetic Resonance Imaging (MRI) Studies

The results of this systematic review may not apply to all MRI systems. In general, the studies cited in this guideline utilized mid or high field strength MRI systems with dedicated surface coils. Their findings and the ensuing guideline's may not apply to low field strength systems. Only one study in our series, performed by Cihangiroglu et al¹, evaluated both low and high field strength systems. This study showed that the interobserver variability was increased with use of the low field strength system and the authors recommended that a high field strength system should be used whenever anatomic detail is necessary for surgical planning. Additional research studies need to be per-formed to evaluate the performance of low field strength MRI relative to high field strength MRI, state-of the-art computed tomography (CT) and CT myelography.

The results of our systematic review also assume adequate or state-of-the-art technique. MRI, and to a lesser extent CT, are user-dependent. The MRI studies cited in this guideline, in general, uti-lized thin (4-5 mm) sections and a combination of T1-, proton density and T2 pulse sequences in both the axial and sagittal planes. State-of-the-art protocols should utilize thin sections and provide excellent signal-to-noise ratios with high inplane resolution. With routine indications, stacked axial sections should be obtained and should include at least the L5-S1, L4-5, L3-4 levels. Additional an-gled or stacked axial sections can be obtained through adjacent or more cephalad levels as indicated.

Evolution of Imaging Technology

Both CT and MRI technology have evolved and continue to evolve over time. In our review, early developmental studies were discarded because they did not use surface coils or because thick (10 mm) sections were used. The studies cited above, however, do not reflect more recent improvements in MRI and CT technologies. MRI coils, gradients and imaging sequences have continued to improve, and have resulted in further increases

in signal-to-noise and further decreases in scan times. New sequences have been introduced, and most MRI centers now utilize multi-echo spin echo sequences for routine PD and T2-weighted imaging. STIR and T2 fat saturation images are also frequently used and may increase the sensitivity of MRI for inflammatory, neoplastic and traumatic pathologies.

CT technologies have also evolved. While one study (not included in the evidentiary tables) evaluated the application of helical scanning to spine imaging, no studies were identified which utilized more current 8 or 16 multidetector technologies. These technologies have resulted in a marked decrease in imaging times and many CT centers now routinely utilize 1 or 2 mm sections in the evaluation of the spine. The use of thin section technique has decreased partial voluming artifact, has improved the quality of sagittal reformations and has improved the ability of CT to evaluate the integrity of lumbar fusions. The impact of these technologies on overall accuracy needs to be studied.

While the accuracy of a state-of-the-art MRI system has not been compared to a state-of-the-art CT system in routine clinical imaging, the technical improvements in each modality have tended to parallel each other and the modalities remain complementary. MRI continues to provide superior soft tissue contrast with excellent visualization of soft tissue pathology, the dural sac interface and neural elements. CT continues to be more sensitive for calcified structures and provides better visuali-zation of both structural integrity and bridging bone. MRI remains a nonionizing modality, while with CT, the dose of ionizing radiation may be increased with routine utilization of 1 or 2 mm sections. A masked, randomized, controlled study comparing the benefits of these two modalities would clarify the impact of these developments on their relative accuracy.

The evolution of MRI technologies has also resulted in the development of "open" MRI systems, small contained MRI systems for placement in a doctor's "back office," upright MRI systems, and axial loading systems that simulate upright physiologic MRI/CT imaging. Evolution is not always synonymous with improved quality, however, and both the accuracy and efficacy of these new sys-tems also need to be evaluated.

What are the most appropriate diagnostic tests for degenerative lumbar spinal stenosis?

In patients with history and physical examination findings consistent with degenerative lumbar spinal stenosis, MRI is suggested as the most appropriate, noninvasive test to confirm the presence of anatomic narrowing of the spinal canal or the presence of nerve root impingement.

Grade of Recommendation: B

Kent et al² performed a systematic review assessing the accuracy of CT, MRI and myelography in diagnosing patients with lumbar spinal stenosis. This meta-analysis identified 14/116 relevant studies with a reference standard other than another imaging test. All studies received a grade of C or D as a result of failure to assemble a representative cohort, small sample size or failure to maintain independent readings. The sensitivity of MRI in the diagnosis of adult spinal stenosis was 81-97%, sensitivity of CT was 70-100% and sensitivity of myelography was 67-78%.

In critique, although the results from the cited studies were difficult to pool, this was a thorough meta-analysis of literature from 1986 to 1991. This study provides Level II diagnostic evidence suggesting that each of these diagnostic studies is useful, and that none of the three is unequivocally superior in the diagnosis of adult lumbar spinal stenosis.

Bischoff et al³ conducted a comparative study of the findings of MRI, myelography and CT myelography with intraoperative findings in 119 levels in 57 patients. They describe specificity and sensitivity values for these studies relative to operative findings. In making the diagnosis of lumbar spinal stenosis, CT myelography and MRI were equally accurate (85%), whereas myelography was the most specific (81%).

In critique of this study, the nonconsecutive patient population was limited to the 12% (59 of 475) of the available patients who had surgery and all three imaging studies preoperatively. This may present a selection bias toward patients with more difficult diagnoses. The interpretation of intraoperative findings was subjective. Also, Figure 1, as included in the article, demonstrates a very subtle degree of stenosis, interpreted as positive by the authors, raising a question about threshold. This study provides Level III diagnostic evidence that the accuracy of CT myelography and MRI are comparable in the diagnosis of lumbar spinal stenosis.

Jia et al⁴ conducted a prospective comparison of MRI to myelography in 78 nonconsecutive patients who had surgery. Findings on MRI and myelography were compared with operative findings as the gold standard. MRI provided an accurate diagnosis in 85.2% of cases and myelography in 90% of cases. The authors found that MRI was as good as myelography for the diagnosis of herniated discs, and recommend MRI because it is noninvasive and nonionizing.

In critique of this early study, details of the raw data were not provided. This study provides Level III diagnostic evidence that MRI is as good as myelography for the diagnosis of herniated discs or stenosis in the majority of patients.

Modic et al⁵ conducted a comparative study of surface coil MRI, CT and X-ray myelography in 60 consecutive patients with a clinical suspicion of a lumbar disc herniation or stenosis who were being evaluated for surgery. MRI was performed in every patient with surface coil technique. Myelography, CT or CT myelography (CTM) was performed in subsets of patients. Forty-eight patients were operated on at 62 levels with surgical findings as the gold standard. Masked interpretations of the imaging procedures were compared to each other and to the results of surgery. There was 86.8% agreement between MRI and CT/CTM at 151 levels. With respect to surgical findings, the accuracy for MRI was 82%, CT/CTM was 83% and myelography was 71%. In addition, myelography missed one metastatic lesion

and CT missed an ependymoma. Findings on CT and MRI were complementary, however, as the diagnostic accuracy increased when studies were used in combination.

In critique, testing of patients was not uniform in that subset of patients who underwent CT and myelography, which introduces potential bias as the patients may have been referred for specific tests depending on the suspected pathology. Not every patient underwent surgery, and the criteria for a surgical diagnosis were not specified. This study provides Level III diagnostic evidence that the accuracy of MRI and CT is comparable in the diagnosis of lumbar disc herniation and stenosis in pa-tients who undergo surgery.

Postacchini et al⁶ performed a study to evaluate the MRI findings and compare the diagnostic accuracy of this method of imaging with that of water soluble myelography and CT scanning in patients with stenosis of the spinal canal.

Twenty-two patients received myelography, CT and MRI. All patients had symptoms in lower limbs, and two had undergone previous surgery. Fifteen had MRI first, seven had myelography and/or CT first. Myelogram and CT were performed on separate occasions (ie, no postmyelographic CT done). MRI was performed with a 1.5T machine and CT was performed with 2-5 mm cuts. All studies were interpreted by a single-masked neuroradiologist. Patients were divided into two groups according to myelography findings. Group 1 consisted of 19 patients whose myelogram showed compression caused by stenosis; group 2 consisted of three patients with scoliosis with stenosis on MRI with negative myelogram. Stenosis was defined as a cross-sectional area of the dural tube less than 120 mm2.

The authors reported that a complete block on myelogram always corresponded to a complete interruption of the dural sac on MRI, but that a partial block on myelogram was often interpreted as a complete block on MRI findings. MRI gave no false negatives. The noncontrast CT was then com-pared to MRI, but not to the myelogram. Of the 13 cases, five showed stenosis on MRI, but not CT. The authors concluded that spinal canal stenosis surgery may be planned on the basis of MRI find-ings alone, except in scoliotic patients.

In critique, the study had a small sample size, with only three patients diagnosed with scoliosis. The CTs and myelograms were performed on separate occasions. This study provides Level III diagnostic evidence that MRI is as sensitive but not as specific as myelography in the diagnosis of lumbar spinal stenosis. Furthermore, in this study MRI was shown to be more accurate than CT in diagnosis of stenosis.

Schnebel et al⁷ conducted a retrospective comparison of imaging studies in patients with lumbar spinal stenosis. A single reader compared MRI and CT myelogram findings in 41 patients, of which eight had surgically confirmed stenosis and six had neurogenic claudication. The ability of CTM and MRI to detect disc degeneration, stenosis and spondylolisthesis was assessed and compared. MRI and CTM correlated in 96.6% of lumbar spinal stenosis cases. MRI was superior to CTM in demonstrating disc degeneration. The authors concluded that MRI is the imaging method of choice in patients with suspected lumbar spinal stenosis.

In critique, this is a retrospective comparison of CTM and MRI read by one individual in a small number of patients with

lumbar spinal stenosis, demonstrating excellent correlation between the two methods. This study provides Level III diagnostic evidence that MRI and CTM provide similar information in patients with lumbar spinal stenosis.

Barz et al⁸ studied 200 patients, 100 with lumbar spinal stenosis and 100 with low back pain, to assess whether the new sedimentation sign on MRI discriminates between nonspecific low back pain (LBP) and symptomatic lumbar spinal stenosis. Of the 100 patients in the lumbar spinal stenosis group (claudication with or without LBP and leg pain, a cross-sectional area < 80 mm2, and a walking distance < 200 m), 94 had a postive sedimentation sign; and 0/100 patients in the LBP group (LBP, no leg pain, no claudication, a cross-sectional area of the dural sac greater than 120 mm2, and a walking distance greater than 1000 m). The sign had excellent intraobserver and interobserver

reliability. The authors concluded that a positive sedimentation sign exclusively and reliably occurs in patients with lumbar spinal stenosis.

In critique, this is a retrospective cohort study as the patients were grouped according to their out-come or diagnosis. To be useful in the diagnosis of lumbar spinal stenosis, the sign needs to be able to discriminate between symptomatic and asymptomatic patients with DSA<80mm2. The study, as constructed, has not been shown to have a discriminating ability better than the DSA alone. In other words, the study has merely shown that all patients with a DSA<80 have a positive sedimentation sign, which one would expect. This study provides Level IV diagnostic evidence that the nerve root sedimentation sign is able to discriminate between patients with lumbar spinal stenosis and patients with LBP.

In patients with history and physical examination findings consistent with degenerative lumbar spinal stenosis, for whom MRI is either contraindicated or inconclusive, CT myelography is sug-gested as the most appropriate test to confirm the presence of anatomic narrowing of the spinal canal or the presence of nerve root impingement.

Grade of Recommendation: B

Englehorn et al⁹, in a prospective study of 20 patients assessed the feasibility and sensitivity of flat panel volumetric computed tomography (FPVCT) for myelographic imaging in lumbar spinal stenosis. In this study, the authors compared the dural sac diameter (D-CSD) and the dural sac cross sectional area (C-CSA) on FPVCT compared to multislice CT myelography (MSCT). The mean D-CSD and C-CSA for all disc levels as measured by MSCT was not statistically significantly different from that on FPVCT. The authors concluded that the diagnostic quality of the reconstructed FPVCT slice images was comparable to those acquired by MSCT, and that with FPVCT, radiographic myelography and postmyelographic computed tomography could be performed with less radiation in a single session on the same imaging system. In conclusion, this study offers preliminary level II diagnostic evidence that the dural sac diameter and dural sac area measured by MSCT and FPVCT are comparable. This is a preliminary study on a developing technique, however, and requires further evaluation.

Bischoff et al⁴ performed a comparative study of the findings of MRI, myelography and CT myelography with intraoperative findings in 119 levels in 57 patients. They describe specificity and sensitivity values for these studies relative to operative findings. In making the diagnosis of lumbar spinal stenosis, CT myelography and MRI were equally accurate (85%), whereas myelography was the most specific (81%).

In critique of this study, the nonconsecutive patient population was limited to the 12% (59 of 475) of the available patients who had surgery and all three imaging studies preoperatively. This may present a selection bias toward patients with more difficult diagnoses. The interpretation of intra-operative findings was subjective. Also, Figure 1 within the article demonstrates

a very subtle degree of stenosis, interpreted as positive by the authors, raising question about threshold. This study provides Level III diagnostic evidence that the accuracy of CT myelography and MRI are comparable in the diagnosis of lumbar spinal stenosis.

Modic et al⁵ conducted a comparative study of surface coil MRI, CT and X-ray myelography in 60 consecutive patients with a clinical suspicion of a lumbar disc herniation or stenosis who were being evaluated for surgery. MRI was performed in every patient with surface coil technique. Myelography, CT or CT myelography was performed in subsets of patients. Forty-eight patients were oper-ated on at 62 levels with surgical findings as the gold standard. Masked interpretations of the imaging procedures were compared to each other and to the results of surgery.

There was 86.8% agreement between MRI and CT/CTM at 151 levels. With respect to surgical find-ings, the accuracy for MRI was 82%, CT/CTM was 83% and myelography was 71%. Myelography missed one metastatic lesion and CT missed an ependymoma. Findings on CT and MRI were com-plementary, however, as the diagnostic accuracy increased when studies were used in combination.

In critique, testing of patients was not uniform in that subset of patients who underwent CT and myelography, which introduces potential bias as the patients may have been referred for specific tests depending on the suspected pathology. Not every patient underwent surgery, and the criteria for a surgical diagnosis were not specified. This study provides Level III diagnostic evidence that the accuracy of MRI and CT is comparable in the diagnosis of lumbar disc herniation and stenosis in patients who undergo surgery.

Schnebel et al⁷ performed a retrospective comparison of imaging studies in patients with lumbar spinal stenosis. A single reader compared MRI and CT myelogram findings in 41 patients, of which eight had surgically confirmed stenosis and six had neurogenic claudication. The ability of CTM and MRI to detect disc degeneration, stenosis and spondylolisthesis was assessed and compared. MRI and CTM correlated in 96.6% of lumbar spinal stenosis cases. MRI was superior to CTM in demonstrating disc degeneration. The authors concluded that MRI is

the imaging method of choice in patients with suspected lumbar spinal stenosis.

In critique, this is a retrospective comparison of CTM and MRI in a small number of patients with lumbar spinal stenosis demonstrating excellent correlation between the two methods. This study provides Level III diagnostic evidence that MRI and CTM provide similar information in patients with lumbar spinal stenosis.

In patients with history and physical examination findings consistent with degenerative lumbar spinal stenosis for whom MRI and CT myelography are contraindicated, inconclusive or inappropriate, CT is the preferred test to confirm the presence of anatomic narrowing of the spinal canal or the presence of nerve root impingement.

Grade of Recommendation: B

Bell et al¹⁰ conducted a prospective comparison of metrizamide myelography and noncontrasted (not postmyelogram) CT to intraoperative findings. The authors developed a "correlation scale" to judge the degree of agreement between the imaging studies and surgical exploration among 122 patients with surgically-confirmed pathology. Masked readings of CT and myelographic images were compared with surgical findings. The strength of correlation was assessed. The details of the CT technique were not specified.

Based on their data, the authors concluded that myelography was 93% accurate and CT was 89% accurate in the diagnosis of lumbar spinal stenosis. The authors concluded that myelography is more accurate than CT in the diagnosis of stenosis.

In critique, site specific findings showed no significant difference between CT and myelography (67% and 68% accurate, respectively) in diagnosing spinal stenosis. This study provides Level II diagnostic evidence that the accuracy of CT and myelography in the diagnosis of lumbar spinal stenosis is comparable.

Bolender et al¹¹ conducted a study comparing the intraoperative findings, as the gold standard, with myelography (with extension views) and CT. The study population included 24 patients with lumbar spinal stenosis confirmed by surgical exploration and 30 patients with abdominal CT scans performed for other reasons.

The AP diameter of the osseous canal on CT correlated with surgical findings in only 20% of cases. On the other hand, the AP diameter of the dural sac on myelography correlated with surgical findings in 83% of cases. The effectiveness of CT was improved by using the dural sac cross-sectional diameter. The authors proposed that a dural sac area (DSA) of 100 mm2 was unequivocal evidence of stenosis, and concluded that myelography was more sensitive than CT and that CT assessment of the DSA was more accurate than measurement of bony diameter of the spinal canal.

In critique of the study, criteria for the intraoperative diagnosis of central stenosis were not detailed. CT technology has evolved significantly since this study was published. This study provides Level II diagnostic evidence that the dimensions of the bony canal may significantly underestimate the severity of canal

narrowing possibly caused by soft tissue. The AP diameter of the dural sac on myelography and the dural sac area on CT represent better measures of central canal stenosis.

Herkowitz et al¹² described the use of CT in the evaluation of levels caudad to a complete, or near complete, myelographic block in 32 patients. They found that CT provided clinically useful infor-mation that was confirmed at the time of surgery. Sixty percent of the nonvisualized levels showed stenosis or a herniated disc that was confirmed at surgery.

In critique, this was an early study showing the value of CT in addition to myelogram in evaluating the spinal canal. This study provides Level II diagnostic evidence that CT can provide useful infor-mation about levels below a myelographic block.

Kent et al² conducted a systematic review assessing the accuracy of CT, MRI and myelography in diagnosing patients with lumbar spinal stenosis. This meta-analysis identified 14/116 relevant studies with a reference standard other than another imaging test. All studies received a grade of C or D because of a failure to assemble a representative cohort, small sample size or failure to maintain independent readings. The sensitivity of MRI in the diagnosis of adult spinal stenosis was 81-97%, sensitivity of CT was 70-100% and sensitivity of myelography was 67-78%.

In critique, although the results from the cited studies were difficult to pool, this was a thorough meta-analysis of literature from 1986 to 1991. This study provides Level II diagnostic evidence (based on the levels of evidence of the studies reviewed) suggesting that each of these diagnostic studies are useful, and that none of the three is unequivocally superior in the diagnosis of adult lumbar spinal stenosis.

Johanson et al¹³ performed a prospective study of X-ray myelography compared to noncontrast CT performed in 1986 on a nonconsecutive series of 30 patients who presented with clinical symptoms of a mononeuropathy, in which an isolated myelogram revealed a unilateral shortening of a nerve root sheath. After an average of six days, the same patients were imaged by CT. In 18 of these patients, the isolated myelogram was interpreted as evidence for lateral recess spinal stenosis; eight of these 18 had the diagnosis changed to "lateral disc herniation" when the CT images were reviewed. In critique, this early report describes a nonconsecutive series of patients, and does not apply a clear gold standard. This early study presents Level III diagnostic evidence that X-ray myelography may allow some isolated root compression, actually

caused by a disc herniation, to be misinterpret-ed as lateral recess stenosis. Noncontrast CT imaging may be more useful than X-ray myelography in the assessment of the etiology of nerve root compression in the lateral recess.

MRI or CT with axial loading is suggested as a useful adjunct to routine imaging in patients who have clinical signs and symptoms of lumbar spinal stenosis, a dural sac area (DSA) of less than 110mm2 at one or more levels, and suspected but not verified central or lateral stenosis on routine unloaded MRI or CT.

Grade of Recommendation: B

Several techniques can be utilized to increase the sensitivity for spinal stenosis with imaging. These may utilize axial loading of the spine, imaging the patient in the upright position or imaging the patient in flexion and extension, and have been utilized in myelography, CT scanning and MRI scan-ning. Papers on these techniques are heterogeneous and several of the techniques have not been critically studied. However, axial loading and postural adjustment techniques appear to have potential diagnostic value.

Wang et al¹⁴ prospectively studies 25 patients, evaluating the effect of axial loading on the DSA on MRI in patients with clinical symptoms consistent with lumbar spinal stenosis. The change in DSA was studied at L5/S1, L4/5, L3/4 and L2/3 in each of the patients, and the authors noted a significant change in the DSA in 30% of discs. Axial loading resulted in a decrease in total DSA for each patient from 20.5% to 6.3% compared to the psoas relaxed position (p <0.01). The decrease in mean DSA, following axial compression was greatest at the L4/5 and L5/S1 levels. In critique, the study used nonconsecutive patients and a small sample size. In summary, the article offers Level III diagnostic evidence that axial loading results in a significant decrease in the DSA in patients with clinical lum-bar spinal stenosis. The effect of these changes on treatment planning was not addressed.

Several additional studies also report significant changes in the dural sac cross-sectional area with axial loading on CT myelography and MRI.¹⁵⁻¹⁸ Willen et al¹⁷, in a study of 172 patients, reported significant changes on axial CT or MRI in 69% of patients with neurogenic intermittent claudication, 14% of patients with sciatica and 0% of patients with isolated back pain.

Willen et al¹⁹ also studied 24 patients to estimate the clinical effect of decompression with or with-out fusion in patients with hidden stenosis detected on axial loaded MRI or CT. These patients were followed for 1-6 years following decompression for lumbar spinal stenosis detected on axial loaded CT or MRI only.

At follow-up, 76% of patients had leg pain less than 25/100 and 62% had back pain less than 25/100 on a VAS scale. Of the patients, 96% were improved or much improved regarding their

leg and back pain. Patients with walking capacity to more than 500m increased from 4% to 87%. Of the 24 patients, 22 were subjectively satisfied with the surgical results, and similar results were seen with the ODI, SF-36 and EQ-5D scores.

The study was downgraded as the authors did not indicate whether patients were consecutive. In conclusion, this study offered Level III evidence that the results of surgery for lumbar spinal stenosis detected only on axial loaded imaging are convincing and comparable to those seen following surgi-cal treatment for lumbar spinal stenosis diagnosed on routine unloaded examinations.

Sortland et a¹²⁰ reported the results of static and dynamic (flexion and extension) water-based myelography in patients with a clinical diagnosis of spinal stenosis. The results were compared to those of a control group of patients with complaints of back pain or sciatica, without a diagnosis of spinal stenosis. This Level IV study noted that patients with a clinical presentation of spinal stenosis frequently demonstrated narrowing of the canal that worsened significantly in extension. In eight of the 36 stenosis patients, a complete myelographic block was seen on the images obtained in extension but not on myelographic images with the patient in the neutral position. In contrast, only small differences in canal dimensions with flexion and extension were noted in the control group.

Similar findings were reported in other Level IV reports. 1-24 All of these authors reported that in some patients, imaging obtained in the flexed or extended position might reveal spinal canal narrowing not documented by static imaging. Unfortunately, there are no evidence-based conclusions available to specifically correlate these observations with patient outcomes.

No high quality studies were found during our search which would allow us to extrapolate these results to open upright imaging with the patient sitting or standing, nor on open upright imaging with patients in the sitting flexed and sitting extended positions.

It is suggested that readers use well-defined, articulated and validated criteria for anatomic canal narrowing on MRI, CTM and CT to improve interobserver and intraobserver reliability.

Grade of Recommendation: B

Lurie et al²⁵ studied 58 patients to determine the intra- and interreader reliability of MRI features of lumbar spinal stenosis, including severity of central, subarticular and foraminal stenoses, grading of nerve root impingement and measurements of cross-sectional area of the spinal canal and thecal sac. Each reader received a handbook containing standardized definitions of stenosis as diagnosed on MRI. Pictorial and diagrammatic examples were provided where appropriate, derived from the literature or by consensus when no relevant publication was available. Prior to the study, the readers evaluated a sample set of images and then met in person to review each image and refine the standardized definitions.

Inter-reader reliability in assessing central stenosis was substantial with an overall K of 0.73, and was moderate to substantial for foraminal stenosis and nerve root impingement with overall K of 0.58, and 0.51, respectively. Subarticular zone stenosis yielded poorer results with an overall K 0.49 and showed marked variability in agreement between reader pairs. Quantitative measures showed inter-reader intraclass correlation coefficients ranging from 0.58 to 0.90. The mean absolute difference between readers in measured thecal sac area was 12.8 mm2 (13%).

The only critique of the study is that the randomization process for the selection of cases was not clearly defined. This study provides Level II diagnostic evidence that there is moderate to substantial intra-reader and inter-reader reliability in the evaluation of spinal stenosis when criteria for diagnosis are defined in advance

Song et al²⁶ studied 100 patients in order to determine whether magnetic resonance myelography (MRM) improves the reliability of MRI in the evaluation of the severity of stenosis in patients with multilevel disease. The most severe level of stenosis and the severity of stenosis at that level as assessed by effacement of subarachnoid space were assessed in each patient. In this study, greater than 50% of the subarachnoid space remaining was defined as grade 1 (mild); less than 50% and no evidence of complete blockage was defined as grade 2 (moderate); and complete blockage was defined as grade 3 (severe).

The average K values for interobserver agreement in the selection of the most severe segment/assessing the degree of stenosis were 0.649/0.727 for MRI alone, 0.782/0.771 for MRM alone, and 0.832/0.784 for MRI with MRM. Intraobserver K values were highest for class MRM alone, followed by MRI with MRM, and then MRI alone. This study offers Level II diagnostic evidence that the interobserver reliability of MRI for identifying and grading lumbar spinal stenosis was excellent and was improved with the use of MRM.

Song et al²⁶ and Lurie et al²⁵ each utilize well defined and articulated criteria for lumbar spinal stenosis and each of these studies show moderate or substantial reliability. Several older

studies show that in the absence of well-defined criteria, the observer reliability of MRI and CT for the diagnosis or grading of stenosis is poor. The paper by Coste et al²⁷ is the oldest of these papers reviewed. The technology evaluated was CT scanning which, while improved since the publication date, was a ma-ture technology in 1994. In this case control study, 20 patients with sciatica were compared to 20 gender and age-matched asymptomatic volunteers. All subjects were scanned at the lower two lumbar disc levels with 4 mm cuts and 1 mm overlap. The 40 scans were independently interpreted by two radiologists and two rheumatologists, all of whom were masked. All the scans were reread four months later in a masked fashion by the same individuals. Inter- and intrarater reliabilities were assessed by kappa statistics.

Four diagnoses were considered: herniated nucleus pulposus (HNP), disc bulge, spinal stenosis and facet arthrosis. Only for a diagnosis of HNP was inter- and intrarater reliability determined to be high by the Landis and Koch criteria employed with an inter-rater reliability of kappa=.7 and intra-rater reliability of kappa=.9. Both inter- and intrarater reliability for disc bulge, spinal stenosis and facet arthrosis were poor. Reliability was the poorest for the diagnosis of spinal stenosis (inter-rater kappa=.20 at L5-S1 and intra-rater kappa=.38 at L-S1).

This study is considered to present Level I prognostic evidence that with unenhanced CT scanning of the lumbar spine, observer reliability is moderate for the diagnosis of herniation, but poor for ste-nosis.

A second study utilizing CT scans was published in 2000 by Drew et al²⁸ in which inter- and intrarater reliability was tested in specifically diagnosing lumbar spinal stenosis. In this study, thirty CT scans were selected from a database by two neuroradiologists to represent normal to severely stenosed lumbar spines in patients not previously operated on. The scans contained both bony and soft-tissue windows, 3 mm cuts and sagittal reconstructions. These 30 scans were each reviewed in a masked fashion by four spinal surgeons and their findings recorded. All scans were reread in a masked fashion by the same surgeons four weeks later.

Analysis of inter-and intrarater reliability was represented by kappa statistics. There was moderate inter-rater agreement by the Landis and Koch criteria (kappa=.58 +/- 0.06) and intrarater agree-ment (kappa=.59 +/- 0.04) on the overall presence or absence stenosis. However, when asked to assess the degree of stenosis on a 7-point scale, inter-rater agreement was poor (kappa=.26 +/- .04). Furthermore, inter-rater reliability worsened when stenosis was assessed from the central canal to the foramen (central stenosis: kappa=.46 +/- .04; lateral recess stenosis: kappa=.32 +/-.04 and foraminal stenosis: kappa=0.18 +/- .04). The authors concluded that the poor reliability of CT scans in diagnosing varying degrees of spinal stenosis brings into question

the results of studies using this diagnostic test for this diagnosis.

The study is considered to present Level I prognostic evidence that with CT, observer reliability is moderate for the general diagnosis of lumbar spinal stenosis and poor for identifying the degree and type of stenosis present.

Speciale et al²⁹ published an MRI study in 2002 asking questions similar to those in the two CT-based studies cited above. In this study, 15 MRI scans of the lumbar spine from patients diagnosed clinically with spinal stenosis were evaluated. All of the patients reported radiculopathy or claudication and 60% reported back pain. These MRIs were read in a masked fashion by seven observers: two orthopedic spinal surgeons, two neurosurgeons and three neuroradiologists. The scans were reread between two and three months after the initial reading, again in a masked fashion. Inter- and intrarater reliable was estimated with kappa statistics.

Inter-rater reliability was fair by the Landis and Koch Scale (kappa=.26 +/-.26). Intrarater reliability was poor overall (kappa=.11). These poor results were interpreted by the authors as stemming from the lack of clearly articulated MRI criteria to support diagnostic categories.

This study provides Level I prognostic evidence that in the absence of well defined and articulated criteria, observer reliability in diagnosing lumbar spinal stenosis by MRI is poor.

A second MRI study addressing observer reliability in diagnosing lumbar spinal stenosis was published in 2004 by Cihangiroglu et al. In this study, 95 patients with acute low back pain or radicu-lopathy were prospectively studied by MRI on either 0.3 Tesla (57 patients) or 1.5 Tesla (38 patients) scanners. The lower three lumbar disc levels only were evaluated. Two independent and masked neuroradiologists read each study and then re-read each study, masked, 15 days later. Final diagno-sis was by a consensus reading a third time by the same radiologists. Inter- and intrarater reliability was assessed by kappa coefficients.

Inter-and intrarater reliability was rated as "almost perfect" (kappa=.81-1.00) for detecting disc pathology; "substantial" (kappa=.61-.80) for defining the disc pathology; but only "mod-

erate" (kappa= .41-.60) for diagnosing root compression and stenosis. For the more difficult root compression and stenosis diagnoses, the higher Tesla MRIs yielded slightly higher scores. The authors concluded that higher field machines should be used for surgical decision making and that MRI findings alone should not be used to make surgical decisions when stenosis is the diagnosis. This study provides Level I prognostic data showing large inter- and intra-rater variability in diagnosing root compres-sion and spinal stenosis by MRI and supports the findings of Speciale et al.²⁹

The early studies evaluating rater reliability in spinal imaging raised serious questions both about the clinical reliability of the diagnosis of lumbar spinal stenosis by CT and MRI scans in the practice of medicine as well as questions about the conclusions reached in early research studies. It is important to keep these studies in mind when evaluating the data and conclusions of the studies reviewed elsewhere in this guideline. The primary issue appears to have been the lack of well-defined and articulated diagnostic criteria for stenosis on cross-sectional imaging modalities, leading to marked variability in interpretations.

The development and adoption of well-defined criteria for the diagnosis of lumbar spinal stenosis is essential to the interpretation of the results of clinical studies, and in the evaluation of individual patients relative to these patients. Two studies suggest quantitative criteria for the diagnosis of central canal stenosis. Hamanishi et al³⁰ reported that a decrease in the dural sac diameter to below 100 mm2 at more than two of three levels was highly associated with the presence of intermit-tent claudication. Bolender et al² demonstrated that the effectiveness of CT was improved by using the dural sac cross-sectional diameter and proposed that a dural sac area (DSA) of 100 mm was un-equivocal evidence of central canal stenosis. Because of variability in the size of the lateral recesses and foramina and in the position of the ganglia and nerve root sleeve between individual patients, any grading system for lateral recess and foraminal stenosis will have to incorporate some measure of perineural effacement, neural displacement, and neural compression.

There is insufficient evidence to make a recommendation for or against a correlation between clinical symptoms or function with the presence of anatomic narrowing of the spinal canal on MRI, CTM or CT.

Grade of Recommendation: I (Insufficient Evidence)

Several studies show conflicting evidence concerning the correlation or lack of correlation between symptoms or function and findings on MRI and CT. This is the justification for including both clinical symptoms and assessment of the narrowing of the spinal canal in the guideline's definition of degenerative lumbar spinal stenosis.

Zeifang et al³¹ in a 2008 study of 63 patients analyzed the correlation between the objectively measured walking distance and the cross sectional area of the dural tube, assessed by MR imaging in patients with symptomatic lumbar spinal stenosis. The study offers Level I diagnostic evidence that the smallest dural sac area on MRI does not correlate with measured walking ca-

pacity in pa-tients with lumbar spinal stenosis.

Sirvanci et al³² in a 2008 study of 63 patients assessed the relationship between the degree of radio-logically established anatomical stenosis and the severity of self-assessed Oswestry Disability Index in patients undergoing surgery for degenerative lumbar spinal stenosis. The study utilized well de-lineated criteria for the diagnosis and grading of stenosis on MRI and reported a poor correlation between the presence and severity of stenosis on MRI and the degree of disability in patients with clinical lumbar spinal stenosis.

Ogikubo et al³³ in a 2007 retrospective study of 82 patients undergoing surgery for lumbar spinal stenosis examined the as-

sociation of typical symptoms and signs of central spinal stenosis and the minimum cross-sectional area (mCSA) of the cauda equina (dural sac). A smaller mCSA showed a direct correlation with greater back and leg pain, a shorter walking distance before claudication and a lower health related quality of life. The mCSA was 52mm2 for patients with walking ability of <100m, 55.8mm2 for those with a walking ability of 100-500m, and 68.8mm2 for those able to walk >500m. In critique of this article, we were unable to determine whether the patients were consecutive. This paper offers Level III diagnostic evidence that the mCSA correlates with back and leg pain, preoperative walking ability and quality of life in patients with lumbar spinal stenosis.

Egli et al³⁴, in a study providing Level III diagnostic evidence about the use of electrophysiologic measures of cauda equina function in 54 patients scheduled for surgery for lumbar spinal stenosis, reported no correlation between the electrophysiologic recordings and the DSA on MRI, the sensory findings or pain intensity. A low correlation was noted, however, between the ASIA motor score and the DSA at the most stenotic level.

Geisser et al³⁵, in a retrospective 2007 study of 50 patients, reported no correlation between the AP diameter of the osseous canal and self-reported pain, perceived function or walking ability. In critique, the AP diameter of the osseous canal is not considered a relevant measure or lumbar spinal stenosis, and to be meaningful, correlation should be made with the AP diameter or cross-sectional area of the dural sac. The study used nonconsecutive patients and a poor gold standard and provides Level IV diagnostic evidence that there is a poor correlation between the osseous diameter of the spinal canal, pain and function.

Haig et al³⁶⁻³⁷, in a retrospective 2006 study and a 2007 study reported on 150 patients evaluating the relationships between clinically diagnosed lumbar spinal stenosis, MRI findings and electrodiagnostic findings. The authors reported a poor correlation between MRI measures of stenosis, electrodiagnostic testing and the clinical impression by a physiatrist. In critique, the study utilized a poor gold standard, the surgeon's diagnosis used to validate the construct agreed with the physiatrist's diagnosis

in only 78 of 126 cases and the patients were nonconsecutive. In conclusion, these two studies provided Level IV diagnostic evidence that there is a poor correlation between MRI measures of stenosis and the clinical diagnosis of lumbar spinal stenosis.

Chiodo et al³⁸, in a separate analysis of the 150 patients from the "Michigan Spine Study," reported that while MRI measurements did not correlate significantly with EMG or clinical measures, H-wave and F-wave findings did correlate with specific anatomic changes on MRI. Again, this study is limited because of a poor gold standard and the use of nonconsecutive patients, providing Level IV diagnostic evidence that an absent tibial H-wave and peroneal F-wave latency correlates with specific measures of stenosis at L4-5 and L5-S1 on MRI.

Kapural et al³⁹, in a retrospective study of 719 patients undergoing epidural steroid injection therapy reported a positive correlation between the severity of stenosis on MRI, the VAS pain score and im-provement following injections. In critique, neither the clinical criteria, nor the imaging criteria for the diagnosis of lumbar spinal stenosis were well enunciated. This study offers Level IV diagnostic evidence for a positive correlation between the severity of stenosis on MRI and patient's pain level.

Lohman et al⁴⁰, in a 2006 study of 117 patients examined the changes in the dural sac area of the lumbar spine on computerized tomography performed without and with axial loading, and studied the correlations between the radiologic findings and clinical symptoms suggestive of spinal stenosis. The authors reported that except for a correlation between the change in the dural sac area at L4–5 with compression and the severity of pain radiating to the leg, no statistically significant correlation between the severity of the clinical symptoms of spinal stenosis and dural cross-sectional areas was found. In critique, the study used nonconsecutive patients and a poor reference standard. In conclusion, the study offers Level IV therapeutic evidence that there is a poor correlation between clinical parameters associated with lumbar spinal stenosis and DSA on routine MRI, and that changes in the DSA at L4-5 on axial loading correlate with leg pain.

Electrodiagnostics

Few studies are dedicated to evaluating the utility of standard electrodiagnostic studies in lumbar spinal stenosis. Studies reviewed suggest that electrodiagnostic studies are helpful for the evaluation of patients in which stenosis alone may not account for the neurologic symptoms.

In the absence of reliable evidence, it is the work group's opinion that imaging studies be considered as a first line diagnostic test in the diagnosis of degenerative lumbar spinal stenosis.

Work Group Consensus Statement

Electromyographic paraspinal mapping is suggested to confirm the diagnosis of degenerative lumbar spinal stenosis in patients with mild or moderate symptoms and radiographic evidence of stenosis.

Grade of Recommendation: B

Haig et al4¹ reported a prospective comparative study in 2005 evaluating the sensitivity and specificity of electrodiagnostic testing, specifically paraspinal mapping, for the clinical syndrome of lumbar spinal stenosis. Parapinous mapping EMG of >4 has a 100% specificity and 30% sensitivity for stenosis compared with either back pain or asymptomatic patients. A composite limb and paraspinal fibrillation score had a specificity of 87.5% and a sensitivity of 47.8%; H-wave a specificity of 91.3% and sensitivity of 36.4%. Seven subjects with previously undiagnosed neuromuscular disease were diagnosed. The authors concluded that electrodiagnostic testing has statistically significant and clinically meaningful specificity for spinal stenosis and detects neuromuscular diseases that may mimic stenosis.

This study provides Level III diagnostic evidence that paraspinal mapping is useful in diagnosing polyneuropathy and myopathy in both stenosis patients and controls, and that paraspinous mapping, a composite limb and paraspinous fibrillation score, and absence of H-waves had a high specificity and low sensitivity for lumbar spinal stenosis compared with asymptomatic controls.

Yagci et al⁴² described a prospective comparative study of 62 nonconsecutive patients evaluating the utility of lumbar paraspinous mapping in the diagnosis of lumbar spinal stenosis.

Clinical criteria assessed included pain that improves with sitting and is exacerbated with standing, thigh pain with 30 seconds of sustained lumbar extension, the presence of neurogenic claudication and the presence of parasthesias. Patients had to meet three of four of these criteria for inclusion in the study. Midline AP diameter of the dural sac was assessed, along with nerve conduction studies and EMG of the lower extremities. Paraspinous mapping showed fibrillation potentials and positive sharp waves in at least two levels in 92.8% of the patients in clinical and radiologic lumbar spinal stenosis; while it was normal in 93.8% of patients in the radiologic spinal stenosis group. In the control group, 6/14 patients had high paraspinous mapping scores, mostly secondary to acute monoradiculopathy caused by disc herniation. If the cutoff value is set at 9, the sensitivity and specificity would be 96.8% and 92.3% respectively. The authors concluded that the paraspinous mapping technique is a sensitive method in the diagnosis and reflects physiology of nerve roots better than the limb EMG.

This study provides Level III diagnostic evidence that lumbar paraspinous mapping is able to discriminate between patients with symptomatic and asymptomatic lumbar spinal stenosis, and may be useful in the presurgical evaluation of patients with equivocal clinical and MRI findings.

There is insufficient evidence to make a recommendation for or against the use of F wave, H reflex, motor evoked potential (MEP), motor nerve conduction studies, somatosensory evoked potentials (SSEP), dermatomal sensory evoked potentials (DSEP) and lower extremity EMG in the confirmation of lumbar spinal stenosis. These studies may be used to help identify other comorbidities.

Grade of Recommendation: I (Insufficient Evidence)

Micankova et al⁴³ performed a prospective comparative study evaluating the results of electrophysiologic testing in 102 consecutive patients with lumbar spinal stenosis to assess the contribution of electrophysiological tests made to diagnosis. Findings on electrodiagnostic tests were compared with findings on CT and clinical exam. On the basis of nerve conduction studies and needle electromyography, the presence of radiculopathy was established in 70.6 % of patients with lumbar spinal stenosis; polyradicular involvement (46.1 % of the patients) was more common than mono-radicular involvement (24.5 % of the patients). Involvement of the L4 root was established in 37.2% of the patients, L5 root in 51.9 % and S1 root in 50.9% of the patients. Abnormal motor evoked potentials were found in 30.7 % of the patients and abnormal somatosensory evoked potentials in 58.8% of the patients with lumbar spinal stenosis. Normal needle electromyography and nerve conduction studies were recorded in 18.6% of the patients. The authors concluded that nerve conduction studies and needle electromyography are the most useful electrophysiological examinations for the evaluation of suspected radiculopathies in patients with lumbar spinal stenosis. Involvement of L5 and S1 roots is the most common finding. The diagnostic contribution of evoked potentials is of limited value in patients with lumbar spinal stenosis. Because the study did not compare with MRI as gold standard, it provides Level IV diagnostic evidence that on the basis of nerve conduction stud-ies and needle electromyography, the presence of radiculopathy was the most common abnormality and was established in 70.6% of patients with lumbar spinal stenosis; polyradicular involvement in 46.1 % of the patients) and monoradicular involvement in 24.5% of the patients). Involvement of the distal nerve roots was the most common. Normal electrodiagnostic studies were seen in 12.7%.

F-Wave Response and H-Reflex

Egli et al³⁴ reported findings from a prospective case series investigating the relationship between electrophysiological recordings and clinical as well as radiological findings in patients suggested to suffer from lumbar spinal stenosis. Severe stenosis was defined as a DSA <.8, while mild stenosis was defined as >.8 and <1.6. Of the 54 patients included in the study, 68% indicated suffering from a severe reduction of walking distance limited to 500 m or less (maximal preoperative walking distance <100 m in 28%, <500 m in 40%, <1 km in 15%, >1 km in 17% of patients). In 70% of patients, the motor and/or sensory (pin prick and light touch) scores were normal. Severe lumbar canal stenosis was diagnosed in 75% of patients, while 25% of patients had mild stenosis. About 88% of patients revealed more than one stenotic segment and 87% of patients showed pathological electro-physiological recordings (abnormal tibial SSEP in 78% of patients, delayed F-wave responses in 15%, and abnormal H-reflex in 52% of patients). Pearson correlations analysis did not find a significant correlation between the electrophysiological recordings and the radiological findings, number of stenotic levels, the sensory deficit (pin prick) and the reported pain intensity. Only the ASIA motor score showed a low correlation to the extent of the most stenotic segment (p = 0.039). The authors concluded that the applied electrophysiological recordings, especially SSEP, can confirm a neurogenic claudication caused by cauda equina involvement and help to differentiate neurogenic from vascular claudication or musculoskeletal disorders of the lower limbs. Therefore, electrophysiological recordings provide additional information to the neurological examination when the clinical relevance of a radiologically-suspected lumbar spinal stenosis needs to be confirmed. This study provides Level III evidence that electrophysiologic studies, in particular the SSEP and nerve conduction studies (NCS), are abnormal in patients more often than the clinical exam. The results of these studies do not correlate with radiologic findings.

Haig et al⁴¹ reported a prospective comparative study in 2005 evaluating the sensitivity and specificity of electrodiagnostic testing, specifically paraspinal mapping, for the clinical syndrome of lumbar spinal stenosis. Parapinous mapping EMG of >4 has a 100% specificity and 30% sensitivity for stenosis compared with either back pain or asymptomatic patients. A composite limb and paraspinal fibrillation score had a specificity of 87.5% and a sensitivity of 47.8%; H-wave a specificity of 91.3% and sensitivity of 36.4%. Seven subjects with previously undiagnosed neuromuscular disease were diagnosed. The authors concluded that electrodiagnostic testing has statistically significant and clinically meaningful specificity for spinal stenosis and detects neuromuscular diseases that may mimic stenosis.

This study provides Level III diagnostic evidence that paraspinal mapping is useful in diagnosing polyneuropathy and myopathy in both stenosis patients and controls, and that paraspinous mapping, a composite limb and paraspinous fibrillation score, and absence of H-waves had a high specificity and low sensitivity for lumbar spinal stenosis compared with asymptomatic controls.

Somatosensory Evoked Potentials (SSEP)

Egli et al³⁴ reported findings from a prospective case series investigating the relationship between electrophysiological recordings and clinical as well as radiological findings in patients suggested to suffer from lumbar spinal stenosis. Severe stenosis was defined as a DSA <.8, while mild stenosis was defined as >.8 and <1.6. Of the 54 patients included in the study, 68% indicated suffering from a severe reduction of walking distance limited to 500 m or less (maximal preoperative walking dis-tance <100 m in 28%, <500 m in 40%, <1 km in 15%, >1 km in 17% of patients). In 70% of patients, the motor and/or sensory (pin prick and light touch) scores were normal. Severe lumbar canal ste-nosis was diagnosed in 75% of patients, while 25% of patients had mild stenosis. About 88% of patients revealed more than one stenotic segment and 87% of patients showed pathological electro-physiological recordings (abnormal tibial SSEP in 78% of patients, delayed F-wave responses in 15%, and abnormal H-reflex in 52% of patients). Pearson correlations analysis did not find a significant correlation between the electrophysiological recordings and the radiological findings, number of stenotic levels, the sensory deficit (pin prick) and the reported pain intensity. Only the ASIA motor score showed a low correlation to the extent of the most stenotic segment (p = 0.039). The authors concluded that the applied electrophysiological recordings, especially SSEP, can confirm a neurogenic claudication caused by cauda equina involvement and help to differentiate neurogenic from vascular claudication or musculoskeletal disorders of the lower limbs. Therefore, electrophysiological recordings provide additional information to the neurological examination when the clinical relevance of a radiologically-suspected lumbar spinal stenosis needs to be confirmed. This study provides Level III evidence that electrophysiologic studies, in particular the SSEP and NCS, are abnormal in patients more often than the clinical exam. The results of these studies do not correlate with radiologic findings.

Liu et al44 described a retrospective case series evaluating the clinical usefulness of assessing lumbar somatosensory evoked potentials (SSEPs) in central lumbar spinal stenosis. Patients were also assessed via MRI and clinical exam. Of the patients included in the study, 40 had MRI and clinical exam findings consistent with lumbar spinal stenosis, while 39 cervical myelopathy patients served as controls. The latencies of lumbar SSEPs in patients with lumbar spinal stenosis and in the control group were 23.0 +/- 2.0 ms and 21.6 +/- 1.9 ms, respectively. There was a statistically significant difference between the lumbar spinal stenosis and control groups (p < 0.05). The latency of lumbar SSEPs was significantly correlated with the VAS score of leg numbness (p < 0.05). The latency of lumbar SSEPs in lumbar spinal stenosis was clearly delayed when the VAS score of leg numbness was 0.8 (p < 0.05). The authors concluded that lumbar SSEPs are able to detect neurological deficit in the lumbar area effectively, and they can reflect part of the subjective severity of sensory disturbance (numbness) in lumbar spinal stenosis. Both lumbar SSEPs and VAS scores of leg numbness may be useful for clinical evaluation in patients with lumbar spinal stenosis. In critique, patients were not consecutively assigned in this small study. Because of these limitations, this potential Level III study provides Level IV evidence that standardized lumbar SSEPs correlated with VAS scores for leg numbness, with no correlation with minimal DSA. This test may be useful in evaluating whether patient's symptoms are neurogenic or vascular in origin.

Molitor et al⁴⁵ conducted a retrospective evaluation of the utility of somatosensory evoked potential (SSEP) in 92 patients with conflicting data from clinical, imaging and neurophysiological testing with respect of the diagnosis of various disorders affecting the nervous system. The gold standard applied was the eventual diagnosis reached by the clinicians after considering all test results. In 14 patients who were eventually diagnosed with lumbar stenosis, SSEPs were found to be useful for excluding demyelinating disease, but not for confirming the diagnosis. Except for the time-consuming segmental stimulation (DSEP), the results of electrodiagnostic testing were frequently disappointing. In critique, the tests were interpreted in a nonmasked fashion and the gold standard was expert consensus opinion. In summary, this study provides Level IV diagnostic evidence that SSEPs were not helpful in diagnosing lumbar stenosis.

Motor Evoked Potentials

Liu et al⁴⁶ discussed results of a retrospective case series evaluating the clinical usefulness of assessing motor evoked potentials (MEP) in 23 patients with lumbar spinal stenosis confirmed with MRI/clinical exam findings. MEP latency (MEPLT) was related to the walking distance, limb symptoms and the VAS for numbness. MEPLT was significantly delayed in patients who showed a walking distance less than 500 m. MEPLT was significantly

delayed in patients who showed a walking dis-tance less than 500 m. MEPLT showed no correlation with duration of symptoms, total JOA score, VAS for back or leg pain, or mCSA. The authors concluded that MEP is useful in lumbar spinal steno-sis assessment. It can reflect the subjective severity of motor disturbance and predict the neurological deficit prior to appearance. In critique, patients were not consecutively assigned in this small study. Because of these limitations, this potential Level III study provides Level IV evidence that MEPLT correlates with walking distance, limb symptoms and VAS for numbness, but shows no correlation with mDSA. This test may be useful in evaluating whether patients symptoms are neurogenic or vascular in origin.

Motor Conduction Studies

Senocak et al⁴⁷ described a retrospective case control study evaluating delays in the motor conduction time in the cauda equina of 15 patients patients with lumbar spinal stenosis compared with 20 controls. The mean conduction time along the cauda equina was significantly prolonged in patients with lumbar spinal stenosis compared with controls. The mean cauda equina motor conduction time was 1.97 +/- 0.67 milliseconds in controls and 3.57 +/- 2.22 milliseconds in patients with lumbar spinal stenosis (P < 0.00). The authors concluded that determining the motor conduction time along the cauda equina using L1 and L5 magnetic stimulation provides an effective alternative method for evaluating the lumbar motor roots in patients with lumbar spinal stenosis. The absolute latency values were significantly prolonged from the L1 level to both the tibialis anterior and the gastrocnemius-soleus muscles, and from the L5 to the tibialis anterior muscle. However, the latency values from the L5 level to the gastrocnemius-soleus muscle were not significantly different from controls. In critique, this was a small study of nonconsecutive patients. Because of these limitations, this potential Level III study provides Level IV diagnostic evidence that motor conduction times in the cauda equina are delayed in patients with lumbar spinal stenosis compared to normal controls.

Dermatomal Somatosensory Evoked Potentials

Shen et al⁴⁸ reported results from a retrospective case control study evaluating the clinical signifi-cance of dermatomal somatosensory evoked potential (DSEP), assessing the degree of nerve root injury following lumbar spinal stenosis in 47 nonconsecutive patients compared with 50 controls. The sensitivity and diagnostic concurrence with surgery of nerve root injury following lumbar spinal stenosis evaluated by DSEP was 95.7%. P40 latencies at L4, L5 and S1 in the case group were significantly longer than in the control group (P < 0.05), and the P1-N1 amplitude in the case group was significantly lower than the control group (P < 0.05-0.01). Nerve root injury was categorized according to DSEP latency as follows: severe damage (disappearance of the P40 wave in 103 derma-tomes), moderate damage (prolongation of the P40 peak latency >/= 3.0 times the standard deviation of the normal mean in 60 dermatomes) and mild damage (prolongation of the P40 peak latency >= 2.5 times the standard deviation of the normal mean in 31 dermatomes). The authors concluded that DSEP can be used to determine the severity of nerve root injury following lumbar spinal stenosis with high sensitivity and specificity. This study provides Level III diagnostic evidence that DSEP latency and amplitude shows significant differences in patients diagnosed with and confirmed at surgery to have lumbar spinal stenosis compared with normal controls.

Future Directions for Research

The work group identified the following potential studies that would generate meaningful evidence to assist in further defining the appropriate diagnostic tests for lumbar spinal stenosis.

Recommendation #1:

Continue to develop reliable and reproducible criteria for the diagnosis by cross-sectional imaging of central, subarticular recess and foraminal stenosis.

Recommendation #2:

Perform additional interobserver and intraobserver variability studies with MRI and CT myelography using dural sac area as a measure of central canal stenosis, and utilizing measures incorporating neural impingement as measures of lateral and foraminal stenosis.

Recommendation #3:

Future studies assessing the effectiveness of therapeutic interventions should utilize previously defined clinical measures of Lumbar Spinal Stenosis, and state of the art measures of central, lateral recess and neural foraminal stenosis on MRI, CT and CTM, and should report subgroup analyses for central/neurogenic claudication v. lateral stenosis/radiculopathy.

Recommendation #4:

Perform additional prospective studies evaluating the significance of additional findings on axial loaded cross-sectional imaging on patient prognosis and surgical decompression in patients with neurogenic intermittent claudication and radiculopathy.

Recommendation #5:

Perform additional prospective studies addressing the utility of paraspinous mapping and electrodiagnostic testing in the evaluation of patients with clinical and radiologic degenerative lumbar spinal stenosis. Future studies should also address the value of these tests in the evaluation of patients with equivocal clinical signs and symptoms, and patients with confounding diagnoses such as diabetes. Future studies should focus on the ability of paraspinous mapping and electrodiagnostic testing to improve outcomes with surgical decompression.

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OUTCOME MEASURES FOR TREATMENT

B. Outcome Measures for Medical/ Interventional and Surgical Treatment

What are the appropriate outcome measures for the treatment of spinal stenosis?

The North American Spine Society has a publication entitled *Compendium of Outcome Instruments for Assessment and Research of Spinal Disorders.* To purchase a copy of the Compendium, visit https://webportal.spine.org/Purchase/ProductDetail.aspx?Product_code=68cdd1f4-c4ac-db11-95b2-001143edb1c1.

For additional information about the Compendium, please contact the NASS Research Department at nassresearch@spine.org.

C. Medical/Interventional Treatment

Do medical/interventional treatments improve outcomes in the management of spinal stenosis compared to the natural history of the disease?

A systematic review of the literature yielded no studies to answer this question.

An extensive review of all articles cited in the reference section found no direct comparison of active treatment (medical/interventional) to an untreated control group (natural history).

Future Directions for Research

The work group identified the following suggestions for future studies, which would generate meaningful evidence to assist in further defining the role of medical treatment for lumbar spinal stenosis.

Recommendation #1:

Future studies of the effects of medical, noninvasive interventions for lumbar spinal stenosis should include an untreated control group when ethically possible.

Recommendation #2:

Future outcome studies of lumbar spinal stenosis should include results specific to each of the medical/interventional treatment methods.

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What is the role of pharmacological treatment in the management of spinal stenosis?

There is insufficient evidence to make a recommendation for or against the use of pharmacological treatment in the management of spinal stenosis.

Grade of Recommendation: I (Insufficient Evidence)

Intramuscular Calcitonin

Eskola et al¹ conducted a double-masked, randomized, controlled, crossover trial of 39 patients with neurogenic claudication from lumbar spinal stenosis. With this design, every patient was treated with intramuscular calcitonin for a portion of the study period so that each patient could serve as their own control. Clinical inclusion criteria were bilateral leg pain and maximum walking tolerance of 1500 m. Radiographic inclusion criterion was less than 10 mm spinal canal diameter on myelography. Outcome measures were walking distance, pain (Visual Analog Scale) and a performance test of power and swiftness of the lower extremities.

At three- to six-month follow-up, walking distance and pain were improved during calcitonin treatment. After crossover, pain relief was better than walking distance improvement. Patients with mild pain or severe neurogenic claudication showed no improvement. In critique of the study, the radiographic inclusion criteria were somewhat contradictory. While the authors stated that all patients had less than 10 mm sagittal canal diameter, they subsequently stated that only 19 of 39 pa-tients had central stenosis. The two groups were not matched for severity of initial symptoms nor were their baseline characteristics statistically compared. The results are not stratified between patients with central or lateral recess stenosis. Notwithstanding the VAS pain score, the other out-come measures were not validated or disease-specific instruments. These data represent Level II therapeutic evidence of the effectiveness of calcitonin in the treatment of lumbar spinal stenosis.

Sahin et al² described a prospective comparative study assessing the short-term effects of physical therapy (PT) alone and in combination with calcitonin on pain, physical examination results and the functional status of patients with neurogenic claudication and diagnosis of lumbar spinal stenosis. Of the 45 consecutive patients included in the study, 22 were assigned to physical therapy and 23 were assigned to physical therapy plus calcitonin. At eight week follow-up, patients experienced significant improvement across all measures with no statistically significant differences noted between the two groups in VAS pain scores, range of motion, functional status (assessed by the Roland Morris Disability Questionnaire) and walking distance. The authors concluded that the use of PT resulted in short-term improved clinical outcomes in patients with lumbar spinal stenosis, but the addition of calcitonin as an analgesic in the short-term treatment of lumbar spinal stenosis along with physical therapy and exercise administration is not necessary.

In critique, this was a small study that did not utilize validated outcome measures or implement an appropriate randomization process. Because of these limitations, this potential Level II study provides Level III therapeutic evidence that PT results in short-term improvement in patients with lumbar spinal stenosis, but addition of calcitonin is of no benefit.

Tafazal et al³ reported a prospective randomized controlled trial testing the efficacy of nasal salmon calcitonin in the treatment of lumbar spinal stenosis. The study assessed outcomes with the VAS, ODI, LBOS, Modified Somatic Perception Questionnaire (MSPQ) and Modified Zung Depression (MZD) score. During the first four weeks of the study, 20 of the 40 consecutive patients included in the study received nasal salmon calcitonin. After the initial four weeks, there was a six week washout period followed by another six weeks in which both groups received calcitonin. At sixteen weeks no significant differences were noted between the two groups, with the exception of low back pain scores which showed more improvement in the calcitonin group. A small percentage of the calcitonin group did report global improvement. The authors concluded that nasal salmon calcitonin does not seem to have a role in the conservative treatment of patients with lumbar spinal stenosis.

In critique, this was a small study which implemented an inadequate randomization process with nonmasked reviewers. With these limitations, this potential Level II study provides Level III therapeutic evidence that calcitonin does not result in improvement for patients with lumbar spinal stenosis.

Eskola et al⁴ performed an "open follow-up study" to test the efficacy of intramuscular calcitonin for the treatment of lumbar spinal stenosis. The methodology was not clearly stated as retrospective or prospective. The study followed 15 patients with neurogenic claudication with lumbar spinal stenosis over a period of six months. Clinical inclusion criteria were bilateral leg pain and maximum walking tolerance of 1500 m. Radiographic inclusion criterion was less than 10 mm spinal canal diameter on myelography. Outcome measures were walking distance, symptom intensity (scored using a numerical system) and a performance test of power and swiftness of the lower extremities.

At three-month follow-up, there was a statistically significant improvement in symptom intensity score in the calcitonin group. At six-month follow-up, there were statistically significant improve-ments in lower extremity performance tests. There was an average improvement of 491 meters walking distance. In critique of this study, the authors did not use a validated outcomes instrument, the study population was small, there was no

control group, follow-up was short and the methodol-ogy unclear. With these limitations, this study provides Level IV therapeutic evidence for the effec-tiveness of intramuscular calcitonin treatment for neurogenic claudication associated with lumbar spinal stenosis.

Intranasal Salmon Calcitonin

Podichetty et al⁵ reported the results of a randomized, doublemasked, controlled trial studying the effectiveness of intranasal salmon calcitonin for the treatment of lumbar spinal stenosis. Fifty-five patients were randomized — 36 to the treatment group and 19 to the control group. After an initial six-week period, the placebo group was given calcitonin as a crossover group; however, the treatment group continued receiving calcitonin. Inclusion criteria were pseudoclaudication, defined as discomfort, pain, numbness, weakness, heaviness or vague discomfort in one or both lower extremities made worse by standing, walking or extension and relieved by sitting, squatting or forward flexion. The investigators stated that stenosis was radiographically confirmed, however, criteria were not listed. Outcome measures included the Modified Oswestry Low Back Pain questionnaire, walking time and distance, Lumbar Canal Stenosis (LCS) specific questionnaire, SF-36 and Visual Analog Scale for pain.

At final follow-up, eight patients withdrew from the calcitonin group and four from the placebo group. Baseline characteristics for the two groups were statistically comparable. There were no significant differences between the treatment and control groups in VAS pain, SF-36 or total walking time or distance. In critique of this study, the patient numbers were low, the follow-up period was relatively short, and there was a fairly high attrition rate (22%). While this study was potentially a Level I investigation, these shortcomings limit the data to Level II therapeutic evidence that intrana-sal salmon calcitonin is not effective for the treatment of lumbar spinal stenosis.

Methylcobalamin

Waikakul and Waikakul⁶ performed a randomized controlled trial to evaluate the effect of methylcobalamin as an adjunct to medical/interventional treatment in 152 patients with lumbar spinal stenosis. Treatment with methylcobalamin was continued for six months; follow-up was two years. Patients reported moderate symptoms. Plain radiographs were obtained for all patients; MRI or CT was obtained in some cases. There were no reported radiographic inclusion criteria. Conservative care was administered to both groups, which included patient education, activity mod-ification, exercises/physical therapy, oral analgesics, muscle relaxants and epidural steroid injections. There were no standard or systematic outcome measurements. Outcomes were limited to physical examination findings and walking distance.

Both groups showed improvement in physical examination findings, but there were no significant differences between them. There was a trend for a greater number of patients who could walk more than 1000 m after treatment; however, this could not be statistically confirmed. In critique of the study, the randomization process was not masked as it relied on medical record numbers. Furthermore, no validated or standardized outcome measures were used. Numerous cointerventions were applied. Lastly, this randomized study demonstrated no significant dif-

ferences in outcomes but did not calculate or report confidence intervals. A potential Level I study, this report had serious design flaws resulting in Level II therapeutic evidence that methylcobalamin is not effective for the treatment of lumbar spinal stenosis.

Intravenous Lipoprostaglandin E(1)

Iwamoto et al⁷ performed a prospective evaluation of 20 elderly men (average age: 67-years-old) treated with intravenous lipoprostaglandin E(1) with neurogenic claudication from lumbar spinal stenosis. The study population included patients with burning sensations in the legs and perineal region while walking, with or without urinary disturbance (12 patients). In an additional 18 patients, symptoms also included radiculopathy. There were no stated radiographic inclusion criteria. Outcome was measured using the Japanese Orthopaedic Association (JOA) score.

Total score (composite JOA score) was statistically improved from 14.3 to 16.8. The authors con-cluded that intravenous treatment with lipoprostaglandin E(1) can improve subjective symptoms in elderly male patients with lumbar stenosis. In critique of this study, the patient population was small, and there were no stated radiographic inclusion criteria. Follow-up was relatively short at six months. As this was a noncomparative, nonrandomized clinical series, this study provides Level IV therapeutic evidence for the efficacy of lipoprostaglandin E(1) for the treatment of lumbar spinal stenosis.

Murakami et al⁸ reported the results of a series of 37 patients with neurogenic claudication with lumbar spinal stenosis treated with intravenous lipoprostaglandin E(1). The study population in-cluded patients with burning sensation in the legs and perineal region while walking, with or without urinary disturbance (cauda equina group, eight patients), those with radicular symptoms only (11 patients) and those with mixed symptoms (21 patients). There were no stated radiographic criteria for inclusion in the study. Outcome was measured using JOA score.

At short-term follow-up (10 days), overall scores improved from 15.8 to 19.2. There were statisti-cally significant improvements in all subcategories of the JOA score except for clinical signs. In subgroup analysis, the cauda equina and mixed group showed statistically significant improvements in overall JOA scores; however, the radicular group did not. According to the authors' categorization of JOA score changes, 22 of 37 patients were considered to have good to excellent results. At long-term follow-up (defined by the authors as 2 to 23 months) of 31 patients with fair, good or excellent initial results, only 10 showed sustained improvement while 21 returned to their baseline levels. In critique of this study, the patient numbers were small, and the follow-up was variable and incom-pletely documented. These data provide Level IV therapeutic evidence that intravenous lipoprosta-glandin E(1) may provide short-term (10 days) benefit in patients with lumbar spinal stenosis but little longterm relief.

Prostaglandin E(2)

Matsudaira et al⁹ reported the findings from a prospective randomized controlled trial examining the effect of Limaprost on health-related quality of life (HRQOL), compared to Etodolac.

Of the 66 patients included in the study, 34 were treated with Limaprost, and 32 with Etodolac for eight weeks. At eight week follow-up, patients treated with Limaprost did significantly better than those receiving Etodolac across virtually all measures, primary and secondary, including SF-36, verbal rat-ing scale of low back pain and leg numbness, walking distance, subjective improvement and satis-faction. In addition, Etodolac did not seem to make much of a difference in general from baseline to eight weeks. The authors concluded that Limaprost was found to be efficacious on most outcome measures, such as HRQOL, symptoms and subjective satisfaction, in lumbar spinal stenosis patents.

In critique, patients and reviewers were not masked to treatment in this small study with short follow-up. Because of these limitations, this potential Level I study provides Level II therapeutic evidence that Limaprost results in significantly better short-term outcomes than Etodolac in patients with lumbar spinal stenosis.

Gabapentin

Yaksi et al¹⁰ described a prospective randomized controlled trial examining whether gabapentin provides effective analgesia in patients with lumbar spinal stenosis. Of the 55 consecutively assigned patients included in the study, 28 received gabapentin and 27 served as controls. All patients received physical therapy. At four month follow-up, walking distance improved in both groups compared with baseline; however, the gabapentin treated group achieved a longer walking distance at the end of the second (P < 0.033), third (P < 0.04), and fourth months (P < 0.001) of the treatment. The VAS scores were significantly lower in the treatment group at the end of the third (P < 0.039) and fourth months (P < 0.006) of the treatment, when compared with the control group. Although no significant changes in motor scores were reported, the patients treated with gabapentin experienced significant improvement related to sensory changes. The authors concluded that a follow-up clinical study is warranted to investigate the efficacy of gabapentin in the treatment of symptomatic lumbar spinal stenosis as part of a comprehensive program of care to include PT.

In critique, patients and reviewers were not masked to treatment in this small study with short follow-up. Because of these limitations, this potential Level I study provides Level II therapeutic evidence that the addition of gabapentin to a PT program for patients with lumbar spinal stenosis can result in greater short-term improvement.

Future Directions for Research

General Recommendation:

The role of routine pharmacological treatment including NSAIDS, muscle relaxants and analgesics, used extensively in the treatment of spinal stenosis as well as other back conditions, needs to be to investigated in patients with spinal stenosis using untreated control groups with spinal stenosis.

The work group identified the following potential study, which would generate meaningful evidence to assist in further defining the role of pharmacological treatment for lumbar spinal stenosis.

Recommendation:

A large, double-masked, randomized controlled trial with a long-term observation period to examine the potential benefits of intramuscular calcitonin for the treatment of lumbar stenosis.

Pharmacological Treatment References

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What is the role of physical therapy/exercise in the treatment of spinal stenosis?

There is insufficient evidence to make a recommendation for or against the use of physical therapy or exercise as stand-alone treatments for degenerative lumbar spinal stenosis.

Grade of Recommendation: I (Insufficient Evidence)

Goren et al¹ performed a prospective randomized controlled trial to assess the effectiveness of therapeutic exercises alone and in combination with ultrasound in the treatment of lumbar spinal stenosis. Of the 45 consecutive patients included in the study, 15 were randomized to each group: exercise with ultrasound, exercise and sham ultrasound, and control. At three week follow-up, there were significant improvements in the Oswestry Disability Index (ODI), pain scores and ambulation for the two treatment groups. The sham group required more pain medication than the ultrasound group. The authors concluded that therapeutic

exercises, including stretching, strengthening and low-intensity cycling exercises improved the level of pain and disability in patients with lumbar spinal stenosis. Supplementation of ultrasound with therapeutic exercises is found to reduce the amount of analgesic consumption.

In critique, this was a small study with a very short three week follow-up. Because of these limitations, this potential Level I study provides Level II therapeutic evidence that an exercise program yields short-term improvement in symptoms related to degenerative lumbar spinal stenosis and that the addition of ul-

trasound decreases the need for oral analgesics.

Koc et al² conducted a prospective randomized controlled trial comparing the effects of epidural steroid injections with a conservative inpatient physical therapy program on pain and function in patients with lumbar spinal stenosis. Of the 29 consecutive patients included in the study, 10 were randomized to physical therapy, 10 to the injection group and nine to the control group. No differ-ence was seen between the physical therapy patients and controls at two week follow-up. At six month final follow-up, all groups showed improvement with no statistically significant differences. The authors concluded that epidural ste-

roid injections and physical therapy are both effective in treating spinal stenosis at up to six months follow-up.

This was a very small study of nonmasked patients with short follow-up and an unspecified randomization method. Patients in all groups received baseline treatment consisting of a home-based therapeutic exercise program. Because of these limitations, this potential Level II study provides Level III therapeutic evidence that at six month follow-up general improvement is seen in controls as well as patients treated with modality-based physical therapy or epidural steroid injection, with no significant differences in improvement between groups.

In the absence of reliable evidence, it is the work group's opinion that a limited course of active physical therapy is an option for patients with lumbar spinal stenosis.

Work Group Consensus Statement

Whereas a systematic search of the literature revealed limited evidence regarding the usefulness of physical therapy and exercise as stand-alone treatments in patients with lumbar spinal stenosis and neurogenic claudication, clinical experience suggests that physical therapy and exercise may be effective in improving outcomes as part of a comprehensive treatment strategy. This conclusion is inferred from the literature noted throughout the degenerative lumbar spinal stenosis guideline.

Future Directions for Research

A randomized controlled trial with long-term follow-up and validated outcome measures would assist in providing evidence to assess the efficacy of physical therapy in the treatment of lumbar spinal stenosis. Ideally, this would be compared to an untreated control group. We recognize this may be a difficult or unethical study to propose over the long term. Other active treatment groups could be substituted as a comparative group. The physical therapy program should be standardized and should include exercise and education at a minimum, and could include separate cohorts of manual therapy and other modalities as well.

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What is the role of manipulation in the treatment of spinal stenosis?

There is insufficient evidence to make a recommendation for or against spinal manipulation for the treatment of lumbar spinal stenosis.

Grade of Recommendation: I (Insufficient Evidence)

Murphy and Hurwitz¹ performed a prospective observational case series of 57 consecutive patients with clinically and radiographically defined lumbar spinal stenosis. The mean age of patients was 65 years, and two-thirds of patients were female. Patients were treated with distraction manipulation (DM) by the standard technique of Cox, neural mobilization (NM) and designated exercises. In some patients, physical therapy with spinal mobilization and stabilization was added. Patients were treated two or three times weekly for a mean number of 13 treatments (range: 2-50). Mean follow-up was 16 months (range: 3-48). There were 41 patients available for long-term follow-up. Outcome measures included the Roland Morris Disability Questionnaire (RMDQ) score, a patient self-assessment of improvement and the average pain intensity rating by VAS.

The authors reported mean improvement in the RMDQ

score at long-term follow-up was 5.2. Clini-cally significant improvement of greater than three points in the RMDQ score was achieved by 66.7% of patients. At long-term follow-up current pain decreased by a mean of 38.4%, average pain by 51.7% and worst pain by 44.7%. Self-rated improvement was 75.6% overall.

In critique, the results of this case series are compromised by the inclusion of additional physical therapies and treatments. The wide range in ages of the study population (32-80 years), number of treatments (2-50), the variable duration of follow-up averaging less than two years (3-48 months) and the 23% study dropout rate decrease the value of this study.

This study provides Level IV therapeutic data suggesting that distraction manipulation and neural mobilization may be beneficial in the treatment of lumbar spinal stenosis.

Future Directions for Research

The work group identified the following suggestions for future studies, which would generate meaningful evidence to assist in further defining the role of manipulation in the treatment of lumbar spinal stenosis.

Recommendation #1:

If ethically possible, future studies should include a controlled trial comparing manipulation to natural history of lumbar spinal stenosis using standardized techniques and validated out-come measures.

Recommendation #2:

Future studies should utilize validated outcome measures to compare manipulation to other medical/interventional treatments for spinal stenosis, and should assess long-term effectiveness and cost effectiveness.

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What is the role of contrast-enhanced, fluoroscopic guidance in the routine performance of epidural steroid injections for the treatment of lumbar spinal stenosis?

Contrast-enhanced fluoroscopy is recommended to guide epidural steroid injections to improve the accuracy of medication delivery.

Grade of Recommendation: A

Nonfluoroscopically-guided caudal epidural injections have a rate of inaccurate placement ranging from 25-53%. ²⁻⁴Nonfluoroscopically-guided lumbar interlaminar epidural injections have a rate of inaccurate placement ranging from 17-30%. ^{1,4}

Mehta et al¹ assessed the ability to accurately access the spinal canal using a nonfluoroscopically-guided interlaminar epidural injection technique in 100 patients with a variety of lumbar spinal conditions. In 17% of cases, the injection was completely or partially outside of the spinal canal. In critique, the population had a variety of lumbar diagnoses, not limited to spinal stenosis. This study provides Level I diagnostic evidence that blind interlaminar injection is correct in 83% of cases.

Renfrew et al² examined the accuracy of needle placement during nonfluoroscopically-guided caudal epidural steroid injection in 328 patients, some of whom had lumbar spinal stenosis. Results were categorized according to technician experience. Injections by physicians who had performed fewer than 10 procedures were in the epidural space in 47% of cases. Injections by those who had performed 10 to 50 procedures were in the epidural space in 53% of cases. Injections by those who had performed more than fifty procedures were correctly placed in 62% of cases. In critique, the population had a variety of lum-

bar diagnoses not limited to spinal stenosis. This study provides Level I diagnostic evidence that blind caudal injection is correct in 47-62% of cases.

Stitz et al³ assessed the accuracy of nonfluoroscopically-guided caudal epidural injections in the lumbar spine of 54 patients. Needles were first placed in a masked manner by palpation of land-marks only. Fluoroscopic evaluation with contrast demonstrated that the needle was in the epidural space in 74.1% of cases. In critique, the population had a variety of lumbar diagnoses, not limited to spinal stenosis. This study provides Level I diagnostic evidence that blind caudal epidural injection is accurately placed in 74% of cases.

White et al⁴ found that in 300 consecutive cases, caudal injection using palpable landmarks alone was incorrectly placed 25% of the time, as confirmed by contrast-enhanced fluoroscopy. Needle placement was incorrect in 30% of cases during interlaminar injection by landmark palpation alone. In critique, the population had a variety of lumbar diagnoses, not limited to spinal stenosis. This study provides Level I diagnostic evidence that blind caudal epidural injection is accurately placed in 75% of cases and that blind interlaminar epidural injection is accurately placed in 70% of cases.

What is the role of epidural steroid injections (ESI) in the treatment of spinal stenosis?

Interlaminar epidural steroid injections are suggested to provide shortterm (two weeks to six months) symptom relief in patients with neurogenic claudication or radiculopathy. There is, however, conflicting evidence concerning long-term (21.5-24 months) efficacy.

Grade of Recommendation: B

Fukusaki et al⁵ conducted a prospective, randomized, double-masked trial evaluating the efficacy of a single interlaminar non-fluoroscopically-guided epidural steroid injection in 53 patients with lumbar spinal stenosis. Patients were randomized to three groups: epidural saline injection (16 patients), epidural local anesthetic (18 patients) and epidural anesthetic plus steroid (19 patients). The clinical inclusion criteria were neurogenic claudication with leg pain and a walking tolerance less than 20 m. Radiographic inclusion criteria were central stenosis with less than 15 mm sagittal canal diameter on CT and/or MRI, lateral recess stenosis or mixed central and lateral recess stenosis. The only outcome measure was walking distance rated as excellent (greater than 100 m), good (20 to 100 m) and poor (less than 20 m).

At one month, 6.3% of the saline patients experienced good or excellent results while 16.7% and 15.8% of the anesthetic and anesthetic-steroid group, respectively, experienced good or excellent results. This difference was significant. However, at three months, there were no significant differences among the groups.

In critique of this study, the only measured outcome was walking distance. In favor of the study, there were no study dropouts and the three groups were homogenous in baseline characteristics. These data provide Level II treatment evidence that a single nonfluoroscopically-guided interlaminar ESI for spinal stenosis can improve walking distance at one month, but not at three months.

Koc et al⁶ reported findings from a prospective, randomized controlled trial comparing the effects of epidural steroid injections and a conservative inpatient physical therapy program on pain and function in patients with lumbar spinal stenosis. Of the 33 patients included in the study, 11 received physical therapy, 10 were treated with epidural steroid injections, and 12 served as controls. All patients were given a home exercise program. At two week follow-up, the ESI group had significant improvement in VAS, and at six months, all improved. The authors concluded that epidural steroid injections and physical therapy are both effective in lumbar spinal stenosis treatment at up to six months follow-up, whereas epidural steroid injections provide better improvement in the short-term.

In critique, this was a small study with nonmasked patients and reviewers. The method of randomization was questionable and the home exercise program given to all patients may have been a confounding treatment variable. Because of these limitations, this potential Level II study provides Level III evidence that there was a two week benefit on pain scores for patients receiving ESI, but by six months, all patients improved and neither physical therapy nor ESI was any better than a simple home ex-

ercise program.

Cuckler et al⁷ performed a prospective, randomized, double-masked trial comparing nonfluoroscop-ically-guided single injections of epidural steroid to placebo injections in 73 patients with radicular pain, 37 of whom experienced neurogenic claudication from lumbar spinal stenosis. The steroid group included 20 patients with stenosis and the placebo group included 17 patients. The outcome measure was physician assessment of pain improvement. Investigators defined a successful out-come as greater than 75% pain decrease.

At an average follow-up of 21.5 months, there was no significant difference in the number of successes in the treatment and control groups. In critique of this study, the number of patients with stenosis in the study was small and the definition of success was subjective and not based on a standardized outcome measure. Furthermore, a group of 15 patients who underwent a second injection with steroid in a nonmasked fashion were not analyzed separately. The attrition rate was not reported. While potentially a Level I randomized controlled trial, the lack of blinding in the treatment of some of the patients would lower the level of evidence from this study to Level II. Fur-thermore, because of the 41% (15 of 37) crossover rate to nonmasked injections, the lack of reporting of the attrition rate, and the lack of validated outcome measures, the work group felt this study should be considered Level III treatment evidence that a single, nonfluoroscopically-guided caudal injection does not produce long-term (average 21.5 months) relief.

Papagelopoulos et al⁸ presented a prospective case series of 50 patients, 13 of which experienced radicular pain from spinal stenosis, who underwent a single nonfluoroscopically-guided interlaminar injection with anesthetic and steroid. Four patients had central stenosis; nine patients had lateral recess stenosis. CT or MRI were performed on all patients, however, the authors did not list specific radiographic inclusion criteria. Follow-up was at a mean of 24 months. The outcome measure was unclear but was presented as excellent, good, fair or poor.

Four patients with central stenosis had excellent results, two experienced some improvement and one patient underwent surgery after six months. In the lateral recess group, seven had excellent results and two experienced some improvement. In critique of this study, the outcome measure was not described and therefore its clinical relevance is unclear. Patient numbers were low. This study provides Level IV therapeutic evidence that a single nonfluoroscopically-guided interlaminar injection can provide some long-term improvement in patients with radicular pain from spinal stenosis.

A multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injections is suggested to produce medium-term (3-36 months) relief of pain in patients with radiculopathy or neurogenic intermittent claudication (NIC) from lumbar spinal stenosis.

Grade of Recommendation: C

The "multiple injection" regimen referred to in this recommendation, and utilized in the studies cit-ed below, should be distinguish from a "series" of injections which has been utilized in several older studies. In a multiple injection protocol, a patient is a candidate for additional injections when their pain recurs or becomes severe again. In these studies, additional injections were performed either on patient demand, or when the patient's pain exceeded a preset level. The purpose of the multiple injection protocol is to control pain over a longer period of time in order to maximize the chance that a patient will respond to medical/interventional therapy. A "series" of injections, typically three, is performed at 24-hour or one week intervals regardless of the patient's symptoms. The patient is not allowed repeat injections if their pain recurs during the course of medical/interventional therapy.

Manchikanti et al⁹ conducted a prospective, randomized controlled trial evaluating the role of caudal epidural injections, with or without steroids, in patients with chronic intractable pain secondary to spinal stenosis. Of the 40 patients included in the study, 20 were randomly assigned to receive an injection with anesthetic and 20 were assigned to receive an injection with anesthetic and steroid. Numeric Rating Scale, Oswestry Disability Index, Return to Work and medication intake all improved, but there were no significant differences in the improvement for any measure. The average number of injections was higher in the group that experienced "successful" pain relief defined as 50% or more. Epidurals were considered to be successful if a patient obtained consistent relief with the first and second injections of at least one and three weeks respectively and if the re-lief with the second injection outlasted the first injection. All others were considered to be failures. The average number of injections in the successful group was 3.6 injections while the average number of injections in the failure group was 2.0. The authors concluded that this preliminary report of the results of a randomized, double-blind equivalence trial of caudal epidural injections with local anesthetic with or without steroids with chronic function-limiting low back pain and lower extremity pain has demonstrated pain relief effectiveness in 55% to 65% of the patients and improvement in functional status in 55% to 80% with three to four procedures over the course of one year.

In critique, this small study presented results at one month that provide Level II therapeutic evidence that steroid injections are equivalent to anesthetic injection alone for short-term treatment of lumbar spinal stenosis. At one year, with less than 80% follow-up, this study provides Level III evidence that steroid injections are equivalent to anesthetic injection alone for medium-term treat-ment of lumbar spinal stenosis.

Botwin et al¹⁰ reported results of a prospective, case series of 34 patients with unilateral radicular leg pain from spinal stenosis

who had failed six weeks of noninvasive medical/interventional treat-ment that included NSAIDs and/or physical therapy. All patients underwent a multiple-injection pro-tocol of transforaminal fluoroscopically-guided contrast-enhanced epidural steroid injections. MRI was obtained in all patients. Radiographic inclusion criteria were mild, moderate or severe central stenosis with lateral recess or foraminal stenosis. Outcome measures were Visual Analog Scale for pain, Roland five-point pain scale, a five-tiered standing and walking tolerance measure and a five-tiered patient satisfaction scale. Follow-up at 12 months was assessed by mailed-questionnaire.

Sixty-four percent of patients experienced improved walking tolerance, 75% reported greater than 50% reduction in pain and 57% experienced improved standing tolerance. Patients had an average of 1.9 injections.

In critique of this study, the patient numbers were small. Notwithstanding the VAS pain score, the other outcome measures were not validated instruments. This study represents Level IV treatment evidence that transforaminal fluoroscopically-guided contrast-enhanced epidural steroid injections can provide long-term (12 months) relief in about two thirds of patients with unilateral radiculopa-thy from lumbar spinal stenosis.

Ciocon et al¹¹ conducted a prospective case series of thirty patients with lumbar spinal stenosis who underwent a series of three caudal epidural steroid injections without fluoroscopic guidance. The agents used were depomedrol and xylocaine. Patients' complaints included leg pain with or without back pain. All had confirmation of stenosis by MRI that was graded as mild in seven patients (23%), moderate in 20 patients (67%) and severe in three patients (10%). Outcome measure included a Roland five-point pain scale and patients were followed for four to 10 months. Pain scores decreased from an average 3.4 to 1.5 after treatment. Notably, the investigators found that the de-gree of pretreatment pain correlated with the degree of radiographic central stenosis. The response to injection was not correlated with the degree of radiographic stenosis.

In critique of this study, patient numbers in this case series were low. These data offer Level IV treatment evidence that a series of three nonfluoroscopically-guided caudal epidural blocks can decrease pain from lumbar spinal stenosis at four to 10 months follow-up.

Delport et al¹² published the outcomes of a retrospective case series of 140 patients with lumbar spinal stenosis treated with a multiple injection protocol of fluoroscopically-guided transforaminal or caudal epidural steroid injections. Radiographic inclusion criterion was MRI-confirmed central, lateral recess or foraminal stenosis at one or more levels. Clinical inclusion criteria included leg pain or neurogenic claudication with or without back pain. The investigators stated they directed injections to the

site of neural compression noted on imaging. They employed caudal blocks for multilevel central canal stenosis and presumably transforaminal injection for single-level disease. Follow-up was conducted by telephone interview between six to 36 months. Outcome measures were pain rated by a three-tiered system, duration of pain relief and the impact on daily activities.

Thirty-two percent reported more than two months of pain relief, 38% reported less than two months, 29% reported no pain relief, 21% reported improvement in daily activities and 20% eventually underwent surgery after an average of 2.23 injections were administered.

In critique, the results were not stratified for the caudal injection versus the transforaminal injections, limiting conclusions of the results of these two techniques. As the investigators stated that they employed caudal injections for multilevel disease, a stratification of results according to extent of disease would also have been useful. This case series provides Level IV diagnostic evidence that multiple fluoroscopically-guided transforaminal or caudal epidural injections can reduce pain and improve daily function for at least two months in about one third of patients with leg pain or neurogenic claudication from spinal stenosis.

Hoogmartens et al13 reported the results of a retrospective case series of 49 patients with lumbar spinal stenosis with neurogenic claudication undergoing a multiple injection protocol of caudal epidural steroid blocks with radiographic guidance. The clinical inclusion criterion was walking distance of 100 m or less. Injections were a combination of local anesthetic and steroid. Imaging was not standardized and not obtained in all patients. There was a 22% dropout rate from the study. The outcome measure was a mailed-questionnaire that judged outcome as excellent, good, fair and poor.

At an average 23-month follow-up, 32% reported good or excellent results, 16% reported fair results and 52% reported poor results. In critique of this study, the details of the outcome questionnaire were not provided, limiting the generalizability of the data. This study offers Level IV diagnostic evidence that a multiple caudal injection protocol produces good or excellent results in about one third of patients at 23-month follow-up.

Future Directions for Research

The work group identified the following potential studies that would generate meaningful evidence to assist in further defining the role of epidural steroid injection in the treatment of lumbar spinal stenosis.

Recommendation #1:

A large double-masked, randomized controlled clinical trial with at least one-year follow-up in patients with unilateral leg pain from lumbar spinal stenosis treated by fluoroscopically-guided contrast-enhanced transforaminal epidural steroid injections in which the control group receives saline placebo injections.

Recommendation #2:

A large double-masked, randomized controlled clinical trial with at least two-year follow-up in patients with neurogenic claudication from lumbar spinal stenosis treated by fluoroscopically-guided interlaminar or caudal epidural steroid injections in which the control group receives saline placebo injections.

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What is the role of ancillary treatments such as bracing, traction, electrical stimulation and transcutaneous electrical stimulation (TENS) in the treatment of lumbar spinal stenosis?

The use of a lumbosacral corset is suggested to increase walking distance and decrease pain in patients with lumbar spinal stenosis. There is no evidence that results are sustained once the brace is removed.

Grade of Recommendation: B

Levendoglu et al¹ described a prospective comparative study investigating the quantitative effects of lumbar corset use on walking time in 70 consecutive lumbar spinal stenosis patients. Symptom initiation time and total walking time were significantly longer when walking with the lumbar corset compared with walking without the corset. The use of a lumbar corset had a similar effect to that of 20% body weight reduction and lengthened the total walking time by reducing mechanical weight bearing. The authors concluded that lumbar corset increased both symptom initiation time and total walking time in patients with lumbar spinal stenosis. Because no validated outcome measures were utilized, this potential Level II study provides Level III therapeutic evidence that corset use helps increase walking distance during the time the corset is being worn.

Prateepavanich et al² performed a self-controlled comparative study of 21 patients with a mean age of 62.5 using a lumbosacral corset for the treatment of symptomatic degenerative lumbar spinal stenosis with neurogenic claudication. Patients with an age over 50, reproducible neurogenic claudication, degenerative changes on radiographs and no contraindications to using a treadmill or cor-set were included in the study. The outcome measures were VAS in daily activities and walking distance.

Patients served as their own control. Each patient was walked on a treadmill with and without the use of a corset, one week apart, and claudication distances were recorded. This process was repeated three times. Patients also reported VAS during daily activities.

There was a statistically significant increase in walking distance (from 314 to 393 feet) and a decrease in pain (VAS from 5.9 to 4.7) with the use of the corset. In critique, the sample size of patients was small. The study is otherwise well designed for the authors' goal. This study provides Level III therapeutic evidence that the use of a lumbosacral corset can increase walking distance before claudication and reduce pain in patients with lumbar spinal stenosis. There is no evidence that use of a brace has any lasting results once discontinued.

Willner³ conducted a prospective case series of 48 patients with a mean age of 45 years. Of these patients 15 had spondylolisthesis, 26 had long-term low back pain of unknown etiology, and the remaining seven had lumbar spinal stenosis confirmed by myelography with symptoms of claudication. All patients were placed in a Flexaform (rigid lumbosacral orthosis) brace for an average of one year. Outcome measures were not defined.

In the group with spinal stenosis, two cases were totally free from pain, four patients reported an obvious improvement with increased walking capacity and in one case the pain was unchanged. In critique, the sample size of patients in this study with spinal stenosis was extremely small and no validated outcome measures were used. There is no documentation of compliance with brace use or pain reduction when out of the brace. This study provides Level IV therapeutic evidence that bracing can reduce pain in spinal stenosis.

There is insufficient evidence to make a recommendation for or against traction, electrical stimulation or TENS for the treatment of patients with lumbar spinal stenosis.

Grade of Recommendation: I (Insufficient Evidence)

An extensive review of all articles cited in the reference section found no direct comparison of ancillary treatments (traction, electrical stimulation or TENS) to an untreated control group (natural history).

There is insufficient evidence to make a recommendation for or against acupuncture in for the treatment of patients with lumbar spinal stenosis.

Grade of Recommendation: I (Insufficient Evidence)

Inoue et al⁴ presented results of a prospective comparative study assessing the effect of paraspinal, pudendal and nerve root acupuncture on spinal stenosis symptoms. Of the 35 consecutive patients included in the study, 10 received paraspinal acupuncture placement, 11 received pudendal placement and 14 received nerve root placement. Results showed significant improvement in symptoms for all three groups of patients. The authors concluded that acupuncture can be effective in a high percentage of patients, and recommended that because the paraspinal point is easiest and safest, it is suggested as the first acupuncture site. If no improvement is seen, pudendal is recommended as the second site and finally nerve root, which is most difficult. Acupuncture at each location showed potential to improve symptoms. This was a small study and did not utilize validated outcome measures. Because of these limitations, this potential Level II study provides Level III therapeutic evidence that acupuncture results in significant improvement in symptoms at two to three month follow-up.

Future Directions for Research

The work group suggests a randomized, controlled trial comparing the use of individual ancillary treatments to a control, preferably masked, in patients with lumbar spinal stenosis.

Recommendation #1:

An appropriately powered study is proposed containing three groups with symptomatic lumbar spinal stenosis comparing soft bracing, rigid bracing and untreated controls (no bracing). Outcome measures could include the ZCQ, VAS, walking distance and a validated, health-related quality of life measure such as the SF-36 or ODI.

Recommendation #2:

Prospective, randomized controlled trials with validated outcomes measures are needed to evaluate efficacy of ancillary treatments such as acupuncture, TENS, traction and electrical stimulation in a comparative manner. When ethical, evaluating the efficacy of these treatments compared to untreated controls would be ideal. Alternatively, this can be used as a comparative group in an RCT with PT, injections and/or medications.

Bracing, Traction, Electrical Stimulation and TENS References

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Bracing, Traction, Electrical Stimulation and TENS Bibliography

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What is the long-term (two to 10 years) result of medical/interventional management of spinal stenosis?

Medical/interventional treatment may be considered to provide long-term (2-10 years) improvement in patients with degenerative lumbar spinal stenosis and has been shown to improve outcomes in a large percentage of patients.

Grade of Recommendation: C

Because of the limited availability of evidence, the work group defined long-term results as any study that included two or more years of follow-up.

Of patients with mild to moderate lumbar spinal stenosis initially receiving medical/interventional treatment and followed for two to 10 years, approximately 20-40% will ultimately require surgical intervention. Of the patients who do not require surgical intervention, 50-70% will have improvement in their pain.

Amundsen et al¹ performed a case control, comparative study of 100 patients with symptomatic spinal stenosis. These patients were divided into three groups: 19 patients with severe symptoms received surgical treatment, 50 patients with moderate symptoms received medical/interventional management and 31 patients were randomly assigned. The surgical group received decompression without fusion, inpatient rehabilitation with a brace, back school and physical therapy when out of the brace. The medical/interventional group was admitted to inpatient rehabilitation for one month, braced for up to three months and participated in back school and physical therapy when out of the brace. Patients were seen at regular intervals for 10 years. Authors assessed patients based on pain (no or light pain, moderate pain, severe pain), degree of stenosis and response to treatment (worse, unchanged, fair, excellent).

To review long-term outcomes, we reviewed 50 patients who were selected for medical/interventional treatment because of moderate symptoms and the 18 medical/interventional patients who were randomly assigned, for a total of 68 patients treated medically/interventionally in this study.

At the conclusion of 10 years, 10 patients in the medical/interventional group had died, 19 patients crossed over to surgery and 39 patients remained in this group. Of the patients remaining in the medical/interventional group, 70% experienced good results based upon the assessment of pain. For evaluation of this article, the reviewers chose to include only the patients in the medical/interventional treatment groups, limiting this study

to a case series, or Level IV evidence. In critique of this study, no standardized outcome measures were used, and substantial numbers of patients died or crossed over to surgical treatment. Further, medical/interventional treatment consisted initially of a one-month stay in an inpatient rehabilitation unit for "back school" which is unlikely to apply in today's medical cost environment, but this program appears reasonably effective. It is unclear if the results of initial treatment rendered differ from the natural history of spinal stenosis.

Simotas et al² studied a case series of 49 people, with a mean age of 69, meeting radiologic and clinical criteria of spinal stenosis. Patients were treated medically/interventionally with exercises, analgesics and epidural steroid injections. Patients were followed an average of 33 months.

Outcome measures were VAS, Roland Morris Disability Questionnaire score, an overall rating of depression and anxiety levels, an outcome measure of lumbar stenosis by Stucki et al³ and a motor examination.

At three years, nine of these patients underwent surgical decompression. Of the remaining 40 patients, 12 reported no or only mild pain, 11 reported mild improvement, 12 reported no change, the remaining five were probably or definitely worse. Two of these patients experienced significant motor deterioration. In critique, this study used validated outcome measures and a defined medical/interventional treatment method. This study provides Level IV evidence that 71% (35 of 49) of patients with lumbar spinal stenosis will remain the same or improve with medical/interventional treatment over three years. The remainder will worsen, 18% (nine of 49) to the point that they require surgery.

Waikakul and Waikakul⁴ performed a prospective cohort study on the treatment of lumbar spinal stenosis using methylcobalamin as an adjunct to medical/interventional care. Conservative care consisted of patient education, activity modification, exercises to strengthen the trunk and abdominal muscles, physical therapy, NSAIDS, analgesics, muscle relaxants and epidural steroid injections. The patients were followed for two years.

Outcome measures were physical examination and distance walked without neurogenic claudication (1000 m). In the group that received medical/interventional care only, 59 out of 82 patients were unable to walk 1000 m without claudication upon entry into the study. At two years, only 12 out of 80 were unable to walk 1000 m without claudication. Two patients underwent surgery.

In the group that was treated with methylcobalamin and medical/interventional care, 50 out of 70 could not initially walk 1000 m without claudication. At two years, 69 of the 70 patients could walk greater than 1000 m without claudication. One single patient required surgical intervention.

In critique, we have opted to judge this study as two case series of medical/interventional care when evaluating long-term outcomes. This study is limited by lack of standardized medical/interventional treatment or standardized outcome measures. This study provides Level IV treatment evidence that medical/interventional care can improve walking ability in spinal stenosis patients. Adding methylcobalamin to the medical/interventional regimen improves walking distance in an added percentage.

In 2005, Zucherman et al⁵ released two-year data on patients treated with X STOP for lumbar spinal stenosis. Patients were randomized into two groups, one treated with X STOP and one treated medically/interventionally. Nonsurgical treatment included at least one epidural steroid injection, NSAIDs, analgesics and physical therapy. Physical therapy included back school, modalities, massage, stabilization and exercises. Patients were followed for two years.

The primary outcome measure was the Zurich Claudication Questionnaire. Secondary outcomes in-cluded the SF-36 and range of motion.

At follow-up, 81 of the 91 medical/interventional patients were available for assessment. Of the patients who were in the medical/interventional group, 44% experienced at least some improvement in their pain and 43% of patients experienced at least some improvement in their physical function. In critique, medical/interventional treatment was not controlled and secondary outcome measure results were not available. Data of two-year outcomes for the medical/interventional group show poorer results than other medical/interventional studies. This study provides Level IV evidence that approximately 40% of patients treated medically/interventionally will show improvements in pain and physical function.

Future Directions for Research

The work group identified the following suggestions for future studies, which would generate meaningful evidence to assist in further defining the role of medical treatment for lumbar spinal stenosis.

Recommendation #1:

Future long-term studies of the effects of medical, noninvasive interventions for lumbar spinal stenosis should include an untreated control group.

Recommendation #2:

Future long-term outcome studies of lumbar spinal stenosis

should include results specific to each of the medical/interventional treatment methods.

Long Term Outcomes (Medical/Interventional) References

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Long Term Outcomes (Medical/Interventional) Bibliography

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This clinical guideline should not be construed as including all proper methods of care or excluding or 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

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D. Surgical Treatment

Does surgical decompression alone improve surgical outcomes in the treatment of spinal stenosis compared to medical/interventional treatment?

Decompressive surgery is suggested to improve outcomes in patients with moderate to severe symptoms of lumbar spinal stenosis.

Grade of Recommendation: B

Athiviraham et al¹ described a prospective comparative study to determine whether surgery is better than medical/interventional treatment of spinal stenosis for patients who are deemed potential surgical candidates in the expert opinion of the senior surgeon. Of the 125 patients included in the study, 96 were treated surgically and 29 opted to receive medical/interventional treatment. At two-year follow-up, the average improvement in Roland Morris Disability Questionnaire (RMDQ) scores for decompression, decompression with fusion and medical/interventional treatment were 6.9, 6.1 and 1.2 respectively. The authors concluded that the majority of patients who choose surgery will experience significant improvement in function, but will have residual symptoms and, therefore, should be counseled about realistic expectation.

In critique, group assignment was based upon patient preference, with those patients with more severe symptoms opting for surgery and those with less severe symptoms opting for medical/interventional treatment. This study provides Level II therapeutic evidence that patients considered surgical candidates who elect to undergo surgery will have statistically significant improvements in their symptoms and this improvement is greater than that experienced by patients who elect medical/interventional treatment. Patients may experience residual symptoms, and should be counseled about realistic treatment expectations.

Malmivaara et al² performed a prospective, randomized controlled trial to assess the effectiveness of decompressive surgery compared to medical/interventional treatment in patients with moderate lumbar spinal stenosis. Of the 94 patients included in the study, 50 were treated with decompression and 44 received an individualized medical/interventional treatment program. Both treatment groups showed improvement during follow-up at one and two years, with greater improvement seen in the surgical group with respect to disability, leg pain and back pain. Walking ability did not differ between the two groups. The authors concluded that although patients improved over the two year follow-up regardless of initial treatment, the decompressive surgery group reported greater improvement in leg pain, back pain and overall disability, with relative benefits decreasing over time, but remaining favorable. Surgery should be suggested, but only

after a trial of medical/interventional treatment. In critique, this study included some patients with spondylolisthesis; however, all surgically treated patients received segmental decompression without fusion, regardless of the presence of spondylolisthesis. Neither patients nor reviewers were masked to treatment. This study provides Level II therapeutic evidence that surgery results in improved outcomes compared with medical/interventional treatment.

Weinstein et al^{3,4} reported results of the SPORT study, originally designed as a prospective randomized controlled trial. With the significant crossover between groups, the study has been divided into two segments: randomized controlled trials (RCT) and prospective observational cohort. The two studies reviewed provided two year and four year data relative to the surgical and medical/interventional treatment of patients with degenerative lumbar spinal stenosis. Of the 654 patients included in the study, 289 remained in the RCT arm and 365 were included in the observational cohort. Outcomes were assessed using validated outcomes instruments including the Oswestry Disability Index (ODI), SF36 and Roland Morris Disability Questionnaire (RMDQ). The as-treated analysis presents data on the 235 medical/interventional patients and 419 surgical patients, showing a significant advantage for surgery for all primary outcomes. These changes remained significant at two years and were maintained through four years. At four year follow-up, the medically/ interventionally treated group "demonstrated only modest improvement over time." In the surgical group, 9% experienced dural tear and there was a 13% reoperation rate.

In critique, there was substantial crossover in the randomized group, with no control or assessment of patient preference. With such significant crossover and lack of control over assignment, in reviewing the two year and four year results of the SPORT study, the work group viewed the entire study as a prospective comparative study. These studies provide Level II therapeutic evidence that patients with symptomatic spinal stenosis treated surgically compared to those treated medically/interventionally maintain substantially greater improvement in pain and function through four years.

Park et al⁵ presented a retrospective comparative study looking at the SPORT study results to determine the impact of multilevel stenosis on surgical and medical/interventional treatment outcomes. Patients with three or more levels of stenosis had somewhat less severe pain at baseline on the SF-36 bodily pain scale compared to one and two levels. Patients with single level stenosis were less likely to present with neurogenic claudication (p <0.001) and more likely to report dermatomal pain radiation. Other baseline symptoms were similar across groups. When comparing surgical to medical/interventional treatments for one, two and three level isolated stenosis, there was a significant surgical treatment effect in most outcomes measures within each subgroup at each time point. The only significant difference in treatment effects between subgroups was at two years for patient satisfaction with symptoms. Patients with single level stenosis had a smaller difference in satisfaction between surgery and medical/interventional treatment, that is, a smaller treatment effect than the other two groups. This study provides Level III therapeutic evidence that patients with spinal stenosis without associated degenerative spondylolisthesis or scoliosis can be managed nonoperatively irrespective of the number of levels involved. If surgery is performed, the number of levels treated does not predict outcome.

Amundsen et al⁶ conducted a case control, comparative study of 100 patients with symptomatic spinal stenosis. Inclusion criteria were sciatic pain in the leg(s) with or without back pain and radiographic evidence of stenosis. These patients were divided into three groups: 19 patients with severe symptoms received surgical treatment, 50 patients with moderate symptoms received medical/interventional management and 31 with moderate to severe symptoms were randomly as-signed. The surgical group received decompression without fusion, inpatient rehabilitation with a brace, back school and physical therapy when out of the brace. The medical/interventional group was admitted to inpatient rehabilitation for one month, braced for up to three months, back school and physical therapy when out of brace. Patients were seen at regular intervals for 10 years. Authors assessed patients based on pain (no or light pain, moderate pain, severe pain), degree of stenosis and response to treatment (worse, unchanged, fair, excellent).

With medical/interventional treatment, a good result was reported by 70% (35 of 50) of patients at six months, 64% (32 of 50) at one year and 57% (28 of 49) at four years. With surgery, a good result was reported by 79% (15 of 19) at six months, 89% (17 of 19) at one year and 84% (16 of 19) at four years. Of the patients randomly assigned to the medical/interventional group, good results were reported for 39% (seven of 18) at six months, 33% (six of 18) at one year and 47% (8 of 17) at four years. Of these patients, 56 % (10 of 18) reported being worse at six months. Of the patients ran-domly assigned to the surgical group, good results were reported for 92% (12 of 13) at six months, 69% (nine of 13) at one year and 92% (11 of 12) at four years.

At the conclusion of 10 years, 10 patients in the medical/interventional group had died, 19 patients crossed over to surgery and 39 patients remained in this group. Of the patients remaining in the medical/interventional group, 70% experienced good results based on the assessment of pain.

In critique, no standardized outcome measures were uti-

lized, and there were substantial numbers of patient deaths and patients crossing over from medical/interventional to surgical treatment. Further, medical/interventional treatment consisted initially of a one-month stay on an inpatient rehabilitation unit for "back school" which is unlikely to apply in today's medical cost environment. In the randomized group, there is no direct statistical analysis comparing the surgical to the medical/interventional group. It is unclear that the results of initial treatment rendered differed from the natural history of spinal stenosis. Also, the medical/interventional group received minimal care (no injections, no indication of continued exercise program, etc).

The surgically treated group improved more than the medically/interventionally treated group, although of the group with medical/interventional treatment, a large number of patients did quite well. This study provides Level II therapeutic evidence that patients with moderate to severe symptoms at presentation will receive a good result about 90% of the time compared with medical/interventional patients who will receive a good result only about 40% of the time. This study also provides Level IV evidence that a cohort of patients with severe symptoms at presentation will have a good outcome with decompression 80-90% of the time and a cohort of patients with moderate symptoms will have a good result with medical/interventional treatment about 70% of the time.

Mariconda et al⁷ reported an incompletely randomized, prospective study of 44 patients comparing single or multilevel laminectomy in patients with mild to moderate leg pain to patients treated with medical/interventional therapy. Outcomes were assessed using the Beaujon Scoring System. Twenty-two patients were assigned to each group. Only 32 of 44 patients were randomly assigned into each group. The mean functional status at one year was improved in both groups. Conservative treatment consisted of bed rest, use of a semirigid orthosis, physical therapy and appropriate exercise program. At four years, the good results were 68% in the surgical group and 33% in the medi-cal/interventional group. Only 2.6% of patients experienced an increase in their spondylolisthesis. There was a reoperation rate of 9% and a cross over rate of 9%.

In critique of this study, patients were relatively young with a mean age of 61 years and an inclusion criterion as young as 40 years of age. Validated outcome measures were not used. The patient sample size was small. There was a mixed surgical technique with occasional undercutting of the contralateral lamina. There was partial randomization in the study with only 73% of the patients randomized. Finally, it is not known how long medical/interventional management was continued. Because of these deficiencies, this study was classified as providing Level III evidence.

This study provides Level III therapeutic evidence to support good outcomes in 68% of patients undergoing decompression for lumbar spinal stenosis compared with medical/interventional management.

Arinzon et al⁸ performed a prognostic case control study investigating the effect of decompression for lumbar spinal stenosis in elderly diabetic patients. The study included 62 diabetic patients and 62 gender- and age-matched nondiabetic controls. The mean follow-up was 40.3 months. Comorbidities were as-

sessed and outcomes were measured using the visual analog scale (VAS), basic activities of daily living (BADL) and walking distance. The authors concluded that decompression for symptomatic spinal stenosis is beneficial in elderly diabetic patients. However, the results are related to successful pain reduction, physical and mental health status, severity of clinical presentation, insulin treatment and duration of diabetes. The benefits in diabetic patients are low as compared with nondiabetic patients with regard to symptom relief, satisfaction, BADL function and rate of complications.

In critique of this study, it highlights the clinical results of lumbar decompression in diabetic patients. Conclusions regarding mental health status were not supported with appropriate outcome tools to assess mental health. They failed to address the degree of stenosis in both the diabetic and control cohort. This study provides Level III prognostic evidence to support decompressive surgery for lumbar spinal stenosis in elderly diabetic patients. It also highlights the higher complication rate (p<0.0001) and less successful pain relief compared with nondiabetic patients (p=0.0067).

Arinzon et al 9 conducted a retrospective, prognostic study of the effects of age on decompressive surgery for lumbar spinal stenosis. Two hundred eighty-three patients were grouped according to age. One group was aged 65-74 years old and the second group was > 75-years-old. Follow-up was up to 42 months with a minimum of nine months. Within both treatment groups there was a significant (p<0.0001) subjective improvement in low back and radicular pain as well as the ability to per-form daily activities. When compared to preoperative levels, the oral scores for pain while performing daily activities were significantly improved (p<0.001) in both treatment groups. The authors concluded that the overall postoperative complication rate was similar between the groups and that age is not a contraindication for surgical decompression of lumbar spinal stenosis. Both groups are equally likely to suffer minor perioperative complications.

In critique of this study, there were no validated outcome tools and a lack of standardized surgical procedures, thus this paper provides Level III prognostic evidence that age greater than 75 years is not a contraindication for lumbar decompression compared with patients 65-74-years-old.

Medical/interventional treatment may be considered for patients with moderate symptoms of lumbar spinal stenosis.

Grade of Recommendation: C

Amundsen et al⁶ conducted a case control, comparative study of 100 patients with symptomatic spinal stenosis. Inclusion criteria were sciatic pain in the leg(s) with or without back pain and radiographic evidence of stenosis. These patients were divided into three groups: 19 patients with severe symptoms received surgical treatment, 50 patients with moderate symptoms received medical/interventional management and 31 patients with moderate to severe symptoms were randomly assigned. The surgical group received decompression without fusion, inpatient rehabilitation with a brace, back school and physical therapy when out of the brace. The medical/interventional group was admitted to inpatient rehabilitation for one month, braced for up to three months, back school and physical therapy when out of brace. Patients were seen at regular intervals for 10 years. Authors assessed patients based on pain (no or light pain, moderate pain, severe pain), degree of stenosis and response to treatment (worse, unchanged, fair, excellent).

With medical/interventional treatment, a good result was reported by 70% (35 of 50) of patients at six months, 64% (32 of 50) at one year and 57% (28 of 49) at four years. With surgery, a good result was reported by 79% (15 of 19) at six months, 89% (17 of 19) at one year and 84% (16 of 19) at four years. Of the patients randomly assigned to the medical/interventional group, good results were reported for 39% (7 of 18) at six months, 33% (6 of 18) at one year and 47% (8 of 17) at four years. Of these patients 56% (10 of 18) reported being worse at six months. Of the patients randomly as-signed to the surgical group, good results were reported for 92% (12 of 13) at six months, 69% (9 of 13) at one year and 92% (11 of 12) at four years.

At the conclusion of 10 years, 10 patients in the medical/interventional group had died, 19 patients crossed over to surgery and 39 patients remained in this group. Of the patients remain-

ing in the medical/interventional group, 70% experienced good results based upon the assessment of pain.

In critique, no standardized outcome measures were utilized, and there was a substantial number of patient deaths and patients crossing over from medical/interventional to surgical treatment. Further, medical/interventional treatment consisted initially of a one month stay on an inpatient reha-bilitation unit for "back school" which is unlikely to apply in today's medical cost environment. In the randomized group, there is no direct statistical analysis comparing the surgical to the medical/interventional group. It is unclear that the results of initial treatment differed from the natural history of spinal stenosis. Also, the medical/interventional group received minimal care (no injections, no indication of continued exercise program, etc). The surgically-treated group improved more than the medically/interventionally treated group, though of the group with medical/interventional treatment, a large number of patients did quite well.

When analyzing the small subset of randomized patients, this study provides Level II treatment evidence that patients with moderate to severe symptoms at presentation will receive a good result about 90% of the time compared with medical/interventional patients who will receive a good result about 40% of the time. Analysis of the surgically treated cohort of severely symptomatic patients provides Level IV evidence that a good outcome with decompression can be expected in 80-90% of patients. Analysis of the cohort of patients with moderate symptoms will have a good result with medical/interventional treatment about 70% of the time.

Johnsson et al¹⁰ studied a case series of 63 patients with moderate to severe lumbar stenosis as diagnosed by myelography (partial block was diagnostic of moderate stenosis, a total block of severe stenosis) and symptoms of neurogenic claudication, ra-

diculopathy or mixed symptoms. All patients were offered surgery. Patients that were too ill to have surgery as determined by anesthesia or declined surgery were placed in the no care group (19 patients); the remaining 44 patients underwent decompressive surgery without fusion. Outcomes included a four-level pain scale, a 100 mm VAS for degree of improvement or deterioration, a measure of walking capacity and electrodiagnostic studies.

At follow-up, 42% (eight of 19) of the patients not operated upon, 33% (10 of 30) of the surgical patients with moderate stenosis and 57% (eight of 14) of the surgical patients with severe stenosis were symptom free. With regard to patient pain rating at follow-up, in the nontreatment group, 32% (six of 19) noted improvement in pain, compared with 57% (17 of 30) in the surgical group with moderate stenosis and 64% (nine of 14) in the surgical group with severe stenosis. Patients who felt their pain was worse at follow-up included 10% (two of 19) in the nontreated group compared with 20% (six of 30) in the surgical group with moderate stenosis and 36% (five of 14) in the surgical group with severe stenosis. Severe deterioration was not found in untreated patients. Electrophysiologic parameters seemed to worsen equally in both groups.

In critique, the authors used nonvalidated outcome measures

as their VAS for pain was divided into only four strata. Length of follow-up was not clearly listed and some data were ambiguous. In this study, no surgery appears to be the same as no treatment other than pain medication, although treatment for this group is not clearly defined. This study demonstrates Level IV treatment evidence that decompression provides improvement in pain 50-60% of the time; however 20-36% of patients are likely to worsen. This study also demonstrates Level IV evidence that medical/interventional management will provide pain relief about 33% of the time, whereas about 10% of the time, pain is likely to worsen.

The work group evaluated three other studies which have been included in a secondary evidentiary table, but excluded from the guideline recommendations for the following reasons:

1. Atlas et al¹¹ included a mixed diagnostic group of patients with degenerative stenosis and herniated discs; 2. Gibson et al¹² is a Cochrane review that discussed the broader topic of lumbar spondylosis which included a wider variety of diagnoses than this work group is addressing. The appropriate articles included in this Cochrane review have been evaluated separately here by the work group and are included in this guideline; and 3. the analysis by Turner et al¹³ included only low quality studies published before 1992 which were individually discarded from the evidentiary table.

In the absence of evidence for or against any specific treatment, it is the work group's recommendation that medical/interventional treatment be considered for patients with mild symptoms of lumbar spinal stenosis.

Work Group Consensus Statement

Patients with mild symptoms are generally excluded from these comparative studies because they would not be considered surgical candidates.

There is insufficient evidence at this time to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis.

Grade of Recommendation: I (Insufficient Evidence)

Although two studies are cited in support of this recommendation, they reference the same group of patients and are thus viewed as a single study. Therefore, until further evidence on a different group of patients is published, evidenceremains insufficient to make a recommendation.

The following studies discuss an approach to one- or two-level lumbar spinal stenosis that results in an indirect decompression of the spinal canal. This differs from more traditional surgical decompressions accomplished by laminectomy or laminotomy. In this approach, a device is placed between two spinous processes with the back in flexion. The device is reported to thereby increase canal size during weight bearing and maintain canal size in extension, effectively, but indirectly, decompressing the canal with this surgical procedure. Because this procedure results in a surgical decompression of the lumbar spinal canal,

the work group chose to place this study in this section of this guideline.

Zucherman et al¹⁴ conducted a prospective, randomized, controlled trial of 191 patients with mild to moderate symptoms of lumbar stenosis. Diagnostic criteria were an age of at least 50 years, the presence of leg, buttock or groin pain with or without back pain that was relieved during flexion, the ability to sit for 50 minutes without pain, the ability to walk at least 50 feet and stenosis at one or two levels as seen on CT or MRI. The surgery group included 100 patients which had placement of the X STOP. The control group consisted of 91 patients who were medically/interventionally managed. Medical/interventional treatment included at least one epidural steroid injection, NSAIDs, analgesics and physical therapy. Physical therapy included back school, modalities, massage, stabilization and exercises. Patients

were followed for two years.

The primary outcome measure was the Zurich Claudication Questionnaire, a validated outcome measure for lumbar spinal stenosis. Secondary outcomes included the SF-36 and range of motion.

At two years, the mean Symptom Severity scores improved by 45.4% from the baseline scores in the X STOP group and by 7.4% in the control group. At the same point, the mean Physical Function scores improved by 44.3% in the X STOP group and by -0.4% in the control group. At the two-year evaluation, 60% (56 of 93) of surgical patients reported a clinically significant improvement in the Symptom Severity domain compared with 19% (15 of 81) of patients in the control group, 57% (53 of 93) of patients reported clinically significant improvement in the Physical Function domain compared with 15% (12 of 81) of patients in the control group, and 73% (68 of 93) of patients were at least somewhat satisfied compared with 36% (28 of 78) of patients in the control group.

In critique, medical/interventional treatment was not controlled and secondary outcome measures were not available. Data on two-year outcomes of the medical/interventional group showed poorer results than other medical/interventional studies. This initial evaluation of the X STOP provided Level I therapeutic evidence that in patients with mild to moderate stenosis, this procedure was more effective than a medical/interventional treatment regimen in similar patients.

Hsu et al¹⁵ reported results from a prospective, randomized controlled trial assessing the benefit of X STOP compared with medical/interventional treatment for the treatment of mild to moderate lumbar spinal stenosis in 191 patients. At all points of follow-up, the X STOP group showed significantly better outcome scores than the medical/interventional treatment group on all measures with the with exception of mean general health, role emotional and mental component summary scores. Of the 91 patients assigned to the medical/interventional treatment group, 24 dropped out and received laminectomy. Six patients in the X STOP group ultimately proceeded with laminectomy. The authors concluded that the X STOP device is significantly more effective than medical/interventional treatment in improving the quality of life for patients with lumbar spinal stenosis.

In critique, there was a significant dropout rate with approximately 30% of the medical/interventional group proceeding to surgery by the two year follow-up. Data for this group were not presented. It should also be noted that this represents data from the original study by Zucherman et al, cited above. Because of these limitations, this study provides Level II therapeutic evidence that the X STOP device is significantly more effective than medical/interventional treatment in improving the outcomes for patients with lumbar spinal stenosis.

Future Directions for Research

The work group identified the following suggestions for future studies, which would generate meaningful evidence to assist in further defining the role of decompression, as compared to a medical/interventional treatment and natural history, for lumbar spinal stenosis.

Recommendation #1:

A large, multicenter, three-arm, randomized, controlled trial using a well-defined group of patients with moderate clinically symptomatic stenosis, comparing lumbar decom-pression to a well-defined medical/interventional treatment program and / or a natural history group of untreated patients is needed.

Recommendation #2:

A large, multicenter, three-arm, randomized, controlled trial using a well-defined group of patients with mild to moderate clinically symptomatic stenosis, comparing the use of interspinous spacers to a microlaminotomy decompression and / or a well-defined medical/interventional treatment program is needed.

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

For patients with degenerative lumbar spinal stenosis with concomitant spondylolisthesis, please refer to treatment recommendations and supporting evidence available in the NASS guideline Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis (2008), available at: http://www.spine.org/Documents/Spondylolisthesis_Clinical_ Guideline.pdf.

Decompression alone is suggested for patients with leg predominant symptoms without instability.

Grade of Recommendation: B

Grob et al¹ conducted a randomized, controlled trial of 45 patients with symptomatic lumbar stenosis with less than 5 mm of intervertebral translation who were randomly assigned to three groups: 1. decompression with laminotomy and medial facetectomy, 2. decompression with arthrodesis of the most stenotic segment and 3. decompression with arthrodesis of all the effected segments. Inclusion criteria included a clinical diagnosis of stenosis and confirmation with CT, myelogram or MRI scan to have a mid sagittal diameter of less than 11 mm. Outcome measure was a result classification (very good, good, fair or poor) based on percentage of subjective pain relief, use of analgesics and reported impairment of daily activities.

Average follow-up duration was 28 months. At this point in follow-up, all groups showed an increase in walking ability and a decrease in pain. There was no difference between the groups noted.

In critique, the sample size of patients is small and no validated outcome measures were used. Intervertebral translation data were not presented in detail. This study provides Level II therapeutic evidence that there is no difference between decompression and decompression with fusion in patients with stenosis and less than 5 mm of intervertebral translation.

Yone et al² performed a prospective, comparative study of 60 patients with lumbar stenosis. Inclusion criteria were the presence of back pain, leg pain or claudication which failed to improve with medical/interventional care and stenosis on imaging though criteria were not clearly defined. Patients were assessed as to whether they had instability based on Posner's definition. Of these 60 patients, 33 met the criteria for instability. Of these 33 patients with instability, all were offered de-compression and fusion. Decompression and fusion was performed in 19 patients while the remain-ing 14 refused fusion and underwent decompression alone. The 27 patients without instability also underwent decompression without fusion. The primary outcome measure was the JOA score. Of the patients who underwent instrumented fusion and the group that had no instability with decompres-sion, 80% of the patients experienced good outcomes. Only 43% of the patients in the group with instability and decompression without fusion experienced good outcomes.

In critique, the sample size of patients undergoing fusion in this study was small. This study provides Level II therapeutic evidence that, in patients with lumbar spinal stenosis meeting Posner's criteria of instability, decompression and fusion is more effective than decompression alone. The results of decompression and fusion in the instability group were comparable to results of decompression alone in the group without instability. However, no fusions were done in this latter group, thus, this study does not directly address the efficacy of decompression versus decompression and fusion in spinal stenosis without instability.

Rampersaud et al³ described a retrospective observational cohort study with prospectively collected outcomes, comparing health and quality of life benefit offered by the surgical treatment of 90 lum-bar spinal stenosis patients to a matched cohort of 90 elective total joint arthroplasty (TJA) patients. The surgical treatment of lumbar stenosis was selected based upon the presenting symptomatology. Of the 90 patients, 28 presented with leg pain with no instability or mechanical back pain for whom decompression alone was selected. For the 62 patients with leg symp-

toms and mechanical back pain with or without documented instability, fusion was added to the compression treatment. Outcomes were assessed using the SF-36 and the Health Related Quality of Life (HRQOL) instruments. No significant differences were found between the health and quality of life benefits for the two groups of spinal surgery patients. The authors concluded that there were no significant differences between the decompression and decompression and fusion groups of spinal stenosis patients and determined that quality of life from spinal surgery is comparable with TJA patients. Further, it was noted that the cost effectiveness of surgical treatment of lumbar spinal stenosis is comparable to TJA. This study provides Level III therapeutic evidence that decompression alone and decom-pression with fusion have comparable health benefits to those established for TJA patients.

Future Directions for Research

The work group would like to point out that a number of these papers were downgraded because of lack of disease-specific outcome measures, and that future research including validated outcome measures could improve the level of evidence.

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What is the long-term result (4+ years) of surgical management of spinal stenosis?

Surgical treatment may be considered to provide long-term (4+ years) improvement in patients with degenerative lumbar spinal stenosis and has been shown to improve outcomes in a large percentage of patients.

Grade of Recommendation: C

Airaksinen et al¹ conducted a retrospective review of surgical outcomes for lumbar spinal stenosis. Of the 497 patients, 438 were available for follow-up at a mean of 4.3 years. The ODI was used as an outcome measure and a masked review was performed. Overall, there were good or excellent results in 62% of patients. This study provides Level IV therapeutic evidence that surgery offers a 62% good or excellent result at four-year follow-up.

Amundsen et al² performed a prospective, comparative study of 100 patients with lumbar spinal stenosis. Patients were assigned to four groups. Those with severe symptoms underwent decompression (surgical group, S, n=19). Those with mild symptoms were treated medical-ly/interventionally (conservative group, C, n=52). Those with moderate symptoms were randomized to medical/interventional (randomized conservative, RC, n=18) or operative care (randomized surgical, n=13). Follow-up was assessed at four and 10 years. All follow-up assessments were performed by the lead author, who also determined the overall treatment result. An intent-to-treat analysis was performed on the randomized groups at four years (ie, crossovers from medical/interventional to operative care were treated as failures). For the 10-year analysis, all surgical patients and all medically/interventionally treated patients were grouped together.

At the four-year follow-up, 84% of the nonrandomized surgical group reported good results; 57% of the nonrandomized, medical/interventional group reported good results; 47% of the randomized, medical/interventional group reported good results; and 92% of the randomized surgical group reported good results. The operative group tended to deteriorate somewhat

over time while the medical/interventional group tended to improve, such that at final follow-up there were good out-comes in 70 to 75% of both groups. Those operated on a delayed basis (crossovers) did not have worse results than those operated on early.

In critique, the method used for assigning patients to treatment groups was biased. Thus, although they characterize one of the arms of their study as randomized, the bias limits the ability to draw conclusions from the data on these patients. Furthermore, the numbers assigned to the randomized groups were small, the numbers were unequal (suggesting bias in the randomization process) and no statistical tests for significance were applied. Outcome assessment by the treating physician using nonvalidated outcome measures introduces further bias.

This study offers Level IV therapeutic evidence that surgery for severe spinal stenosis provides good or excellent results in approximately 80% of patients at four-year follow-up and the results were relatively stable at 70% good or excellent results at 10 years. It also offers Level IV evidence that patients who have medical/interventional therapy first but then cross over to surgery will not harm their chances of success with surgery.

Atlas et al³ conducted a prospective outcome study of 148 patients comparing the results between patients treated surgically for spinal stenosis and those treated medically/interventionally. There was a 33% drop rate, primarily caused by death. The surgical group experienced worse symptoms initially. There was a 39% crossover to the surgical group. Validated outcome measures were used. At four-year follow-up, the results favored surgery. Over time the surgical results deteriorated, with the two

groups converging at final follow-up. At eight- to 10-year follow-up, 50% of surgical patients reported improved back pain, 67% reported improved leg pain, 54% reported improvement in their predominant symptom, 55% were satisfied with their current state and 82% would choose the same treatment.

In critique, there was a high dropout rate in this study, primarily caused by death. This is expected in this age group, but nonetheless complicates data interpretation. This study provides Level IV therapeutic evidence that at eight to 10 years, 50-67% of patients undergoing surgical treatment demonstrated improvements in pain and satisfaction, although this represents a deterioration relative to their short- and intermediate-term results.

Cornefjord et al 4 studied a retrospective case series of 124 patients having surgery for lumbar spinal stenosis, with a fourto 12-year follow-up. Ninety-six patients (77%) were available for follow-up. A masked observer assessed nonvalidated measures of lower extremity pain, low back pain and walk-ing distance. There were significant improvements (all p < 0.001) in all three outcome measures and patient satisfaction was 65%.

In critique, validated outcome measures were not used. This study provides Level IV therapeutic evidence that 65% of patients treated surgically for spinal stenosis will have a satisfactory outcome at four- to 12-year follow-up.

Gelalis et al⁵ reported a retrospective case series of 54 patients assessing the long-term results of decompressive surgery for lumbar spinal stenosis. Outcomes were assessed at a mean of 11.6 years (6-17 year range) using non-validated outcome measures including patient assessment of low back pain, leg pain, working ability, walking ability and an analysis of patient satisfaction. Of the patients included in the study, 72% reported excellent outcomes at long-term follow-up. Patients with prolonged preoperative symptoms had poor to fair results and were less satisfied with treatment. This study provides Level IV therapeutic evidence that surgical treatment results in significant improvements in long-term outcomes.

Herno et al⁶ conducted a retrospective case series of the results from surgical decompression for lumbar spinal stenosis. Of the 146 patients studied, 119 were available for follow-up at a mean of 6.8 years and 108 were available at a mean of 12.8 years. The ODI and other outcome measures were used. At six years, the average ODI was 34.5 and overall good and excellent results were 67%. At 12 years, these results were 30.2 and 69% respectively.

In critique, there was no masked outcome measurement. There was a 26% drop-out rate. This study provides Level IV therapeutic evidence that patients treated surgically for spinal stenosis will have 67% good or excellent results at seven years and that the results will be maintained at 13 years.

Hurri et al⁷ performed a retrospective review of the long-term outcomes on 134 patients diagnosed with lumbar spinal stenosis. At 12-year follow-up, 48 had died, and of the remaining 86 patients, 75 were available. Of the remaining 75 patients, 57 were treated surgically and 18 medically/interventionally. Patients were evaluated by telephone with nonvalidated outcome measures as well as the ODI. Sixty-three percent of the operative group improved, while 18% actually worsened. The final ODI was 29.

In critique, there was a high drop out rate, even for studies in this population. Furthermore, a validated outcome measure was only implemented at follow-up. This study provides Level IV therapeu-tic evidence that 63% of patients treated surgically for spinal stenosis will improve at long-term follow-up.

Javid et al⁸ conducted a prospective study of 170 patients with lumbar spinal stenosis that underwent surgery. Of the 170 patients, 83 had central stenosis, 61 had stenosis and HNP and 23 had lateral recess stenosis. Follow-up was performed anywhere from one to 11 years, with a mean of five years. Twenty-four patients were lost to follow-up. Among the spinal stenosis patients, 64-70% experienced good results.

In critique, there was no masked outcome measurement, nonvalidated measures were used and there was large variability in the length of outcome. This study provides Level IV therapeutic evidence that patients treated surgically for spinal stenosis can expect 64-70% good or excellent results.

Jolles et al⁹ performed a retrospective review of 155 patients treated surgically for lumbar spinal stenosis, with five- to eight-year follow-up. Of the 155 patients, 77 were available for follow-up. Validated outcome measures were used. Seventy-nine percent experienced good or excellent results.

In critique, there was a high drop out rate, even for studies in this population. This study provides Level IV therapeutic evidence that patients treated surgically for spinal stenosis can expect 79% good or excellent results at a five-year follow-up.

Jonsson et al¹⁰ conducted a prospective study of 105 patients with lumbar spinal stenosis treated surgically. Of the 105 patients, 88 were available for five-year follow-up. The reviewer was masked, and outcomes were measured with a nonvalidated four-point scale (excellent, fair, no change or poor). Sixty-four percent experienced good or excellent results.

In critique, a nonvalidated outcome measure was used. This study provides Level IV therapeutic evidence that patients treated surgically for spinal stenosis can expect 64% good or excellent results at a five-year follow-up.

Katz et al¹¹ performed a retrospective review of 88 patients who underwent surgery for lumbar spinal stenosis. Follow-up data were available in 55 patients. Of these patients, 85% experienced some initial improvement. Thirty-three percent reported severe low back pain at final follow-up and 20% experienced severe lower extremity pain. Overall, 75% of patients were satisfied at final follow-up.

In critique, a nonvalidated outcome measure was used. 37% were lost to follow-up, most as a result of death. This study provides Level IV therapeutic evidence that 75% of patients treated surgically for spinal stenosis will be satisfied at seven- to 10-year follow-up, although 33% experienced severe low back pain.

Kim et al¹² conducted a retrospective review of a national insurance database of 1015 patients to investigate the 10-year survival rate of elderly patients who underwent spinal surgery for lumbar stenosis and compare rates with the general population. The Kaplan-Meier Survival Method was utilized to assess life expectancy. Patients who underwent spine surgery had a better survival rate than a matched general population in each group (50-59, 60-69, 70-85), with a reported 94% 10 year survival rate. The authors concluded that surgery improves quality of life and does not have a negative effect on long-term survival compared

with an age-matched cohort. This study provides Level IV therapeutic evidence that elderly patients who undergo spine surgery for spinal stenosis have mortality rates that are as good as or better than the corresponding general population. Therefore, surgery for spinal stenosis is a justifiable procedure even in elderly patients.

Oertel et al¹³ described a retrospective case series of 133 patients examining long-term results of unilateral laminotomy for bilateral decompression in lumbar stenosis. At a mean 5.6 year follow-up, 92% had persistent postoperative symptom improvement, with 85% of patients experiencing excellent to fair results according to the Finneson-Cooper scale. This study provides Level IV evidence that 85% of surgically treated spinal stenosis patients can achieve long-term improvements in outcomes.

Tuite et al¹⁴ retrospectively reviewed 119 patients undergoing decompression surgery for lumbar spinal stenosis with a mean follow-up of 4.6 years. Seventy-nine percent reported improvement at one year and 66% at final follow-up.

In critique, nonvalidated outcome measures were used and were only collected at follow-up. This study provides Level IV therapeutic evidence that 79% of patients treated surgically for spinal stenosis will have a good result at one year, declining to 66% at mean 4.6-year follow-up.

There were many additional Level IV studies, the results of which were consistent with those cited above. Although they are not addressed in the text of the guideline, information is available on the evidentiary table. 15-21 The committee did note that there was no better than level IV evidence for long-term effects of surgical treatment for spinal stenosis. However, it was further acknowledged that owing to the definition of long-term, specifically five years or beyond, it is unlikely that there will ever be high level evidence when studying this question. Thus, even studies that are retrospective and without control groups still offer important and valuable information if other features are of good quality, such as drop outs, valid outcome measures and well defined patient populations and interventions.

Surgical decompression may be considered in patients aged 75 or greater with lumbar spinal stenosis.

Grade of Recommendation: C

Patients aged 75 or greater with lumbar spinal stenosis show the same benefit from decompression as your patients aged 65-74.

Arinzon et al²² performed a retrospective, prognostic study of the effects of age on decompressive surgery for lumbar spinal stenosis in 283 patients grouped according to age. One group included ages 65-74 and the second group was greater than 75 years old. Follow-up was up to 42 months with a minimum of nine months. Within both treatment groups there was a significant (p<0.0001) subjective improvement in low back and radicular pain as well as the ability to perform daily activi-ties. When compared to preoperative levels, the oral scores for pain while performing daily activities were significantly improved (p<0.001) in both treatment groups. The authors concluded that the overall postoperative complication rate was similar between the groups and that age is not a contraindication for surgical decompression of lumbar spinal stenosis. Both groups are equally likely to suffer minor perioperative complications.

In critique of this study, there were no validated outcome tools and a lack of standardized surgical procedures, thus this paper provides Level III prognostic evidence that age greater than 75 years is not a contraindication for lumbar decompression compared with patients 65-74 years old.

Kim et al¹² conducted a retrospective review of a national insurance database of 1015 patients to investigate the 10 year survival rate of elderly patients who underwent spinal surgery for lumbar stenosis and compare rates with the general population. The Kaplan-Meier Survival Method was utilized to assess life expectancy. Patients who underwent spine surgery had a better survival rate than a matched general population in each group (50-59, 60-69, 70-85), with a reported 94% 10 year survival rate. The authors concluded that surgery improves quality of life and does not have a negative effect on long-term survival compared with an age-matched cohort. This study provides Level IV thera-

peutic evidence that elderly patients who undergo spine surgery for spinal stenosis have mortality rates that are as good as or better than the corresponding general population.

Surgery for spinal stenosis is a justifiable procedure even in elderly patients.

Future Directions for Research

The work group identified the following suggestions for future studies, which would generate meaningful evidence to assist in further defining the role of medical treatment for lumbar spinal stenosis. It is acknowledged that the opportunity for assessing long-term outcomes in this group of patients is severely limited by the age-related morbidities in this patient group, thus it is unlikely that outcome studies longer than those noted above are practically feasible.

Recommendation #1:

Future long-term studies of the effects of surgical interventions for lumbar spinal stenosis should include an untreated control group, when ethically feasible.

Recommendation #2:

Future long-term outcome studies of lumbar spinal stenosis should include results specific to each of the surgical treatment methods.

Recommendation #3:

Large cohort studies utilizing transparently unbiased databases, such as exist in Scandinavia and large medical systems (eg, HMOs), could serve to validate these long-term results.

Surgical Long Term Outcome References

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V. Appendices

APPENDIX A: Acronyms

AP	antero-posterior	MSCT	multislice CT myelography
BADL	basic activities of daily living	MSPQ	Modified Somatic Perception Question-
CT	computed tomography		naire
CTM	CT myelography	MZD	Modified Zung Depression
DM	distraction manipulation	NASS	North American Spine Society
DSA	dural sac area	NCS	nerve conduction studies
DSEP	dermatomal somatosensory evoked po-	NIC	neurogenic intermittent claudication
	tential	NM	neural mobilization
EBM	evidence-based medicine	NSAIDs	nonsteroidal anti-inflammatory drugs
EMG	electromyelography	OCS	Oxford Claudication Score
ESI	epidural steroid injection	ODI	Oswestry Disability Index
ETT	exercise treadmill test	PPV	positive predictive value
FPVCT	flat panel volumetric computed tomogra-	QALY	quality adjusted life years
	phy	RCT	randomized controlled trial
HNP	herniated nucleus pulposus	RMDQ	Roland Morris Disability Questionnaire
HRQOL	health-related quality of life	ROC	Receiver Operating Characteristic
JOA	Japanese Orthopaedic Association	SIP	sickness impact profile
LBOS	low back outcome score	SLR	straight leg raise
LR	likelihood ratio	SSEP	somatosensory evoked potentials
LSO	lumbosacral orthosis	SSHQ	self-administered, self-reported history
mCSA	minimum cross-sectional area		questionnaire
MEP	motor evoked potentials	SSS	Swiss Spinal Stenosis Questionnaire
MEPLT	MEP latency	SWT	shuttle walking test
MR	magnetic resonance	TENS	transcutaneous electrical nerve stimula-
MRI	magnetic resonance imaging		tion
MRM	magnetic resonance myelography	VAS	visual analog scale
MSBQ	Maine Seattle Back Questionnaire	ZCQ	Zurich Claudication Questionnaire

APPENDIX B: Levels of Evidence For Primary Research Question¹

Types of Studies						
	Therapeutic Studies – Investigating the results of treatment	Therapeutic Studies – Investigating the results of treatment	Diagnostic Studies — Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model		
Level I	 High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals Systematic review² of Level I RCTs (and study results were homogenous³) 	 High quality prospective study⁴ (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) Systematic review² of Level I studies 	Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) Systematic review2 of Level I studies	 Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses Systematic review² of Level I studies 		
Level II	 Lesser quality RCT (eg, < 80% follow- up, no blinding, or improper randomiza- tion) Prospective⁴ com- parative study⁵ Systematic review² of Level II studies or Level I studies with inconsistent results 	 Retrospective⁶ study Untreated controls from an RCT Lesser quality prospective study (eg, patients enrolled at different points in their disease or <80% follow-up) Systematic review² 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 costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses Systematic review² of Level II studies 		
Level III	 Case control study⁷ Retrospective⁶ comparative study⁵ Systematic review² of Level III studies 	• Case control study ⁷	 Study of nonconsecutive patients; without consistently applied reference gold standard Systematic review² of Level III studies 	 Analyses based on limited alternatives and costs; and poor estimates Systematic review² of Level III studies 		
Level IV	Case series ⁸	Case series	Case-control studyPoor reference standard	Analyses with no sensitivity analyses		
LevelV	Expert opinion	Expert opinion	Expert opinion	Expert opinion		

- I. 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 (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, 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" (eg, failed total arthroplasty) are compared to those who did not have outcome, called "controls" (eg, successful total hip arthroplasty).
- 8. Patients treated one way with no comparison group of patients treated in another way.

APPENDIX C: 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.

APPENDIX D: Linking Levels of Evidence to Grades of Recommendation

Grade of Recommendation	Standard Language	Levels of	Evidence
Α	Recommended	Two or more consistent Level I studies	
В	Suggested	One Level I study with additional supporting Level II or III studies	Two or more consistent Level II or III studies
С	May be considered; is an option	One Level I, II or III study with supporting Level IV studies	Two or more consistent Level IV studies
I (Insufficient or Conflicting Evidence)	Insufficient evidence to make recommendation for or against	A single Level I, II, III or IV study without other supporting evidence	More than one study with inconsistent findings*

^{*}Note that in the presence of multiple consistent studies, and a single outlying, inconsistent study, the Grade of Recommendation will be based on the level of the consistent studies.

APPENDIX E: Protocol for NASS Literature Searches

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care or use of new technologies is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence, which will be instrumental to these activities. It is important that all searches conducted at NASS employ a solid search strategy, regardless of the source of the request. To this end, this protocol has been developed and NASS-wide implementation is recommended.

NASS research staff will work with the requesting parties and the NASS-contracted medical librarian to run a comprehensive search employing at a minimum the following search techniques:

- 1. A comprehensive search of the evidence will be conducted using the following clearly defined search parameters (as determined by the content experts). The following parameters are to be provided to re-search staff to facilitate this search.
 - Time frames for search
 - Foreign and/or English language
 - Order of results (chronological, by journal, etc.)
 - Key search terms and connectors, with or without MeSH terms to be employed
 - Age range
 - Answers to the following questions:
 - o Should duplicates be eliminated between searches?
 - o Should searches be separated by term or as one large package?
 - o Should human studies, animal studies or cadaver studies be included?

This search will encompass, at minimum, a search of PubMed, EMBASE, Cochrane and Web of Sci-ence. Additional databases may be searched depending upon the topic.

- 2. Search results with abstracts will be compiled by the medical librarian in Endnote software. The medi-cal librarian typically responds to requests and completes the searches within two to five business days. Results will be forwarded to the research staff, who will share it with the appropriate NASS staff member or requesting party(ies). (Research staff has access to EndNote software and will maintain a database of search results for future use/documentation.)
- 3. NASS staff shares the search results with an appropriate content expert (NASS Committee member or other) to assess relevance of articles and identify appropriate articles to review.
- 4. NASS research staff will work with Galter library to obtain requested full-text articles for review.
- 5. NASS members reviewing full-text articles should also review the references at the end of each article to identify additional articles which should be reviewed, but may have been missed in the search.

Following this protocol will help ensure that NASS recommendations are (1) based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the cur-rent best research evidence available. Research staff will maintain a search history in EndNote for future use or reference.

APPENDIX E1: Literature Search Parameters (January 2006 – July 2010)

Databases Searched:

MEDLINE (PubMed) ACP Journal Club Cochrane Database of Systematic reviews Database of Abstracts of Reviews of Effectiveness (DARE) Cochrane Central Register of Controlled Trials EMBASE Drugs and Pharmacology Web of Science

Natural History of Degenerative Lumbar Spinal Stenosis Search Strategies

Search Strategies by Clinical Question:

- 1. What is the best working definition of spinal stenosis?
- 2. What is the natural history of spinal stenosis?

(("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND (("lumbosacral region" [MeSH Terms] OR ("lumbosacral" [All Fields] AND "region" [All Fields]) OR "lumbosacral region" [All Fields] OR "lumbar" [All Fields]) OR lumbosacral [All Fields] OR "lumbar vertebrae" [MeSH]) AND ("humans" [MeSH Terms] AND English [lang] AND ("2006" [PDAT] : "3000" [PDAT]))) AND (("natural history" [MeSH Terms] OR ("natural" [All Fields] AND "history" [All Fields]) OR "natural history" [All Fields]) OR (natural Fields] OR conservative [All Fields]) OR (nonsurgical [All Fields]) OR nonsurgical/injectable [All Fields] OR nonsurgical/nonphyperbaric [All Fields] OR nonsurgical/nonpharmaceutical [All Fields]] OR nonsurgical/nonterminal [All Fields] OR nonsurgical [All Fields]] OR nonsurgical [All Fields]] OR nonsurgical [All Fields]] OR nonsurgical [All Fields]] OR non surgical [All Fields]] OR nonoperative [All Fields]]

Databases Searched:

- MEDLINE (PubMed)
- ACP Journal Club
- Cochrane Database of Systematic reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Cochrane Central Register of Controlled Trials
- EMBASE Drugs and Pharmacology
- Web of Science

Diagnosis/Imaging of Degenerative Lumbar Spinal Stenosis Search Strategies

Search Strategies by Clinical Question:

1. What are the most appropriate historical and physical findings consistent with the diagnosis of degenerative lumbar spinal stenosis?

(("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND (("lumbosacral region" [Mesh Terms] OR ("lumbosacral" [All Fields] AND "region" [All Fields]) OR "lumbosacral region" [All Fields] OR "lumbar" [All Fields]) OR lumbosacral[All Fields] OR "lumbar vertebrae" [MeSH]) AND (English [lang] AND ("2006" [PDAT] : "3000" [PDAT]))) AND ("Diagnosis" [MeSH:noexp] OR "Diagnosis, Differential" [MeSH] OR "Diagnostic Imaging" [MeSH] OR "Diagnostic Techniques, Neurological" [MeSH] OR "Physical Examination" [MeSH] OR "Myography" [MeSH] OR "Disability Evaluation [MeSH] OR "Medical History Taking" [MeSH] OR "diagnosis" [Subheading] OR (diagnos[title] OR diagnos's [title] OR diagnosa [title] OR diagnosability[title] OR diagnosable[title] OR diagnoscitur[title] OR diagnose[title] OR diagnose'[title] OR diagnosed[title] OR diagnosed'[title] OR diagnosenthesaurus[title] OR diagnoser[title] OR diagnoses[title] OR diagnoses/subtype[title] OR diagnoses'[title] OR diagnosi[title] OR diagnosia[title] OR diagnosic[title] OR diagnosics[title] OR diagnosics[title] OR diagnosirs[title] OR diagnosis[title] OR diagnosis/a[title] OR diagnosis/assessment[title] OR diagnosis/detection[title] OR diagnosis/ differential[title] OR diagnosis/entry[title] OR diagnosis/exclusion[title] OR diagnosis/human[title] OR diagnosis/management[title] OR diagnosis/molecular[title] OR diagnosis/normal[title] OR diagnosis/nursing[title] OR diagnosis/oral[title] OR diagnosis/ patient[title] OR diagnosis/physical[title] OR diagnosis/prognosis[title] OR diagnosis/root[title] OR diagnosis/screening[title] OR diagnosis/surgeon's[title] OR diagnosis/taxonomy[title] OR diagnosis/therapy[title] OR diagnosis/thrombolytic[title] OR diagnosis agnosis/treatment[title] OR diagnosis'[title] OR diagnosisal[title] OR diagnosisand[title] OR diagnosisf[title] OR diagnosisf[title] OR diagnosiso[title] OR diagnosisof[title] OR diagnosiss[title] OR diagnosissf[title] OR diagnosisto[title] OR diagnosisto[title] OR diagnositc[title] OR diagnositic[title] OR diagnositics[title] OR diagnositics[title] OR diagnositic] OR diagnoss[title] OR diagnost[title] OR diagnostant[title] OR diagnostc[title] OR diagnosted[title] OR diagnostest[title] OR diagnostial[title] OR diagnostic[title] OR diagnostic/antigenic[title] OR diagnostic/clinical[title] OR diagnostic/genetic[title] OR diagnostic/gps[title] OR diagnostic/interpretive[title] OR diagnostic/interventional[title] OR diagnostic/management[title] OR diagnostic/patient[title] OR diagnostic/prognostic[title] OR diagnostic/rehabilitation[title] OR diagnostic/sociodemographic[title] OR diagnostic/surgical[title] OR diagnostic/syndromic[title] OR diagnostic/therapeutic[title] OR diagnostic/treatment[title] OR diagnostic'[title] OR diagnostics[title] OR diagnostical[title] OR diagnostical[title] OR diagnostical[title] OR diagnostical[title] OR diagnostical[title] OR diagnosticate[title] OR diagnosticates[title] OR diagnosticates[title] OR diagnosticians[title] OR diagnosticians[title] OR diagnosticians[title] OR diagnosticis[title] OR diagnosticis[title] OR diagnosticised[title] O

2. What are the most appropriate diagnostic tests for degenerative lumbar spinal stenosis?

(("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND (("lumbosacral region" [MeSH Terms] OR ("lumbosacral" [All Fields] AND "region" [All Fields]) OR "lumbosacral region" [All Fields] OR "lumbar" [All Fields]) OR lumbosacral[All Fields] OR "lumbar vertebrae" [MeSH]) AND (English [lang] AND ("2006" [PDAT] : "3000" [PDAT]))) AND (("Diagnostic Techniques and Procedures" [MeSH] OR (diagnos[title] OR diagnos's[title] OR diagnosa[title] OR diagnosability[title] OR diagnosable[title] OR diagnoscitur[title] OR diagnose[title] OR diagnosed[title] OR diagnosed[title] OR diagnosed[title] OR diagnosenthesaurus[title] OR diagnoser[title] OR diagnoses[title] OR diagnoses/subtype[title] OR diagnoses'[title] OR diagnoses[title] OR diagnosia[title] OR diagnosic[title] OR diagnosics[title] OR diagnosing[title] OR diagnosirs[title] OR diagnosis[title] OR diagnosis/a[title] OR diagnosis/assessment[title] OR diagnosis/detection[title] OR 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valid/invalid/no[All Fields] OR valid/ reliable[All Fields] OR valid/reliable/responsive[All Fields] OR valid'[All Fields] OR valid'cryptosporidium[All Fields] OR valida[All Fields] OR validable[All Fields] OR validacao[All Fields] OR validacia[All Fields] OR validacia[validacio[All Fields] OR validacion[All Fields] OR validaciones[All Fields] OR validaco[All Fields] OR validacion[All Fields] OR validaciones[All Fiel validadas[All Fields] OR validade[All Fields] OR validados[All Fields] Fields] OR validalasi[All Fields] OR validalt[All Fields] OR validamine[All Fields] OR validamines[All Fields] OR validamycin[All Fields] OR validamycins[All Fields] OR validandi[All Fields] OR validant[All Fields] OR validare[All F validarea[All Fields] OR validaron[All Fields] OR validart[All Fields] OR validas[All Fields] OR validase[All Fields] OR validase[All Fields] OR validate[All Fields] OR valid Fields] OR validata[All Fields] OR validatability[All Fields] OR validatable[All Fields] OR 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Databases Searched:

- MEDLINE (PubMed)
- ACP Journal Club
- Cochrane Database of Systematic reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Cochrane Central Register of Controlled Trials
- EMBASE Drugs and Pharmacology
- Web of Science

Medical/Interventional Treatment of Degenerative Lumbar Spinal Stenosis Search Strategies

Search Strategies by Clinical Question:

1. Do medical/interventional treatments improve outcomes in the management of spinal stenosis compared to the natural history of the disease?

(("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND (("lumbosacral region" [Mesh Terms] OR ("lumbosacral" [All Fields] AND "region" [All Fields]) OR "lumbosacral region" [All Fields] OR "lumbosacral" [All Fields] OR "lumbosacral [All Fields]] OR (nonsurgical [All Fields]] OR nonsurgical [All Fields]] OR non surgical [All Fields]] OR non surgical [All Fields]] OR nonoperative [All Fields]] OR "therapeutics" [Mesh Terms]] OR "therapeutics" [Mesh Terms]] OR "therapeutics" [Mesh Terms]] OR "therapeutics" [All Fields]]) OR "therapeutics" [All Fields]] OR "therapeutics" [All Fields]]) OR interventional [All Fields]]))

2. What is the role of pharmacological treatment in the management of spinal stenosis?

(("Narcotics" [MeSH] OR "Narcotics" [Pharmacological Action] OR "Analgesics" [MeSH] OR "Analgesics" [Pharmacological Action]) OR ("Drug Therapy" [MeSH] OR "drug therapy" [Subheading]) OR "Adrenal Cortex Hormones" [MeSH] OR "Steroids" [MeSH] OR "Anti-Inflammatory Agents, Non-Steroidal" [MeSH] OR "Anti-Inflammatory Agents, Non-Steroidal" [Pharmacological Action]) OR "Anti-Inflammatory Agents" [MeSH] OR "Anti-Inflammatory Agents" [Pharmacological Action] OR "Analgesics, Opioid" [Pharmacological Action] OR "Analgesics, Non-Narcotic" [Pharmacological Action]) AND (("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND ("lumbosacral region" [Mesh] OR lumbosacral [All Fields]) OR lumbosacral [All Fields] OR

"lumbar vertebrae" [MeSH]) AND (English [lang] AND ("2006" [PDAT] : "3000" [PDAT])))

3. What is the role of physical therapy/exercise in the treatment of spinal stenosis?

(("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND (("lumbosacral region" [MeSH Terms] OR ("lumbosacral" [All Fields] AND "region" [All Fields]) OR "lumbosacral region" [All Fields] OR "lumbar" [All Fields]) OR lumbosacral[All Fields] OR "lumbar vertebrae" [MeSH]) AND (English [lang] AND ("2006" [PDAT] : "3000" [PDAT]))) AND ("Physical Therapy Modalities" [MeSH] OR "Exercise Movement Techniques" [MeSH] OR "Exercise" [MeSH] OR "Physical Fitness" [MeSH] OR "Exercise Test" [MeSH] OR treadmill[all fields] OR ("physical therapy modalities" [MeSH Terms] OR ("physical" [All Fields] AND "therapy" [All Fields] AND "modalities" [All Fields]) OR "physical therapy modalities" [All Fields] OR ("physical" [All Fields] AND "therapy"[All Fields]) OR "physical therapy"[All Fields]) OR ("exercise"[MeSH Terms] OR "exercise"[All Fields]))

4. What is the role of manipulation in the treatment of spinal stenosis?

(("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND (("lumbosacral region" [Mesh Terms] OR ("lumbosacral" [All Fields] AND "region" [All Fields]) OR "lumbosacral region" [All Fields] OR "lumbar" [All Fields]) OR lumbosacral[All Fields] OR "lumbar vertebrae" [MeSH]) AND (English [lang] AND ("2006" [PDAT] : "3000" [PDAT]))) AND ("Musculoskeletal Manipulations" [MeSH] OR manipulation [all fields] OR "Chiropractic" [MeSH] OR ("chiropractic" [MeSH] OR "chiropractic" [All Fields]))

5. What is the role of epidural steroid injections in the treatment of lumbar spinal stenosis? (exclude subcutaneous and intramuscular if possible)

(("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND (("lumbosacral region" [MeSH Terms] OR ("lumbosacral" [All Fields] AND "region" [All Fields]) OR "lumbosacral region" [All Fields] OR "lumbar" [All Fields]) OR lumbosacral[All Fields] OR "lumbar vertebrae" [MeSH]) AND (English [lang] AND ("2006" [PDAT] : "3000" [PDAT]))) AND (("Injections" [MeSH] OR injection[title] OR injections[title]) NOT ("Injections, Intramuscular" [MeSH] OR "Injections, Subcutaneous"[MeSH]))

6. What is the role of ancillary treatments such as bracing, traction, electrical stimulation and transcutaneous electrical stimulation (TENS) in the treatment of lumbar spinal stenosis?

(("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND (("lumbosacral region" [MeSH Terms] OR ("lumbosacral" [All Fields] AND "region" [All Fields]) OR "lumbosacral region" [All Fields] OR "lumbar" [All Fields]) OR lumbosacral[All Fields] OR "lumbar vertebrae" [MeSH]) AND (English [lang] AND ("2006" [PDAT]: "3000" [PDAT]))) AND ("Electric Stimulation Therapy" [MeSH] OR "electric stimulation" [MeSH] OR "electrical stimulation" [all fields] OR ("transcutaneous electric nerve stimulation" [MeSH Terms] OR ("transcutaneous" [All Fields] AND "electric" [All Fields] AND "nerve"[All Fields] AND "stimulation"[All Fields]) OR "transcutaneous electric nerve stimulation"[All Fields] OR "tens"[All Fields]) OR "Traction"[MeSH] OR ("traction"[MeSH Terms] OR "traction"[All Fields]) OR "Acupuncture"[MeSH] OR "Acupuncture Therapy"[MeSH] OR ("acupuncture"[MeSH Terms] OR "acupuncture"[All Fields] OR "acupuncture therapy" [MeSH Terms] OR ("acupuncture" [All Fields] AND "therapy" [All Fields]) OR "acupuncture therapy"[All Fields]))

7. What is the long-term result (2+ years) of medical/interventional management of spinal stenosis?

(("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND (("lumbosacral region"[MeSH Terms] OR ("lumbosacral" [All Fields] AND "region" [All Fields]) OR "lumbosacral region" [All Fields] OR "lumbar" [All Fields]) OR lumbosacral [All Fields] OR "lumbar vertebrae" [MeSH]) AND (English [lang] AND ("2006"[PDAT]: "3000"[PDAT]))) AND (("therapy"[Subheading] OR "Therapeutics"[MeSH] OR medical management[all fields] OR "medical treatment" [all fields] OR nonoperative [all fields] OR non-operative [all fields] OR nonsurgical[all fields] OR non-surgical[all fields] OR conservative[all fields]) AND ("Longitudinal Studies" [MeSH] OR long-term[All Fields]))

- MEDLINE (PubMed)
- ACP Journal Club
- Cochrane Database of Systematic reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Cochrane Central Register of Controlled Trials
- **EMBASE** Drugs and Pharmacology
- Web of Science

Surgical Treatment of Degenerative Lumbar Spinal Stenosis Search Strategies

Search Strategies by Clinical Question:

1. Does surgical decompression alone improve surgical outcomes in the treatment of spinal stenosis compared to medical/interventional treatment?

((("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND (("lumbosacral region" [Mesh Terms] OR ("lumbosacral" [All Fields] AND "region" [All Fields]) OR "lumbosacral region" [All Fields] OR "lumbar" [All Fields]) OR lumbosacral [All Fields] OR "lumbar vertebrae" [Mesh]) AND (English [lang] AND ("2006" [PDAT] : "3000" [PDAT]))) AND ("Decompression, Surgical" [Mesh] OR "Laminectomy" [Mesh] OR laminectomy [title] OR decompression [title] OR laminotomy [title] OR foraminotomy [title])) AND ("therapy" [Subheading] OR "Therapeutics" [Mesh] OR medical management [all fields] OR non-operative [all fields] OR non-surgical [all fields] OR non-surgical [all fields] OR conservative [all fields])

2. Does the addition of lumbar fusion, with or without instrumentation, to surgical decompression improve surgical outcomes in the treatment of spinal stenosis compared to treatment by decompression alone?

((("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND (("lumbosacral region" [Mesh Terms] OR ("lumbosacral" [All Fields] AND "region" [All Fields]) OR "lumbosacral region" [All Fields] OR "lumbar" [All Fields]) OR lumbosacral [All Fields] OR "lumbar vertebrae" [Mesh]) AND (English [lang] AND ("2006" [PDAT]: "3000" [PDAT]))) AND ("Decompression, Surgical" [Mesh] OR "Laminectomy" [Mesh] OR laminectomy [title] OR decompression [title] OR laminotomy [title] OR foraminotomy [title])) AND ("arthrodesis" [Mesh] OR "fusion" [title] OR "arthrodesis" [title])

3. What is the long-term result (4+ years) of surgical management of spinal stenosis?

((("Spinal Stenosis" [Mesh] OR "spinal stenosis" [All Fields] OR "canal stenosis" [All Fields]) AND (("lumbosacral region" [Mesh Terms] OR ("lumbosacral" [All Fields] AND "region" [All Fields]) OR "lumbosacral region" [All Fields] OR "lumbar" [All Fields]) OR lumbosacral [All Fields] OR "lumbar vertebrae" [Mesh]) AND (English [lang] AND ("2006" [PDAT] : "3000" [PDAT]))) AND ("Surgical Procedures, Operative" [Mesh] OR "surgery" [Subheading] OR surgical [title] OR surgery [title])) AND ("Longitudinal Studies" [Mesh] OR long-term [All Fields])

- MEDLINE (PubMed)
- ACP Journal Club
- Cochrane Database of Systematic reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Cochrane Central Register of Controlled Trials
- EMBASE Drugs and Pharmacology
- Web of Science

APPENDIX E2: Literature Search Parameters (19966 – April 2006)

Databases Searched:

MEDLINE (PubMed) ACP Journal Club Cochrane Database of Systematic reviews Database of Abstracts of Reviews of Effectiveness (DARE) Cochrane Central Register of Controlled Trials EMBASE Drugs and Pharmacology Web of Science

Natural History of Degenerative Lumbar Spinal Stenosis Search Strategies

Search Strategies by Clinical Question:

1. What is the best working definition of spinal stenosis?

Reviewed three book chapters (see reference section).

2. What is the natural history of spinal stenosis?

Spinal Stenosis - natural hx - broad

("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND (natural history [Text Word]) OR natural course [All Fields] OR nonsurgical [All Fields] OR non-operative [All Fields] OR (conservative [All Fields] AND ("therapy" [Subheading]) OR ("therapeutics" [TIAB] NOT Medline [SB]) OR "therapeutics" [MeSH Terms] OR treatment [Text Word] OR therapy [Text Word])) OR untreated [All Fields]) AND English [lang]

Spinal Stenosis - natural hx - narrow

("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ((natural history [Text Word] OR natural course [Text Word] OR untreated [Text Word]) AND English [lang])

Databases Searched:

- MEDLINE (PubMed)
- ACP Journal Club
- Cochrane Database of Systematic reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Cochrane Central Register of Controlled Trials
- EMBASE Drugs and Pharmacology
- Web of Science

Diagnosis/Imaging of Degenerative Lumbar Spinal Stenosis Search Strategies

Search Strategies by Clinical Question:

1. What are the most reliable historical and physical findings consistent with the diagnosis of spinal stenosis?

Spinal Stenosis - diagnosis - broad

("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Diagnosis" [MeSH:noexp] OR "Diagnosis, Differential" [MeSH] OR "Diagnostic Imaging" [MeSH] OR "Diagnostic Techniques, Neurological" [MeSH] OR "Physical Examination" [MeSH] OR "Myography" [MeSH] OR "Disability Evaluation" [MeSH] OR "Medical History Taking" [MeSH] OR "diagnosis" [Subheading] AND English [lang] AND "humans" [MeSH Terms]

Spinal Stenosis - diagnosis - narrow

"spinal stenosis/diagnosis" [MAJR] AND English [lang] AND "humans" [MeSH Terms]

2. What are the most reliable diagnostic tests for spinal stenosis?

Spinal Stenosis - dx tests - sensitivity and specificity

("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Diagnostic Techniques and Procedures" [MeSH] AND ("Sensitivity and Specificity" [MeSH] OR (accura [text word] OR accuracies [text word] OR accuracte [text word] OR accuracy/text word] OR accuracy/consistency [text word] OR accuracy/cost [text word] OR accuracy/efficacy [text word] OR accuracy/error [text word] OR accuracy/pitfalls [text word] OR accuracy/planning/speed [text word] OR accuracy/precision [text word] OR accuracy/prediction [text word] OR accuracy/prediction

racy/recovery[text word] OR accuracy/reliability[text word] OR accuracy/sensitivity[text word] OR accuracy/speed[text word] OR accuracy/stability[text word] OR accuracy/time[text word] OR accuracy/timeliness[text word] OR accuracy/trueness[text word] OR accuracy/validity[text word] OR accuracy'[text word] OR accuracy's[text word] OR accuracyobtainable[text word] OR accuracyof[text word] OR accuracysuperior[text word] OR accuracyto[text word] OR accuracywise[text word] OR accurad[text word] OR accurage[text word] OR accural[text word] OR accurance[text word] OR accurancy[text word] OR word] OR accurasee[text word] OR accurat[text word] OR accuratam[text word] OR accuratc[text word] OR accurate[text word] OR accurate/adequate[text word] OR accurate/complete[text word] OR accurate/incomplete[text word] OR accurate/ reliable[text word] OR accurate/timely[text word] OR accurate'[text word] OR accurateand[text word] OR accurated[text word] OR accuratedly[text word] OR accurateestimation[text word] OR accurately[text word] OR accurately/consistently[text word] OR accurately/efficiently[text word] OR accurately'[text word] OR accuratelytermed[text word] OR accuratelythan[text word] OR accurateness[text word] OR accurater[text word] OR accurates[text word] OR accuratest[text word] OR accuration[text word] OR accurative[text word] OR accuratized[text word] OR accuratly[text word] OR accuraty[text word] OR accurative[text word] word]) OR (valid[Text word] OR valid/analog[Text word] OR valid/endogenous[Text word] OR valid/invalid[Text word] OR valid'[Text word] OR valida[Text word] OR validable[Text word] OR validacion[Text word] OR validade[Text word] OR validado[Text word] OR validamine[Text word] OR validamines[Text word] OR validamycin[Text word] OR validamycins[Text word] OR validat[Text word] OR validata[Text word] OR validatability[Text word] OR validatable[Text word] OR validate[Text word] OR validate'[Text word] OR validated[Text word] OR validated/discovered[Text word] OR validated/extended[Text word] OR validated/phenotyped[Text word] OR validated'[Text word] OR validatedfurther[Text word] OR validates[Text word] OR validatibility[Text word] OR validatible[Text word] OR validating[Text word] OR validating/determining[Text word] OR validating/ sustaining[Text word] OR validating'[Text word] OR validation[Text word] OR validation/adaptation[Text word] OR validation/ calibration[Text word] OR validation/characterization[Text word] OR validation/evaluation[Text word] OR validation/feedback[Text word] OR validation/process[Text word] OR validation/refinement[Text word] OR validation/revision[Text word] OR validation/ standardisation[Text word] OR validation/testing[Text word] OR validation/verification[Text word] OR validation/vindication[Text word] OR validation'[Text word] OR validation's[Text word] OR validational[Text word] OR validationinebreak[Text word] OR validations[Text word] OR validative[Text word] OR validatol[Text word] OR validator[Text word] OR validator's[Text word] OR validators[Text word] OR validatory[Text word] OR validaty[Text word] OR validazione[Text word] OR valide[Text word] OR valided[Text word] OR validee[Text word] OR validees[Text word] OR validfor[Text word] OR validiated[Text word] OR validiert[Text word] OR validierung[Text word] OR validierungsversuch[Text word] OR validified[Text word] OR validimax[Text word] OR validipes[Text word] OR validire[Text word] OR validisation[Text word] OR validised[Text word] OR validitate[Text word] OR validitates[Text word] OR validitation[Text word] OR validite[Text word] OR validited[Text word] OR validities[Text word] OR validiting[Text word] OR validition[Text word] OR validity[Text word] OR validity[Text word] OR validity accuracy[Text word] OR validity/applicability[Text word] OR validity/credibility[Text word] OR validity/effective[Text word] OR validity/invalidity[Text word] OR validity/no[Text word] OR validity/quality[Text word] OR validity/reliability[Text word] OR validity/representativity[Text word] OR validity/screening[Text word] OR validity/test[Text word] OR validity/utility[Text word] OR validity'[Text word] OR validity's[Text word] OR validityof[Text word] OR validiy[Text word] OR validization[Text word] OR validly[Text word] OR validness[Text word] OR validol[Text word] OR validone[Text word] OR validoxylamine[Text word] OR validoxylamines[Text word] OR validty[Text word] OR validum[Text word] OR validus[Text word] OR validus'[Text word] OR validy[Text word] OR validyne[Text word]) OR (reliab[Text word] OR reliabaly[Text word] OR reliabe[Text word] OR reliabel[Text word] OR reliabilities[Text word] OR reliability[Text word] OR reliabile[Text word] OR reliability[Text word] OR reliabili word] OR reliabilism[Text word] OR reliabilists[Text word] OR reliabilit[Text word] OR reliabilitat[Text word] OR reliabilitats word] OR reliabilities/precisions[Text word] OR reliability[Text word] OR reliability[Text word] OR reliability/agreement[Text word] OR reliability/durability[Text word] OR reliability/generalisability[Text word] OR reliability/internal[Text word] OR reliability/ practicability[Text word] OR reliability/quality[Text word] OR reliability/repeatability[Text word] OR reliability/reproducibility[Text word] OR reliability/responsibility[Text word] OR reliability/sensitivity[Text word] OR reliability/significance[Text word] OR reliability/sensitivity ability/stability[Text word] OR reliability/usefulness[Text word] OR reliability/validity[Text word] OR reliability/value[Text word] OR reliability'[Text word] OR reliabilty[Text OR reliablty[Text word] OR reliable[Text word word] OR reliable'[Text word] OR reliablefor[Text word] OR reliables[Text word] OR reliablitity[Text word] OR reliablity[Text word] OR reliablity'[Text word] OR reliably[Text word] OR reliably[Text word])) AND English[lang] AND "humans" [MeSH Terms])

- MEDLINE (PubMed)
- ACP Journal Club
- Cochrane Database of Systematic reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Cochrane Central Register of Controlled Trials
- EMBASE Drugs and Pharmacology
- Web of Science

Medical/Interventional Treatment of Degenerative Lumbar Spinal Stenosis Search Strategies

Search Strategies by Clinical Question:

1. What are the appropriate outcome measures for the medical/interventional treatment of spinal stenosis?

(("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("therapy" [Subheading] OR "Therapeutics" [MeSH] OR medical management [Text word] OR non-operative [Text word] OR nonsurgical [text word] OR conservative [text word]) AND ("Outcome Assessment (Health Care)" [MeSH] OR "Treatment Outcome" [MeSH] OR treatment outcome [text word] OR outcome measures [text word]) AND English [lang]) NOT (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("therapy" [Subheading] OR "Therapeutics" [MeSH] OR medical management [Text word] OR non-operative [Text word] OR nonsurgical [text word] OR conservative [text word]) AND ("Outcome Assessment (Health Care)" [MeSH] OR "Treatment Outcome" [MeSH] OR treatment outcome [text word] OR outcome measures [text word]) AND Case Reports [ptyp] AND English [lang])

2. Do medical, noninvasive treatments improve outcomes in the treatment of spinal stenosis compared to the natural history of the disease?

(("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND (natural history [Text Word] OR natural course [All Fields] OR nonsurgical [All Fields] OR non-operative [All Fields] OR (conservative [All Fields] AND ("therapy" [Subheading] OR ("therapeutics" [TIAB] NOT Medline [SB]) OR "therapeutics" [MeSH Terms] OR treatment [Text Word] OR therapy [Text Word])) OR untreated [All Fields]) AND English [lang]) NOT (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND (natural history [Text Word] OR natural course [All Fields] OR nonsurgical [All Fields] OR non-operative [All Fields] OR (conservative [All Fields] AND ("therapy" [Subheading] OR ("therapeutics" [TIAB] NOT Medline [SB]) OR "therapeutics" [MeSH Terms] OR treatment [Text Word] OR therapy [Text Word])) OR untreated [All Fields] AND Case Reports [ptyp])

3. What is the role of pharmacological treatment in the management of spinal stenosis?

((("Narcotics" [MeSH] OR "Narcotics" [Pharmacological Action] OR "Analgesics, Non-Narcotic" [MeSH]) OR ("Drug Therapy" [MeSH] OR "drug therapy" [Subheading]) OR "Adrenal Cortex Hormones" [MeSH] OR "Steroids" [MeSH] OR ("Anti-Inflammatory Agents, Non-Steroidal" [MeSH] OR "Anti-Inflammatory Agents, Non-Steroidal" [Pharmacological Action]) OR "Anti-Inflammatory Agents" [MeSH]) AND ("Spinal Stenosis" [MeSH]) OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word]) OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields]) OR spinal canal stenosis [All Fields]) AND English [lang]) NOT ((("Narcotics" [MeSH]) OR "Narcotics" [Pharmacological Action] OR "Analgesics, Non-Narcotic" [MeSH]) OR ("Drug Therapy" [MeSH]) OR "drug therapy" [Subheading]) OR "Adrenal Cortex Hormones" [MeSH] OR "Steroids" [MeSH] OR ("Anti-Inflammatory Agents, Non-Steroidal" [MeSH]) OR "Anti-Inflammatory Agents, Non-Steroidal" [Pharmacological Action]) OR "Anti-Inflammatory Agents" [MeSH]) AND ("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("Spinal Stenosis" [Text Word]) OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields]) AND Case Reports [ptyp] AND English [lang])

4. What is the role of physical therapy/exercise therapy in the treatment of spinal stenosis?

(("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Physical Therapy Modalities" [MeSH] OR "Exercise Movement Techniques" [MeSH] OR "Exercise" [MeSH] OR "Physical Fitness" [MeSH] OR "Exercise Test" [MeSH] OR treadmill [text word] OR physical therapy [text word] OR exercise [text word]) AND English [lang]) NOT (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Physical Therapy Modalities" [MeSH] OR "Exercise Movement Techniques" [MeSH] OR "Exercise" [MeSH] OR "Physical Fitness" [MeSH] OR "Exercise Test" [MeSH] OR treadmill [text word] OR physical therapy [text word] OR exercise [text word]) AND Case Reports [ptyp] AND English [lang])

5. What is the role of manipulation in the treatment of spinal stenosis?

(("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Musculoskeletal Manipulations" [MeSH] OR manipulation [text word] OR "Chiropractic" [MeSH] OR chiropractic [text word]) AND English [lang]) NOT (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Musculoskeletal Manipulations" [MeSH] OR manipulation [text word] OR "Chiropractic" [MeSH] OR chiropractic [text word]) AND Case Reports [ptyp] AND English [lang])

- 6. What is the role of injections in the treatment of spinal stenosis? (exclude subcutaneous and intramuscular if possible)
 - (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Injections" [MeSH] NOT ("Injections, Intramuscular" [MeSH] OR "Injections, Subcutaneous" [MeSH])) AND English [lang]) NOT (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Injections" [MeSH] NOT ("Injections, Intramuscular" [MeSH] OR "Injections, Subcutaneous" [MeSH])) AND Case Reports [ptyp] AND English [lang])
- 7. What is the role of other modalities such as traction, electrical stimulation and TENS in the treatment of spinal stenosis? (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Electric Stimulation Therapy" [MeSH] OR "electric stimulation" [MeSH Terms] OR electrical stimulation [text word] OR "Traction" [MeSH] OR traction [text word] OR "Acupuncture" [MeSH] OR "Acupuncture Therapy" [MeSH] OR acupuncture [text word]) AND English [lang]) NOT (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Electric Stimulation Therapy" [MeSH] OR "electric stimulation" [MeSH Terms] OR electrical stimulation [text word] OR "Enst word] OR "Traction" [MeSH] OR traction [text word] OR "Acupuncture" [MeSH] OR "Acupuncture Therapy" [MeSH] OR acupuncture [text word]) AND Case Reports [ptyp] AND English [lang])
- 8. What is the long-term result (10+ years) of medical/interventional management of spinal stenosis?

((("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("therapy" [Subheading] OR "Therapeutics" [MeSH] OR medical management [Text word] OR non-operative [Text word] OR nonsurgical [text word] OR conservative [text word]) AND ("Outcome Assessment (Health Care)" [MeSH] OR "Treatment Outcome" [MeSH] OR treatment outcome [text word] OR outcome measures [text word]) AND English [lang]) AND ("Longitudinal Studies" [MeSH] OR long-term [All Fields]) AND English [lang]) NOT ((("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("therapy" [Subheading] OR "Therapeutics" [MeSH] OR medical management [Text word] OR non-operative [Text word] OR nonsurgical [text word] OR conservative [text word]) AND ("Outcome Assessment (Health Care)" [MeSH] OR "Treatment Outcome" [MeSH] OR treatment outcome [text word] OR outcome measures [text word]) AND English [lang]) AND ("Longitudinal Studies" [MeSH] OR long-term [All Fields]) AND Case Reports [ptyp] AND English [lang])

- MEDLINE (PubMed)
- ACP Journal Club
- Cochrane Database of Systematic reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Cochrane Central Register of Controlled Trials
- EMBASE Drugs and Pharmacology
- Web of Science

Surgical Treatment of Degenerative Lumbar Spinal Stenosis Search Strategies

General search on surgical management:

Spinal Stenosis - surgical mgt. - all

((("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang]) NOT (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "animals" [MeSH Terms:noexp])) OR ((("Spinal Stenosis" [MeSH] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "animals" [MeSH Terms:noexp]) AND (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "humans" [MeSH Terms])) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "humans" [MeSH Terms]))

Search Strategies by Clinical Question:

1. What are the appropriate outcome measures for the surgical treatment of spinal stenosis?

(((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery"[Subheading]) AND English[lang]) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis[TextWord])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "animals" [MeSH Terms:noexp])) OR ((("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "animals" [MeSH Terms:noexp]) AND (("Spinal Stenosis" [MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "humans" [MeSH Terms]))) AND ("Outcome Assessment (Health Care)" [MeSH] OR "Treatment Outcome" [MeSH] OR treatment outcome[text word] OR outcome measures[text word])

2. Do surgical treatments improve outcomes in the treatment of spinal stenosis compared to the natural history of the disease?

(((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery"[Subheading]) AND English[lang]) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis[TextWord])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "animals" [MeSH Terms: noexp])) OR ((("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "animals" [MeSH Terms:noexp]) AND (("Spinal Stenosis" [MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "humans" [MeSH Terms]))) AND ((natural history [Text Word] OR natural course [All Fields] OR nonsurgical [All Fields] OR non-operative[All Fields] OR (conservative[All Fields] AND ("therapy"[Subheading] OR ("therapeutics"[TIAB] NOT Medline[SB]) OR "therapeutics" [MeSHTerms] OR treatment [TextWord] OR therapy [TextWord])) OR untreated [All Fields]) AND English [lang]) AND English[lang]

3. What is the role of decompression in the treatment of spinal stenosis?

(("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("patho-

logic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Decompression, Surgical" [MeSH] OR "Laminectomy" [MeSH])) NOT (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND ("Decompression, Surgical" [MeSH] OR "Laminectomy" [MeSH]) AND "animals" [MeSH Terms:noexp])

- 4. Does surgical decompression alone improve surgical outcomes in the treatment of spinal stenosis compared to medical/interventional treatment alone or the natural history of the disease?
 - ((natural history[Text Word] OR natural course[All Fields] OR nonsurgical[All Fields] OR non-operative[All Fields] OR (conservative[All Fields] OR ("therapy"[Subheading] OR ("therapeutics"[TIAB] NOT Medline[SB]) OR "therapeutics"[MeSH Terms] OR treatment[Text Word] OR therapy[Text Word])) OR untreated[All Fields]) AND English[lang]) AND ((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Decompression, Surgical"[MeSH] OR "Laminectomy"[MeSH])) NOT (("Spinal Stenosis"[MeSH] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Decompression, Surgical"[MeSH] OR "Laminectomy"[MeSH]) AND "animals"[MeSH Terms:noexp]))
- 5. Does the addition of lumbar fusion, with or without instrumentation, to surgical decompression improve surgical outcomes in the treatment of spinal stenosis compared to treatment by decompression alone?
 - ("Decompression, Surgical" [MeSH] OR "Laminectomy" [MeSH]) AND "Arthrodesis" [MeSH] AND ("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis [All Fields] OR spinal canal stenosis [All Fields]) AND English [lang] AND "humans" [MeSH Terms]
- 6. What is the long-term result (10+ years) of surgical management of spinal stenosis?

Spinal Stenosis - surg mgt. and long-term (broader search)

("Longitudinal Studies" [MeSH] OR long-term [All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND ("Spinal Stenosis" [MeSH] OR spinal stenosis [TextWord] OR ((lateral recess [All Fields]) OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word]) OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR spinal stenosis [All Fields] OR spinal stenosis [All Fields]) AND English [lang] AND "humans" [MeSH Terms]

Spinal Stenosis - surg mgt. and outcomes - long-term (narrow search)

("Longitudinal Studies" [MeSH] OR long-term[All Fields]) AND (((("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang]) NOT (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess [All Fields] OR foraminal [All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis [All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "animals" [MeSH Terms:noexp])) OR ((("Spinal Stenosis" [MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "animals" [MeSH Terms:noexp]) AND (("Spinal Stenosis" [MeSH] OR spinal stenosis [Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction" [Text Word] OR "constriction, pathologic" [MeSH Terms] OR stenosis [Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative" [MeSH] OR "surgery" [Subheading]) AND English [lang] AND "humans" [MeSH Terms]))) AND ("Outcome Assessment (Health Care)"[MeSH] OR "Treatment Outcome" [MeSH] OR treatment outcome [text word] OR outcome measures[text word]))

- MEDLINE (PubMed)
- ACP Journal Club
- Cochrane Database of Systematic reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Cochrane Central Register of Controlled Trials
- EMBASE Drugs and Pharmacology
- Web of Science

VI. Degenerative Lumbar Spinal Stenosis Guideline References

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