



# North American Spine Society



Evidence-Based Clinical Guidelines  
for Multidisciplinary Spine Care



**Clinical Guidelines for Diagnosis  
and Treatment of Lumbar Disc  
Herniation with Radiculopathy**

Evidence-Based Clinical Guidelines for Multidisciplinary  
Spine Care

# Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy



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### 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 Lumbar Disc Herniation with Radiculopathy

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# Table of Contents

I.	Introduction . . . . .	5
II.	Guideline Development Methodology . . . . .	6
III.	Natural History of Lumbar Disc Herniation with Radiculopathy. . . . .	9
IV.	Recommendations for Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy	
A.	Diagnosis/Imaging . . . . .	12
B.	Outcome Measures for Treatment . . . . .	25
C.	Medical/Interventional Treatment . . . . .	26
D.	Surgical Treatment . . . . .	57
E.	Value of Spine Care . . . . .	80
V.	Appendices	
A.	Acronyms. . . . .	82
B.	Levels of Evidence for Primary Research Questions . . . . .	83
C.	Grades of Recommendations for Summaries or Reviews of Studies. . . . .	84
D.	Linking Levels of Evidence to Grades of Recommendation . . . . .	85
E.	NASS Literature Search Protocol . . . . .	86
VI.	References . . . . .	87

A technical report, including the literature search parameters and evidentiary tables developed by the authors, can be accessed at [http://www.spine.org/Documents/LDH\\_Guideline\\_Technical\\_Report.pdf](http://www.spine.org/Documents/LDH_Guideline_Technical_Report.pdf)

# I. Introduction

## Objective

The objective of the North American Spine Society (NASS) *Clinical Guideline for the Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy* is to provide evidence-based recommendations to address key clinical questions surrounding the diagnosis and treatment of lumbar disc herniation with radiculopathy. The guideline is intended to reflect contemporary treatment concepts for symptomatic lumbar disc herniation with radiculopathy as reflected in the highest quality clinical literature available on this subject as of July 2011. 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 lumbar disc herniation with radiculopathy. The goal is to provide a tool that assists practitioners in improving the quality and efficiency of care delivered to these patients. The NASS *Clinical Guideline for the Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy* provides a definition and explanation of the natural history, outlines a reasonable evaluation of

patients suspected to have lumbar disc herniation with radiculopathy and outlines treatment options for adult patients with this diagnosis.

**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. 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 leg pain, numbness or weakness in a dermatomal or myotomal distribution as a result of a primary lumbar disc herniation.

## 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 A*) and grades of recommendation (*Appendix B*) 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 indicate 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 recommendations. Recommendations are then graded based upon the level of evidence. To better understand how levels of evidence inform the grades of recommendation and the standard nomenclature used within the recommendations see *Appendix C*.

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 intervention "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 intervention. 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 shortcomings in the execution of the study would be used to downgrade the levels of evidence for the study's conclusions. 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

*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.*

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

### Consensus Development Process

Voting on guideline recommendations was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 (“extremely inappropriate”) to 9 (“extremely appropriate”). Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8 or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved af-



ter these rounds, no recommendation was adopted.

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

#### **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: Review and Revision Process**

The guideline recommendations will be reviewed every three years by an EBM-trained multidisciplinary 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.

#### **Nomenclature for Medical/Interventional Treatment**

Throughout the guideline, readers will see that what has traditionally been referred to as “nonoperative,” “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 Lumbar Disc Herniation with Radiculopathy

**What is the best working definition of lumbar disc herniation with radiculopathy?**

**Localized displacement of disc material beyond the normal margins of the intervertebral disc space<sup>1</sup> resulting in pain, weakness or numbness in a myotomal or dermatomal distribution.**

### Work Group Consensus Statement

**What is the natural history of lumbar disc herniation with radiculopathy?**

In order to perform a systematic review of the literature regarding the natural history of patients with lumbar disc herniation with radiculopathy, the above definition of lumbar disc herniation 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 that this is an anatomic definition, which 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 disc material outside of the normal margins of the intervertebral disc space. 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 disc herniation was examined for its utility as a prognostic factor. The central question asked was: “What happens to patients with lumbar disc herniation with radiculopathy who do not receive treatment?”

To address the natural history of lumbar disc herniation with radiculopathy, the work group performed a comprehensive literature search and analysis. The group reviewed 65 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 1966 and March 2011.

To meet the work group’s definition of “natural history,” literature evaluated could include no treatment with the exception of analgesic medications. All identified studies failed to meet the guideline’s inclusion criteria because they did not adequately present data about the natural history of lumbar disc herniation with radiculopathy. 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 stud-

ies but are, in fact, reports of the results of one or more medical/interventional treatment measures.

Because of the limitations of the available literature, the work group was unable to definitively answer the question posed related to the natural history of lumbar disc herniation with radiculopathy. In lieu of an evidence-based answer, the work group reached consensus on the following statements addressing natural history.

**In the absence of reliable evidence relating to the natural history of lumbar disc herniation with radiculopathy, it is the work group’s opinion that the majority of patients will improve independent of treatment. Disc herniations will often shrink/regress over time. Many, but not all, papers have demonstrated a clinical improvement with decreased size of disc herniations.**

### Work Group Consensus Statement

#### Definition and Natural History References

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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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# IV. Recommendations for Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy

## 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 the accuracy and the effect of testing on the 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.<sup>1</sup> 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.<sup>1</sup> 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 imaging/testing or offered surgery. For this reason, in our systematic review, we have attempted to identify those symptoms or findings which have a high likelihood ratio for lumbar disc herniation with radiculopathy — those symptoms or findings expected in patients diagnosed with lumbar disc herniation with radiculopathy but not in those who do not have the condition. The use of these criteria should increase the prevalence of this disease confirmed by cross-sectional imaging<sup>1</sup> or surgery.

Cross-sectional imaging exams have a low intrinsic specificity as evidenced by a significant incidence of pathologic findings in asymptomatic populations.<sup>2,3</sup> 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 radicular symptoms.

The gold standard in the majority of the studies confirming the presence of a herniated disc was cross-sectional imaging and/or surgery. The gold standard in the diagnosis of lumbar disc herniation is surgery; however, when assessing the validity of subjective complaints or physical examination findings, use of cross-sectional imaging as a gold standard may be considered an acceptable substitute. The validity of surgery as a gold standard can be questioned, however, as findings at surgery can be subjective.

### Future Directions for Research

Additional sufficiently-powered observational studies of history/physical examination findings and diagnostic tests are needed to determine their value in influencing treatment assignment and outcome in patients with lumbar disc herniation with radiculopathy.

### Assessing Evidence for Diagnostic Tests References

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## What history and physical examination findings are consistent with the diagnosis of lumbar disc herniation with radiculopathy?

**Manual muscle testing, sensory testing, supine straight leg raise, Lasegue's sign and crossed Lasegue's sign are recommended for use in diagnosing lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: A**

Jensen et al<sup>1</sup> reported a prospective case series calculating the positive predictive value and negative predictive value of sensory and motor abnormalities as signs of the level of a lower lumbar disc herniation. All 52 consecutive patients included in the study had a disc herniation diagnosed by myelogram and confirmed at surgery. Sensory abnormalities were found in 54% of patients with a herniated disc. The positive predictive value (PPV) of sensory disturbances in the L5 dermatome as a sign of a L4-5 disc herniation was 76% and the negative predictive value (NPV) was 55%. The PPV of sensory disturbance in the S1 dermatome as a sign of a L5-S1 disc herniation was 50% and the NPV was 62%. Motor weakness was found in 54% of patients. The PPV of paresis of dorsiflexion of the foot as a sign on herniated disc at L4-5 was 69% and the NPV was 47%. The PPV of paresis of the four lateral toes as a sign of L4-5 herniated disc was calculated to be 76% and the NPV to be 51%. The authors concluded that pin prick sensibility, especially in the foot, and muscular strength of dorsiflexion of the foot and extension of the lateral four toes should be tested in patients with a suspected lumbar nerve compression syndrome. If a lower herniated nucleus pulposus is suspected, hypalgesia in the L5 dermatome and paresis of the above mentioned muscle synergies offer rather specific clues as to the level of the herniation, but these signs are unfortunately not very sensitive. This study provides Level I diagnostic evidence that sensory and motor testing of a patient with a suspected lumbar disc herniation and sciatica can provide specific clues to the level of disc herniation, but are not very sensitive in determining the exact level.

Kortelainen et al<sup>2</sup> described findings from a prospective case series evaluating the reliability of the clinical diagnosis of level of ruptured disc and the utility of lumbar myelography for gaining further information. Of the 403 patients included, all had lumbar disc herniation diagnosed by myelogram and confirmed at surgery. For L5, pain projection was 79% reliable; the reliability rose to 86% with extensor hallucis longus (EHL) weakness. S1 pain was 56% reliable; a dropped Achilles reflex raised reliability to 80%; and the addition of a sensory deficit raised the probability to 86%. Myelography was accurate in 90.8% with a

3.7% false positive rate and a 5.5% false negative rate. The authors concluded that the cough impulse test was positive in 74% of patients with a disc herniation. Lasegue's sign was positive in 94% of patients with a disc herniation. However, these findings are non-specific. A positive straight leg raise occurred less frequently with high level lumbar disc herniations and was more commonly positive under 30 degrees for lower herniations. Projected pain could be localized according to the distribution of the lumbosacral roots in 93% of cases. Pain projection was the most important symptom localizing the level, particularly in the area of the fifth lumbar root. Part of the sensory disturbance, as well as the pain projection, from the L4-5 disc is distributed to the first sacral area. The Achilles reflex was of value in the diagnosis of L5-S1 disc ruptures when associated with pain projection and sensory deficit in the first sacral root. The patellar reflex had no value in the diagnosis of low lumbar lesions. EHL weakness was due to L4-5 rupture in 70% of cases and was a strong sign of L4-5 rupture even if first sacral root projection was present. This study provides Level I diagnostic evidence that physical examination, including subjective and objective findings such as positive straight leg raise, sensory testing and myotomal weakness, in a patient with a suspected lumbar disc herniation and sciatica can provide specific clues to the level of disc herniation.

Poiraudeau et al<sup>3</sup> described a prospective case series including 78 consecutive patients, of which 43 had MRI, CT or myelogram confirmation of lumbar disc herniation, evaluating the reliability, sensitivity, specificity, positive predictive value and negative predictive value for the diagnosis of sciatica associated with disc herniation of the bell test and hyperextension test. Lasegue's sign had the best sensitivity (0.77-0.83), while the crossed leg test had the best specificity (0.74-0.89). Overall, the positive predictive value for all four signs were fair (0.55-0.69) and the negative predictive values were weak to fair (0.45-0.63). The authors concluded that the clinical values of the Bell test and hyperextension test are of interest and at least similar to those of Lasegue's and Crossed Lasegue's signs. The combination of hyperextension with Crossed Lasegue's has excellent specificity and a good positive predictive value for the diagnosis of sciatica associated with disc herniation. Thus, the Bell test and hyperextension test could be performed systematically in standardized physical examination of sciatica. This study provides Level I diagnostic evidence that all four diagnostic tests (hyperextension, Bell, Lasegue's and Crossed Lasegue's) are useful in diagnosing lumbar disc herniation with radiculopathy.

Rabin et al<sup>4</sup> reported a prospective case series of 57 consecutive patients with MRI confirmed lumbar disc herniation, comparing the sensitivity of two methods of performing the straight-

leg raise (SLR) test, one in the supine position and the other in the seated position, in patients presenting with signs and symptoms consistent with lumbar radiculopathy. The sensitivity (95% CI) of the supine SLR test in reproducing the patient's radicular pain in light of an MRI scan indicating the presence of nerve root compression was 0.67 (95% CI, 0.53-0.79). The sensitivity (95% CI) of the seated SLR test was at 0.41 (95% CI, 0.29-0.55). This represented a statistically significant difference with a p value of 0.003. The authors concluded that the traditional SLR test performed in a supine position is more sensitive in reproducing leg pain than the seated SLR test in patients presenting with signs and symptoms consistent with lumbar radiculopathy with MRI evidence of nerve root compression. This study provides Level I diagnostic evidence that the supine SLR is moderately sensitive in diagnosing lumbar disc herniation with radiculopathy. The supine SLR is more sensitive than the seated SLR in diagnosing lumbar disc herniation with radiculopathy.

Vucetic et al<sup>5</sup> reported a prospective case series of 163 consecutive patients with surgically confirmed lumbar disc herniation investigating if the physical signs could predict the degree of lumbar disc herniation. Lumbar range of motion and Crossed Lasegue testing were helpful in predicting 71% of ruptured annulus and 80% of intact annulus. The authors concluded that lumbar range of motion and Crossed Lasegue sign were the only significant physical examination findings, which predict the degree of herniation. This study provides Level I diagnostic evidence that Crossed Lasegue testing and lumbar range of motion in the sagittal plane may be helpful in predicting the type of disc herniation.

**The supine straight leg raise, as compared with the seated straight leg raise, is suggested for use in diagnosing lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: B**

Summers et al<sup>6</sup> described a prospective case series of 67 consecutive patients with MRI confirmed lumbar disc herniation testing the construct validity of the Flip Test against the passive supine straight leg raise (SLR) in patients with classic clinical signs of sciatica. The kappa was calculated taking different cut-off points, and maximum agreement occurred at 48°/49° SLR (Kappa 0.771; 95% CI, 0.611 - 0.932). The authors concluded that the Flip Test remains a useful check of nerve root tension but only for patients with supine SLRs below 45°. The most reliable response was not a flip but the demonstration of pain on extension of the knee. The authors recommend the term "sitting SLR test," as a more accurate and less misleading name. This study provides Level I diagnostic evidence that sitting and supine straight leg raising tests have discrepancy. Flip Test (Sitting SLR) is positive when supine straight leg raising test is positive at less than 45 degrees.

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**There is insufficient evidence to make a recommendation for or against the use of the cough impulse test, Bell test, hyperextension test, femoral nerve stretch test, slump test, lumbar range of motion or absence of reflexes in diagnosing lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: I (Insufficient Evidence)**

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localized according to the distribution of the lumbosacral roots in 93% of cases. Pain projection was the most important symptom localizing the level, particularly in the area of the fifth lumbar root. Part of the sensory disturbance, as well as the pain projection, from the L4-5 disc is distributed to the first sacral area. The Achilles reflex was of value in the diagnosis of L5-S1 disc ruptures when associated with pain projection and sensory deficit in the first sacral root. The patellar reflex had no value in the diagnosis of low lumbar lesions. EHL weakness was due to L4-5 rupture in 70% of cases and was a strong sign of L4-5 rupture even if first sacral root projection was present. This study provides Level I diagnostic evidence that physical examination, including subjective and objective findings such as positive straight leg raise, sensory testing and myotomal weakness, in a patient with a suspected lumbar disc herniation and sciatica can provide specific clues to the level of disc herniation.

Poiraudeau et al<sup>3</sup> described a prospective case series including 78 consecutive patients, of which 43 had MRI, CT or myelogram diagnosing lumbar disc herniation. The study assessed the reliability, sensitivity, specificity, positive predictive value and negative predictive value for the diagnosis of sciatica associated with disc herniation of the bell test and hyperextension test. Lasegue's sign had the best sensitivity 0.77-0.83, while the crossed leg test had the best specificity (0.74-0.89). Overall, the positive predictive value for all four signs were fair (0.55-0.69) and the negative predictive values were weak to fair (0.45-0.63). The authors concluded that the clinical values of the Bell test and hyperextension test are of interest and at least similar to those of Lasegue's and Crossed Lasegue's signs. The combination of hyperextension with Crossed Lasegue's has excellent specificity and a good positive predictive value for the diagnosis of sciatica associated with disc herniation. Thus, the Bell test and hyperextension test could be performed systematically in standardized physical examination of sciatica. This study provides Level I diagnostic evidence that all four diagnostic tests (hyperextension, Bell, Lasegue's and Crossed Lasegue's) are useful in diagnosing lumbar disc herniation with radiculopathy.

Christodoulides et al<sup>7</sup> published a retrospective case series to determine the diagnostic value of a femoral nerve stretch test combined with a straight leg raise. Of the 200 patients included in the study, 40 had surgical confirmation of a lumbar disc herniation. All 40 patients with positive femoral nerve stretch testing had a disc herniation confirmed by surgical exploration. Two patients with negative myelographic studies were found to have lateral disc herniations at surgery. The authors concluded that in patients with suspected L4/5 disc protrusion, the induction of sciatica during the femoral nerve stretch test is diagnostic of a lesion at this level. This study provides Level III diagnostic evidence that in patients with suspected L4/5 disc protrusion, the induction of sciatica during the femoral nerve stretch test is diagnostic of a lesion at this level.

Majlesi et al<sup>8</sup> conducted a prospective case control study to measure the sensitivity and specificity of the Slump test and compare it with the straight leg raise test in patients with and without lumbar disc herniations. Of the 75 patients included in the study, 38 had MRI-confirmed lumbar disc herniation and 37 had negative imaging for herniation. When all the patients were considered, the sensitivity of the Slump test was 0.84, and

its specificity was 0.83. The sensitivity of the straight leg raise test was 0.52, and its specificity was 0.89. These make the positive predictive values of the Slump and the straight leg raise 0.84 (CI, 0.74-0.90), and 0.83 (CI, 0.67-0.92), respectively. And the negative predictive values were 0.83 (CI, 0.73-0.90) and 0.64 (CI, 0.57-0.69), respectively. The authors concluded that the results of this study show that, although overlooked over the years, due to its sensitivity, the Slump test may be a valuable tool for suggesting a diagnosis of lumbar disc herniation, and could be used extensively. This study provides Level III diagnostic evidence that the Slump test and straight leg raise have similar specificity in the diagnosis of a herniated lumbar disc, but the Slump test is more sensitive.

Albeck et al<sup>9</sup> described a prospective case series including 80 patients with surgically-confirmed lumbar disc herniation verifying the reliability of clinical parameters in the diagnosis of lumbar disc herniation. Using clinical parameters, when a disc was present the level of the disc herniation was predicted accurately in 93%. However, only sciatica was predictive of disc herniation; onset, worker's compensation, scoliosis, segmental spasm, trunk list, "provided" pain, finger-floor distance, straight leg raise, paresis, muscle wasting, impaired reflex and hypesthesia were not reliably predictive of a disc herniation. The authors concluded that in patients with monoradicular sciatica, further clinical parameters do not add to the diagnosis of lumbar disc herniation. This study provides Level III diagnostic evidence that monoradicular sciatica is predictive of a disc herniation affecting the fifth lumbar or first sacral root.

Jonsson et al<sup>10</sup> performed a prospective comparative study to determine the frequency of some of the common symptoms in patients with lumbar nerve-root compression and to evaluate the frequency of neurological disturbances in different groups of patients. Of the 300 consecutive, surgically treated patients in the study, 100 had lumbar disc herniation diagnosed by myelogram, MRI and/or CT. Reduced spinal mobility was very common, being found in 96% of patients with disc herniation. The median duration of preoperative leg pain was two years in stenosis as compared with five months in cases of disc herniation. Of the patients with complete disc herniation, 63% had a straight leg raise of less than 30 degrees. In patients with disc hernia there was a motor deficit of the involved root in 69% and a sensory disturbance in 60%. The authors concluded that the preoperative duration of symptoms was significantly shorter in patients with disc herniation. Pain at rest, at night and on coughing was as common in lateral stenosis as in disc herniation, but regular consumption of analgesics was more common in patients with disc herniation. Positive straight leg raising tests were very common in disc herniation. Sensory disturbances were most common in patients with complete disc herniations. This study provides Level II diagnostic evidence that nerve root tension signs are often positive in patients with a disc herniation.

### Future Directions for Research

Additional sufficiently-powered observational studies of the predictive value of the cough impulse test, Bell test, hyperextension test, femoral nerve stretch test, Slump test, lumbar range of motion, and presence or absence of reflexes are needed to determine their utility in diagnosing lumbar disc herniation with radiculopathy.



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## Diagnosing Lumbar Disc Herniation with Radiculopathy with Imaging

**What are the most appropriate diagnostic tests (including imaging and electrodiagnostics), and when are these tests indicated in the evaluation and treatment of lumbar disc herniation with radiculopathy?**

There is a relative paucity of high quality studies on advanced imaging in patients with lumbar disc herniation. It is the opinion of the work group that in patients with history and physical examination findings consistent with lumbar disc herniation with radiculopathy, MRI be considered as the most appropriate, noninvasive test to confirm the presence of lumbar disc herniation. In patients for whom MRI is either contraindicated or inconclusive, CT or CT myelography are the next most appropriate tests to confirm the presence of lumbar disc herniation.

### Work Group Consensus Statement

**In patients with history and physical examination findings consistent with lumbar disc herniation with radiculopathy, MRI is recommended as an appropriate, noninvasive test to confirm the presence of lumbar disc herniation.**


**Grade of Recommendation: A**

Jackson et al<sup>1</sup> conducted a prospective comparative study assessing the relative accuracies of CT, myelography, CT myelography and MRI in the diagnosis of a herniated nucleus pulposus. Of the 59 consecutive patients included in the study, 52 had surgical confirmation of herniated nucleus pulposus and 7 were controls. MRI was the most accurate test with 76.5% accuracy, CT myelography was 76%, CT was 73.6% and myelography was 71.4%. CT myelography had the lowest false negative rate at 27.2% whereas MRI had the lowest false positive rate at 13.5%. Although the difference was not statistically significant, CT myelography had the greatest sensitivity (72.8%) and MRI had the greatest specificity (86.5%). The authors concluded that MRI compares very favorably with other currently available imaging modalities for diagnosing lumbar disc herniation. This study provides Level I diagnostic evidence that MRI, CT myelography, myelography and CT show equivalent rates in diagnosing lumbar disc herniation in symptomatic patients.

Jannsen et al<sup>2</sup> described a retrospective case series of 60 consecutive patients with surgically confirmed lumbar disc herniation, comparing the accuracy, sensitivity, specificity, cost and safety of MRI, myelography and post-myelographic CT scan in the diagnosis of lumbar disc herniation. MRI accurately predicted operative findings in 98/102 disc levels (96%), while the accuracy of myelography (81%) and post-myelogram CT scan (57%) was significantly less. When myelography and CT scan were combined, the accuracy was 84%. The authors concluded that the results of this study reflect that MRI is a clinically superior diagnostic test in the evaluation of patients with suspected lumbar disc herniation, and that it should be the diagnostic study of choice when available. This study provides Level I diagnostic evidence that MRI provides the most sensitivity and specificity in the diagnosis of lumbar disc herniation when compared to myelography or CT myelography.

Pfirman et al<sup>3</sup> reported a retrospective case series describing a system for grading lumbar nerve root compromise depicted on routine MRI images, to evaluate its reliability and to correlate image-based grades with surgical grades. Of the 80 consecutive surgically treated patients included in the study, 68 had MRI grading for lumbar nerve root compromise consistent with surgical findings. The Spearman correlation coefficient was high between MRI grading and surgical findings ( $r = 0.86$ ,  $p < 0.001$ ). The authors concluded that the MR image-based grading system used in this study enables discrimination between grades of nerve root compromise in the lumbar spine with sufficient reliability for both research and clinical purposes. This

study provides Level I diagnostic evidence that there is a high correlation between MRI interpretation and operative findings of disc herniations.

**In patients with history and physical examination findings consistent with lumbar disc herniation with radiculopathy, CT scan, myelography and/or CT myelography are recommended as appropriate tests to confirm the presence of lumbar disc herniation.** 

**Grade of Recommendation: A**

Jackson et al<sup>1</sup> conducted a prospective comparative study assessing the relative accuracies of CT, myelography, CT myelography and MRI in the diagnosis of a herniated nucleus pulposus. Of the 59 consecutive patients included in the study, 52 had surgical confirmation of herniated nucleus pulposus and 7 were controls. MRI was the most accurate test with 76.5% accuracy, CT myelography was 76%, CT was 73.6% and myelography was 71.4%. CT myelography had the lowest false negative rate at 27.2% whereas MRI had the lowest false positive rate at 13.5%. Although the difference was not statistically significant, CT myelography had the greatest sensitivity (72.8%) and MRI had the greatest specificity (86.5%). The authors concluded that MRI compares very favorably with other currently available imaging modalities for diagnosing lumbar disc herniation. This study provides Level

I diagnostic evidence that MRI, CT myelography, myelography and CT show equivalent rates in diagnosing lumbar disc herniation in symptomatic patients.


Fries et al<sup>4</sup> reported results of a prospective comparative study comparing CT to myelography in the diagnosis of herniated nucleus pulposus in 185 consecutive patients with surgically confirmed lumbar disc herniation. Using CT imaging the true positive rate was 92% to diagnose a disc herniation whereas it was 87% using myelography. The false negative rate was 8% using CT and 13% using myelography. The true negative rate using CT was 78% and 89% with myelography. The false positive rate with CT was 22% and 11% with myelography. The study provides Level I diagnostic evidence that CT and myelography show comparable rates of diagnosis of lumbar disc herniation.

Jannsen et al<sup>2</sup> described a retrospective case series of 60 consecutive patients with surgically confirmed lumbar disc herniation, comparing the accuracy, sensitivity, specificity, cost and safety of MRI, myelography and post-myelographic CT scan in the diagnosis of lumbar disc herniation. MRI accurately predicted operative findings in 98/102 disc levels (96%), while the accuracy of myelography (81%) and post-myelogram CT scan (57%) was significantly less. When myelography and CT scan were combined, the accuracy was 84%. The authors concluded that the results of this study reflect that MRI is a clinically superior diagnostic test in the evaluation of patients with suspected lumbar disc herniation, and that it should be the diagnostic study of choice when available. This study provides Level I diagnostic evidence that MRI provides the most sensitivity and specificity in the diagnosis of lumbar disc herniation when compared to myelography or CT myelography.

## Electrodiagnostics

**Electrodiagnostic studies may have utility in diagnosing nerve root compression though lack the ability to differentiate between lumbar disc herniation and other causes of nerve root compression. When the diagnosis of lumbar disc herniation with radiculopathy is suspected, it is the work group's opinion that cross-sectional imaging be considered the diagnostic test of choice and electrodiagnostic studies should only be used to confirm the presence of comorbid conditions.**

## Work Group Consensus Statement

**Somatosensory evoked potentials are suggested as an adjunct to cross-sectional imaging to confirm the presence of nerve root compression but are not specific to the level of nerve root compression or the diagnosis of lumbar disc herniation with radiculopathy.** 

**Grade of Recommendation: B**

Pape et al<sup>5</sup> reported a retrospective case series including 65 consecutive patients with myelogram or CT/myelogram confirmed lumbar disc herniation to study the validity of sensory nerve somatosensory evoked potentials (SEP) to diagnose L4, L5, and S1 sensory radiculopathy in sciatica and to examine whether SEP-diagnosed nerve root compromise is associated with the type of radiologically diagnosed degeneration of the lumbar spine, the presence of sensory sciatic symptoms during registration, the spinal level, the number of nerve root lesions, previous sciatic episodes, and the duration of the present episode. The true-

positive rate was higher in patients with facet joint hypertrophy with or without additional disc disease than in patients with disc pathology only, and highest if the sciatic sensory symptoms were present during the SEP registration. The authors concluded that SEP can be used as an additional diagnostic procedure to imaging studies if the latter do not fully clarify whether or not there is nerve root compromise. This study provides Level I diagnostic evidence that SEP has strong validity in patients with nerve root compression but has low specificity in the diagnosis of lumbar disc herniation.

Beyaz et al<sup>6</sup> conducted a prospective case-control study to determine whether sensory evoked potentials (SEPs) make a contribution beyond that of conventional methods, to compare lumbar recordings to cortical ones, and to compare following sensory nerve stimulated SEPs to following mixed nerve stimulated ones in the diagnosis of lumbar disc herniation. Of the 38 patients included in the study, there were 18 controls. Sensitivities were 50% for EMG, 39% for lumbar-recorded sural SEP, 33% for scalp recorded sural SEP, 28% for H reflex, 22% for lumbar recorded post tibial, 17% for scalp post tibial and 6% for F wave. Specificities were 100% for EMG, late response and scalp-recorded posterior tibial SEP; and 50% for lumbar-recorded sural SEP. The authors concluded that SEPs may provide diagnostic information beyond conventional electrodiagnostic methods and that lumbar-recorded SEPs may have an advantage over scalp-recorded SEPs, and sensory nerve stimulated SEPs over mixed nerve stimulated SEPs. This study provides Level III diagnostic evidence that SEPs may provide diagnostic information beyond conventional electrodiagnostic studies. Electromyography, nerve conduction studies and F-waves are of limited utility. H-reflexes have a relatively high sensitivity and specificity in the diagnosis of S1 radiculopathy.

Dumitru et al<sup>7</sup> described a retrospective case-control study evaluating the diagnostic utility of both dermatomal and segmental somatosensory evoked potentials (SEPs) with respect to unilateral/unilevel L5 or S1 nerve root compromise. The 20 patients included in the study had CT/MRI imaging to confirm disc herniation. The specificity for both segmental and dermatomal evaluations were found to be equal to or greater than 93%, with most values approaching 98%. Unfortunately, the sensitivities for these same techniques were considerably less. The superficial peroneal nerve segmental study proposed for assessing L5 radicular insults demonstrated the best sensitivity with values at 70% and 60%, respective confidence intervals of 90% and 95%. Dermatomal responses for the fifth lumbar root evaluating these same L5 radiculopathies revealed sensitivities of 50% for both with 90% and 95% confidence interval levels. The SEP evaluations of S1 radicular insults for sural nerve and S1 dermatomal responses demonstrated respective sensitivities of 30% and 20% for both studies at 90% confidence intervals, while the respective 95% confidence interval values were 30% and 10%. The authors concluded that the clinical utility of both segmental and dermatomal SEPs are questionable in patients with known unilateral/unilevel L5 and S1 nerve root compromise. This study provides Level III diagnostic evidence that SEPs are specific for the diagnosis of lumbar radiculopathy when compared to asymptomatic controls, though are less reliable in determining the exact level of involvement.

**Electromyography, nerve conduction studies and F-waves are suggested to have limited utility in the diagnosis of lumbar disc herniation with radiculopathy. H-reflexes can be helpful in the diagnosis of an S1 radiculopathy, though are not specific to the diagnosis of lumbar disc herniation.**

**Grade of Recommendation: B**

Albeck et al<sup>8</sup> reported a case series of 25 consecutive patients in order to assess the diagnostic value of electrophysiological tests in patients with sciatica. Of these 25 patients, 20 had surgical confirmation of lumbar disc herniation. A high predictive value was found for the H reflex examination, but low for the other modalities. The authors concluded that the diagnostic value of electrophysiological tests in patients with sciatica is limited. Due to the small sample size, this potential Level I study provides Level II diagnostic evidence that electrodiagnostic testing (electromyography, nerve conduction studies, F-waves, somatosensory evoked potentials) has limited diagnostic value in patients with lumbar disc herniation with radiculopathy, though H-reflex has a high positive predictive value for S1 radiculopathy.

Tullberg et al<sup>9</sup> described a prospective case series of 20 consecutive patients with surgically confirmed lumbar disc herniation to determine the accuracy and value of EMGs to assist with diagnosing and directing treatment, and evaluating patients postoperatively. Of the patients included in the study 65% had some abnormal electrophysiologic findings, but only 25% correlated with CT localization. The authors concluded that EMG is not useful to diagnose the exact location of a herniated lumbar disc but may be useful when diagnostic studies and clinical findings disagree. Due to the small sample size, this potential Level I study provides Level II evidence that electromyography has limited utility in the diagnosis of lumbar disc herniation with radiculopathy.

Beyaz et al<sup>6</sup> conducted a prospective case control study to determine whether sensory evoked potentials (SEPs) make a contribution far beyond that of conventional methods, to compare lumbar recordings to cortical ones, and to compare following sensory nerve stimulated SEPs to following mixed nerve stimulated ones in the diagnosis of lumbar disc herniation. Of the 38 patients included in the study, there were 18 controls. Sensitivities were 50% for EMG, 39% for lumbar-recorded sural SEP, 33% for scalp recorded sural SEP, 28% for H reflex, 22% for lumbar recorded post tibial, 17% for scalp post tibial and 6% for F wave. Specificities were 100% for EMG, late response and scalp-recorded posterior tibial SEP; and 50% for lumbar-recorded sural SEP. The authors concluded that SEPs may provide diagnostic information beyond conventional electrodiagnostic methods and that lumbar-recorded SEPs may have an advantage over scalp-recorded SEPs, and sensory nerve stimulated SEPs over mixed nerve stimulated SEPs. This study provides Level III diagnostic evidence that SEPs may provide diagnostic information beyond conventional electrodiagnostic studies. Electromyography, nerve conduction studies and F-waves are of limited

utility. H-reflexes have a relatively high sensitivity and specificity in the diagnosis of S1 radiculopathy.

Dillingham et al<sup>10</sup> described a prospective case series including 206 patients assessing the minimum number of muscles needed to identify subjects with EMG and surgically confirmed lumbosacral disc herniations. Selected four muscle EMG screens identified over 97% of EMG confirmed radiculopathies and over 89% of surgically confirmed disc herniations. The authors concluded that these findings underscore the utility of four muscle EMG screens in the evaluation of patients with suspected lumbosacral radiculopathy. This study provides Level III diagnostic evidence that a four muscle electromyography screen is sensitive in the diagnosis of nerve root compression, though this is not specific for the level of involvement.

Marin et al<sup>11</sup> conducted a prospective case-control study to assess the sensitivity and specificity of the clinical and electrodiagnostic extensor digitorum brevis reflex (EDBR) in a normal population and in patients with MRI or CT confirmed L-5 and S-1 radiculopathies, in an effort to find a useful L-5 deep tendon reflex. The study included 53 controls, 17 L-5 and 18 S-1 radiculopathy subjects. The sensitivity of electrodiagnostic extensor digitorum brevis reflex was 35% for the L5 root and 39% for the S1 root and 37% for combined radiculopathy. The specificity was 87%. The H reflex sensitivity for L5 was 6% and S1 was 50% with a specificity of 91%. The authors concluded that EDBR clinical and electrodiagnostic reflexes have low sensitivities, high specificities, and do not discriminate L-5 from S-1 root involvement. Due to the small sample size, this potential Level III study provides Level IV diagnostic evidence that the extensor digitorum brevis reflex electrophysiological studies and clinical exam do not distinguish between L5 or S1 radiculopathy and are not ideal screening tools.

**There is insufficient evidence to make a recommendation for or against the use of motor evoked potentials or extensor digitorum brevis reflex in the diagnosis of lumbar disc herniation with radiculopathy.**

### Grade of Recommendation: I (Insufficient Evidence)

Tabaraud et al<sup>12</sup> performed a prospective case-control study to determine how accurate motor evoked potentials (MEP) are in the diagnosis of radiculopathy in patients with complaints of radiculopathy with or without objective neurological signs. Of the patients included in the study, 45 had surgical confirmation of disc herniation and there were 25 controls. MEP latency prolongation >0.8 msec occurred in 72% of patients with L5 radiculopathy and 66% with S1 radiculopathy. The authors concluded that subclinical radiculopathy can be detected by motor EMG for L5 and S1 radiculopathy. This study provides Level III diagnostic evidence that MEPs may be helpful in diagnosing radiculopathy.

Marin et al<sup>11</sup> conducted a prospective case-control study to assess the sensitivity and specificity of the clinical and electrodiagnostic extensor digitorum brevis reflex (EDBR) in a normal population and in patients with MRI or CT confirmed L-5 and S-1 radiculopathies, in an effort to find a useful L-5 deep tendon reflex. The study included 53 controls, 17 L-5 and 18 S-1 radiculopathy subjects. The sensitivity of electrodiagnostic extensor digitorum brevis reflex was 35% for the L5 root and 39% for the S1 root and 37% for combined radiculopathy. The specificity was 87%. The H reflex sensitivity for L5 was 6% and S1 was 50% with a specificity of 91%. The authors concluded that EDBR clinical and electrodiagnostic reflexes have low sensitivities, high specificities, and do not discriminate L-5 from S-1 root involvement. Due to the small sample size, this potential Level III study provides Level IV diagnostic evidence that the extensor digitorum brevis reflex electrophysiological studies and clinical exam do not distinguish between L5 or S1 radiculopathy and are not ideal screening tools.

### Other Diagnostics

**There is insufficient evidence to make a recommendation for or against the use of thermal quantitative sensory testing or liquid crystal thermography in the diagnosis of lumbar disc herniation with radiculopathy.**

### Grade of Recommendation: I (Insufficient Evidence)

Samuelsson et al<sup>13</sup> performed a prospective case-control study including 69 consecutive patients with surgically confirmed lumbar disc herniations to evaluate whether thermal quantita-

tive sensory testing (QST) is applicable in the study of sensory dysfunction in lumbosacral disc herniations. The discriminant analysis showed that the proportion of herniated discs classified correctly was 48% in patients with disc herniations at the L4/5 level and 71% at the L5/S1 level. The authors concluded that there was a significant difference in thermal thresholds between all dermatomes representing different nerve root levels as well as between the side of the herniated disc and the corresponding asymptomatic side. However, thermal QST seems to have the same poor predictive value for identifying the anatomic location of a herniated lumbar disc as conventional electrophysiologic methods. This study provides Level I diagnostic evidence that thermal quantitative sensory testing has differing thresholds be-

tween symptomatic and normal dermatomes, but is not accurate in localizing the level.

### Future Directions for Research

The work group recommends performance of appropriately powered studies comparing thermal quantitative sensory testing and liquid crystal thermography to a gold standard such as surgery or MRI in the diagnosis of lumbar disc herniation with radiculopathy.

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## B. Outcome Measures for Medical/Interventional and Surgical Treatment

What are the **appropriate outcome measures** for the treatment of lumbar disc herniation with radiculopathy?



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](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](mailto:nassresearch@spine.org).

## C. Medical/ Interventional Treatment



### What is the role of pharmacological treatment in the management of lumbar disc herniation with radiculopathy?

**TNF alpha inhibitors are not suggested to provide benefit in the treatment of lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: B**

Genevay et al<sup>1</sup> conducted a prospective randomized controlled trial to assess the efficacy of adalimumab, a tumor necrosis factor alpha inhibitor, in patients with radicular pain due to lumbar disc herniation. Of the 61 consecutively assigned patients included in the study, 31 received adjuvant treatment with two subcutaneous injections of adalimumab at seven-day intervals and 30 received placebo. Outcomes were assessed at six months using the Visual Analog Scale (VAS) leg and low back pain, Oswestry Disability Index (ODI), SF-12, work status, drug use and whether patients proceeded to surgery. “Responders” were defined as having VAS scores for leg pain and back pain or ODI which improved by greater than 30% without having surgery. “Low Residual Disease” was defined by VAS scores of 0-20, without surgery, and ODI of 20 or less. A significant, small effect size is reported in favor of the experimental group on days one and two after treatment for leg pain. On these days, the two groups’ confidence intervals overlap. At six months, the number of patients meeting the “Responder” and “Low Residual Disease” criteria was significantly greater in the experimental group. At six months the number of patients meeting the “Responder” criteria for back pain was significantly greater in the experimental group. At week six, one patient in the experimental group and five patients in the placebo group proceeded to surgery. At 24 weeks, those numbers increased to six and 13, respectively. The authors concluded that a short course of adalimumab added to the treatment regimen of patients experiencing acute and severe sciatica resulted in a small decrease in leg pain and significantly fewer surgical procedures. This study provides Level I therapeutic evidence that in contrast to the authors’ conclusion, a subcutaneous injection of adalimumab does not result in overall improvement at six weeks or six months, relative to placebo. The authors utilized nonvalidated interpretation of outcome measures to support their conclusion that treatment was effective, however, when evaluating the VAS, ODI and SF-12 there was overlap in confidence intervals.

Korhonen et al (2005)<sup>2</sup> and (2006)<sup>3</sup> performed a prospective randomized controlled trial to evaluate the efficacy of infliximab, a monoclonal antibody against tumor necrosis factor

(TNF)-alpha in the treatment of disc herniation-induced sciatica. The 2005 study described 12-week results and the 2006 study reported results at one year. Of the 40 consecutive patients included in the study, 21 were assigned to receive a 5 mg/kg, single infusion of infliximab while 19 patients were infused with saline. Outcomes were assessed at three months and one year using VAS leg pain and back pain, ODI, improvement of straight leg raise restriction, sick leave and whether patients went on to surgery. At 12 weeks there was no clinically significant difference between the treatment and placebo groups in back or leg pain, ODI or sick leave. The authors concluded that results do not support the use of a single infusion of infliximab 5 mg/kg to treat moderate to severe disc herniation induced sciatica. At one year, there was no clinically significant difference between groups relative to leg or back pain (VAS), greater than 75% pain reduction, Health-Related Quality of Life, or straight leg raise. The authors concluded that they could not recommend the clinical use of infliximab in disc herniation induced sciatica. Due to the small sample size, these potential Level I studies provide Level II therapeutic evidence that a single intravenous dose of infliximab, 5 mg/kg, is no better than a placebo for the treatment of sciatica due to lumbar disc herniation at 12 weeks and one year.

**There is insufficient evidence to make a recommendation for or against the use of a single infusion of IV glucocorticosteroids in the treatment of lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: I (Insufficient Evidence)**

Finkh et al<sup>4</sup> reported results from a prospective randomized controlled trial testing the short-term efficacy of a single IV pulse of glucocorticosteroids on the symptoms of acute discogenic sciatica. Of the 60 patients included in the study, 31 received an intravenous bolus of 500 mg of methylprednisolone and 29 received an injection of normal saline. During the study, all patients received standard therapy (NSAID, tramadol, acetaminophen) and physical therapy. Some patients received additional treatment after three days. Outcomes were assessed at one, two, three, 10 and 30 days using VAS sciatica, low back pain and global pain; McGill pain scale; ODI and signs of radicular irritation. For the primary outcome measure, the maximum mean

VAS sciatic scale improvement of 5.7 cm occurred on day one. None of the secondary outcome measures was significantly different between the two groups. As expected, no durable benefit was observed at day 30 with a single intravenous bolus of glucocorticoids for any outcome. The authors concluded that a single intravenous pulse of glucocorticoid provides a small and transient improvement in sciatic leg pain. The transient benefit and small effect size of intravenous glucocorticoids on symptoms of acute sciatica probably do not warrant a large clinical use in this indication. This study provides Level I therapeutic evidence that a single intravenous infusion of glucocorticoids provides only temporary (three days) relief of pain. A glucocorticoid bolus has no effect on functioning or objective signs of radicular irritation related to lumbar disc herniation.

**There is insufficient evidence to make a recommendation for or against the use of 5-HT receptor inhibitors in the treatment of lumbar disc herniation with radiculopathy.**

#### Grade of Recommendation: I (Insufficient Evidence)

Kanayama et al<sup>5</sup> performed a prospective randomized controlled trial to evaluate the efficacy of the 5-HT receptor inhibitor in the treatment of symptomatic lumbar disc herniation. Of the 40 consecutively assigned patients included in the study, 20 received oral 5-HT receptor inhibitor daily for two weeks and 20 received oral diclofenac daily for two weeks. Outcomes were assessed at two weeks using the VAS and at greater than one year to identify any additional health care utilized. The mean VAS improvement rates in the 5-HT inhibitor and diclofenac groups were 33% and 46% for low back pain, 32% and 32% for leg pain, 35% and 32% for leg numbness, respectively. There was no statistical difference between the two groups. No additional medical interventions were required in 50% of the 5-HT receptor inhibitor treated patients and 15% of those receiving diclofenac. Surgery was required in 20% of the 5-HT receptor inhibitor group and 30% of the NSAID group. The authors concluded that the efficacy of 5-HT receptor inhibitor was comparable with that of NSAID in the treatment of symptomatic lumbar disc herniation. This study provides Level II therapeutic evidence that at two weeks, 5-HT receptor inhibitors and diclofenac provide comparable relief from low back pain, leg pain and leg numbness due to lumbar disc herniation.

**There is insufficient evidence to make a recommendation for or against the use of gabapentin in the treatment of lumbar disc herniation with radiculopathy.**

#### Grade of Recommendation: I (Insufficient Evidence)

Kasimcan et al<sup>6</sup> reported results of a prospective case series assessing the effects of gabapentin on reduction of the severity of radicular pain and improvement of quality of life in patients with lumbar disc herniation and /or lumbar spinal stenosis over a relatively short period. Of the 78 patients included in the study, 33 had lumbar disc herniation with radiculopathy. Patients received a titration of gabapentin three times daily to a maximum dose of 2400 mg/day. Outcomes were assessed at three months via VAS radicular pain, Odom's criteria and walking distance. Mean scores for VAS, walking distance and Odom's criteria all showed a statistically significant improvement at three months compared to baseline. Walking distance improved from 0-100 m in 29 patients to 1000 m in 24 patients at three months. Odom's criteria was good or excellent in 28 patients at three months. The authors concluded that gabapentin monotherapy can reduce pain and increase walking distance significantly in patients with lumbar disc herniation. This study provides Level IV therapeutic evidence that gabapentin three times daily titrated to a maximum dose of 2400 mg/day can significantly reduce radicular pain and improve function.

**There is insufficient evidence to make a recommendation for or against the use of agmatine sulfate in the treatment of lumbar disc herniation with radiculopathy.**

#### Grade of Recommendation: I (Insufficient Evidence)

Keynan et al<sup>7</sup> conducted a prospective randomized controlled trial to evaluate the therapeutic efficacy of agmatine sulfate in patients with herniated lumbar disc associated radiculopathy. Of the 99 consecutively assigned patients, 38 patients dropped out or were excluded because of "unreliable data collection." Of the remaining 61 patients, 31 received a 14 day course of 2,670 grams /day of oral agmatine sulfate and 30 patients received identical capsules of indigestible dietary fiber. Concomitant treatment was permitted which could include physical therapy, medication, epidural steroid injections and discectomy. Outcomes were assessed at two months using VAS back and leg pain, McGill Pain, ODI and SF-36. Symptoms improved in both groups over time. In the period immediately following treatment, at 15-20 days, statistically significant enhanced improvements were seen in the treatment group compared to the placebo group. At 45-50 days and 75-80 days, the difference between treatment and placebo group did not meet statistical significance. There was no significant difference in the use of physical therapy, medication, epidural steroid injections and discectomy between the groups. The authors concluded that during the period immediately after taking agmatine sulfate, people suffering from lumbar disc associated radiculopathy undergo significant improvement in their symptoms and general health-related quality of life as compared to those taking placebo. This study provides Level II therapeutic evidence that a two-week treatment of agmatine is more effective than placebo in treatment of lumbar disc herniation with

radiculopathy. The therapeutic efficacy is not demonstrated beyond the 20-day follow-up.

**There is insufficient evidence to make a recommendation for or against the use of amitriptyline in the treatment of lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: I (Insufficient Evidence)**

Pirbudak et al<sup>8</sup> conducted a prospective randomized controlled trial to determine the efficacy of amitriptyline as an adjunct to epidural steroid injections in the management of chronic lumbar radicular pain. All patients received a blind interlaminar epidural injection at the involved level with 10 ml solution of betamethasone dipropionate (10mg) plus betamethasone sodium phosphate (4mg) and bupivacaine (0.25%). In addition, a postural exercise program was initiated during the follow-up period. The injection was repeated at the end of the second week, if the improvement was partial, and at the end of the sixth week, if there was still incomplete recovery. Of the 92 patients included in the study, 46 received 10 mg/day amitriptyline orally (titrated up to 50 mg/day according to clinical response) for nine months. The 46 patients assigned to the control group received placebo (sugar) tablets instead of amitriptyline. Outcomes were assessed at two weeks, six weeks, three months, six months and nine months using VAS, ODI and a self-rating of recovery (complete recovery, partial recovery, no recovery at all). At six months and nine months results, the placebo group outcomes did not differ statistically when compared with baseline values. The amitriptyline group experienced statistically significant improvements compared with baseline values ( $p=0.002$ ) and when compared with the placebo group. The authors concluded that epidural steroid and amitriptyline combination proved beneficial in the management of chronic low back pain associated with radiculopathy. This study provides Level I therapeutic evidence that the addition of amitriptyline to blind lumbar interlaminar epidural steroid injections provides significant relief as compared with placebo and interlaminar epidural steroid injections at up to nine months.

**Future Directions for Research**

**General Recommendation:**

The role of routine pharmacological treatment including NSAIDs, muscle relaxants, oral corticosteroids, neuromodulators and analgesics, used extensively in the treatment of many back conditions, needs to be investigated in patients with lumbar disc herniation with radiculopathy compared with untreated control groups with the diagnosis.

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 disc herniation with radiculopathy.

**Recommendation #1:**

A randomized controlled trial (RCT) investigating the efficacy of IV glucocorticosteroids in the treatment of lumbar disc herniation with radiculopathy would be helpful in providing additional evidence to address efficacy of this treatment.

**Recommendation #2:**

A randomized controlled trial (RCT) investigating the efficacy of TNF alpha inhibitors in the treatment of lumbar disc herniation with radiculopathy would be helpful in providing additional evidence to address efficacy of this treatment.

**Recommendation #3:**

A randomized controlled trial (RCT) investigating the efficacy of 5-HT receptor inhibitors in the treatment of lumbar disc herniation with radiculopathy would be helpful in providing additional evidence to address efficacy of this treatment.

**Recommendation #4:**

A randomized controlled trial (RCT) investigating the efficacy of agmatine sulfate in the treatment of lumbar disc herniation with radiculopathy would be helpful in providing additional evidence to address efficacy of this treatment.

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## What is the role of physical therapy/exercise in the treatment of lumbar disc herniation with radiculopathy?



**There is insufficient evidence to make a recommendation for or against the use of physical therapy/structured exercise programs as stand-alone treatments for lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: 0 (Insufficient Evidence)**

Bakhtiary et al<sup>1</sup> reported results of a prospective randomized controlled trial investigating the effect of lumbar stabilizing exercise in patients with lumbar disc herniation. Of the 60 patients included in this crossover design study, 30 were assigned to each treatment group. Patients in Group A received four weeks of lumbar stabilizing exercise, followed by four weeks of no exercise. Patients in Group B received four weeks of no exercise, followed by four weeks of lumbar stabilizing exercise. The lumbar stabilizing exercise protocol included four stages of stabilizing exercises from easy to advanced. Outcomes were assessed at

four and eight weeks using VAS; range of trunk flexion; range of left and right straight leg raise; and time required to complete the following activities of daily living (ADL): laying prone on the floor from standing position, standing up from laying prone on the floor, climbing steps (five steps), 10 meter walking (fastest pace possible, without pain). Significant differences between groups A and B were seen in the mean changes on all outcome measures at the end of four weeks. After crossover, there were no significant differences between the groups in any of the outcomes measured at eight weeks. The authors concluded that a

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lumbar stabilizing exercise protocol may increase lumbar stability and improve ADL performance in patients who have suffered with a herniated lumbar disc for more than two months. The results of this study may encourage physiotherapists to use LSE to treat patients with lumbar herniated disc. Due to the inability to mask patients to treatment and the low baseline pain values, this potential Level I study provides Level II therapeutic evidence that four weeks of lumbar stabilization exercise results in decreased pain and improved function in patients with lumbar disc herniation with radiculopathy.

Thackeray et al<sup>2</sup> performed a prospective randomized controlled trial to investigate the therapeutic outcomes of physical therapy after selective nerve root blocks (SNRB) and of SNRBs alone in people with low back pain and sciatica due to disc herniation. Of the 44 patients included in the study, 21 received SNRB in combination with physical therapy, described as end-range directional exercises with or without mechanical traction, strengthening, flexibility, stabilization and cardiovascular exercise. The remaining 23 patients in the control group received only SNRBs. Outcomes were assessed at six months using the Low Back Pain Disability Questionnaire (DISQ), Numeric Pain Rating Scale, Global Rating of Change (GROC), Fear Avoidance Belief Questionnaire, Sciatic Bothersome Index and body pain diagram. Intention-to-treat analysis (adjusted) and as-treated analysis both showed no significant difference in outcomes between the control and treatment groups. The authors concluded that the results of this pilot study failed to show that physical therapy interventions, intended to centralize symptoms after SNRBs, were more beneficial than SNRBs alone. Due to the small sample size, this potential Level II study provides Level III therapeutic evidence that supervised exercises intended to reduce symptoms after selective nerve root blocks were no more beneficial than selective nerve root blocks alone.

**In the absence of reliable evidence, it is the work group's opinion that a limited course of structured exercise is an option for patients with mild to moderate symptoms from lumbar disc herniation with radiculopathy.**

### Work Group Consensus Statement

Whereas a systematic search of the literature revealed limited evidence regarding the usefulness of structured exercise programs as stand-alone treatments in patients with lumbar disc herniation with radiculopathy, clinical experience suggests that structured exercise may be effective in improving outcomes as part of a comprehensive treatment strategy. This conclusion is inferred from the literature noted throughout the lumbar disc herniation with radiculopathy guideline.

### Future Directions for Research

An RCT with long-term follow-up and validated outcome measures would assist in providing evidence to assess the efficacy of

physical therapy/structured exercise in the treatment of lumbar disc herniation with radiculopathy. When ethically possible, this would be compared to an untreated control group. Other active treatment groups could be substituted as a comparative group. The physical therapy/structured exercise program should be standardized.

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## What is the role of spinal manipulation in the treatment of lumbar disc herniation with radiculopathy?



Spinal manipulation is an option for symptomatic relief in patients with lumbar disc herniation with radiculopathy.

### Grade of Recommendation: C

Santilli et al<sup>1</sup> described a prospective randomized controlled trial assessing the short- and long-term effects of spinal manipulation on acute back pain and sciatica with disc protrusion. Of the 102 patients included in the study, 53 were treated with spinal manipulation and 49 received sham manipulation. Outcomes were assessed at 180 days using VAS 1 (back and buttock), VAS 2 (leg), SF-36, disc morphology and Kellner Rating (psychological profile). A significantly greater number of patients treated with spinal manipulation had no back, buttock or leg pain at 180 days (VAS 1: 28% vs. 6%, VAS 2: 55% vs. 20%). There was no significant difference in the SF-36, psychological testing and disc morphology between the groups. The authors concluded that active spinal manipulations have more effect than simulated manipulations on pain relief for acute back pain and sciatica with disc protrusion. This study provides Level I therapeutic evidence that spinal manipulation is significantly more effective than sham treatment for the relief of back and leg pain due to acute (less than 10 days) lumbar disc herniation with radiculopathy.

Burton et al<sup>2</sup> performed a prospective randomized controlled trial to test the hypothesis that manipulative treatment provides at least equivalent 12 month outcomes when compared with treatment by chemonucleolysis for patients with sciatica due to

confirmed lumbar disc herniation. Of the 40 patients included in the study, 20 were treated with manipulation and 20 with chemonucleolysis. Outcomes were assessed at 12 months using the Roland Morris Disability Questionnaire, a pain thermometer (back and leg) and lumbar range of motion. By 12 months both groups had significant improvements in mean scores on back and leg pain and Roland Morris without significant differences between groups. The authors concluded that osteopathic manipulation can be considered a safe and effective treatment option for patients with a lumbar radicular syndrome due to lumbar disc herniation, in the absence of clear indications for surgical intervention. Although this study is a randomized controlled trial, it provides case series (Level IV) therapeutic evidence that spinal manipulation is beneficial in treating patients with lumbar disc herniation with radiculopathy.

McMorland et al<sup>3</sup> conducted a prospective randomized controlled trial to compare the clinical efficacy of spinal manipulation against microdiscectomy in patients with sciatica secondary to lumbar disc herniation. Of the 40 consecutive patients included in the study, 20 were treated with spinal manipulative therapies and 20 received microdiscectomy. Outcomes were assessed at 12 weeks and one year using the SF-36, McGill Pain Questionnaire, Aberdeen Back Pain Scale and Roland Morris.

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Of patients with lumbar radiculopathy due to lumbar disc herniation, 60% who failed three months of medical management obtained comparable relief to those patients that underwent successful surgery. The authors concluded that of patients with sciatica that fail three months of medical management, 60% will benefit from spinal manipulation to the same degree as if they undergo surgical intervention. For the 40% that are unsatisfied, surgery provides an excellent outcome. Although this study is a randomized controlled trial, it provides case series (Level IV) therapeutic evidence that spinal manipulation is beneficial in treating patients with lumbar disc herniation with radiculopathy.

**There is insufficient evidence to make a recommendation for or against the use of spinal manipulation as compared with chemonucleolysis in patients with lumbar disc herniation with radiculopathy.**

**Grade of Recommendation (I Insufficient Evidence)**

Burton et al<sup>2</sup> performed a prospective randomized controlled trial to test the hypothesis that manipulative treatment provides at least equivalent 12 month outcomes when compared with treatment by chemonucleolysis for patients with sciatica due to confirmed lumbar disc herniation. Of the 40 patients included in the study, 20 were treated with manipulation and 20 with chemonucleolysis. Outcomes were assessed at 12 months using the Roland Morris Disability Questionnaire, a pain thermometer (back and leg) and lumbar range of motion. By 12 months both groups had significant improvements in mean scores on back and leg pain and Roland Morris without significant differences between groups. The authors concluded that osteopathic manipulation can be considered a safe and effective treatment option for patients with a lumbar radicular syndrome due to lumbar disc herniation, in the absence of clear indications for surgical intervention. Due to the small sample size, this potential Level II study provides Level III therapeutic evidence that spinal manipulation is as effective as chemonucleolysis in patients without clear indications for surgical intervention.

### Future Directions for Research

A randomized controlled trial (RCT) investigating the efficacy of spinal manipulation in the treatment of lumbar disc herniation with radiculopathy would be helpful in providing additional evidence to address efficacy of this treatment.

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## What is the role of traction (manual or mechanical) in the treatment of lumbar disc herniation with radiculopathy?

**There is insufficient evidence to make a recommendation for or against the use of traction in the treatment of lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: I (Insufficient Evidence)**

Unlu et al<sup>1</sup> conducted a prospective randomized controlled trial comparing the outcomes of traction, ultrasound (US) and low power laser (LPL) therapies in patients with acute lower back pain and leg pain caused by lumbar disc herniation. Of the 60 consecutive patients included in the study, 20 were assigned to each treatment group: mechanical traction with 35-50% body weight, ultrasound and low power laser. Outcomes were assessed at three months using VAS, ODI, Roland Morris, clinical signs and MRI disc morphology. There were significant reductions in pain and disability scores between baseline and follow-up in all three groups. There was a significant reduction in the size of the disc herniation on MRI after treatment. There was no correlation between clinical findings, pain and disability scores, and change in lumbar disc herniation size. The authors concluded that traction, ultrasound and low power laser therapies were all effective in the treatment of this group of patients with acute lumbar disc herniation. Because the randomization method was not defined, along with the small sample size, this potential Level I study provides Level II evidence that pain and disability due to acute lumbar radiculopathy secondary to lumbar disc herniation may improve over three months in patients undergoing mechanical traction with 35-50% body weight; however, it is equal in effectiveness to low power laser and ultrasound. The study provides case series (Level IV) evidence that pain and disability due to acute lumbar radiculopathy secondary to LDH may improve over three months in patients undergoing mechanical traction with 35-50% body weight. Since the study did not include an untreated control group, the possibility of spontaneous improvement in this group of patients cannot be excluded.

### Future Directions for Research

An RCT with long-term follow-up and validated outcome measures would assist in providing evidence to assess the efficacy of traction in the treatment of lumbar disc herniation with radiculopathy. When ethically possible, this would be compared to an untreated control group. Other active treatment groups could be substituted as a comparative group.

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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 disc herniation with radiculopathy?

**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%.<sup>1-3</sup> Nonfluoroscopically-guided lumbar interlaminar epidural injections have a rate of inaccurate placement ranging from 17-30%.<sup>3,4</sup>

Renfrew et al<sup>1</sup> examined the accuracy of needle placement during nonfluoroscopically-guided caudal epidural steroid injection in 328 patients, some of whom had lumbar disc herniation with radiculopathy. 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 lumbar diagnoses not limited to lumbar disc herniation with radiculopathy. This study provides Level I diagnostic evidence that blind caudal injection is correct in 47-62% of cases.

Stitz et al<sup>2</sup> 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 landmarks 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 lumbar disc herniation with radiculopathy. This study provides Level I diagnostic evidence that blind caudal epidural injection is accurately placed in 74% of cases.

White et al<sup>3</sup> 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 lumbar disc herniation with radiculopathy. 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.

Mehta et al<sup>4</sup> 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 lumbar disc herniation with radiculopathy. This study provides Level I diagnostic evidence that blind interlaminar injection is correct in 83% of cases.

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## What is the role of epidural steroid injections (ESI) for the treatment of lumbar disc herniation with radiculopathy?

**Transforaminal epidural steroid injection is recommended to provide short-term (2-4 weeks) pain relief in a proportion of patients with lumbar disc herniations with radiculopathy.**

**Grade of Recommendation: A**

Ghahreman et al<sup>1</sup> reported results from a prospective randomized controlled trial assessing the efficacy of transforaminal injection of steroid and local anesthetic, local anesthetic alone, normal saline alone, intramuscular injection of steroid or normal saline on radicular pain secondary to lumbar disc herniation. Of the 150 consecutively assigned patients, 28 received transforaminal steroid and local anesthetic, 27 had transforaminal local anesthetic, 27 received transforaminal normal saline, 30 had intramuscular steroid and 28 received intramuscular normal saline. Outcomes were assessed at one month and 12 months using Numeric Rating Scale, Roland Morris, SF-36, proportion of patients who underwent each treatment who obtained complete relief or at least 50% relief of pain for at least one month after treatment, Patient-Specified Functional Outcome Scale, use of other healthcare, duration of relief and proportion of patients who required rescue treatment or surgery. Of the transforaminal epidural steroid group, 54% experienced greater than 50% radicular pain relief at one month after treatment (CI, 0.36-0.72). This outcome was statistically significant compared to the transforaminal normal saline, transforaminal local anesthetic, intramuscular normal saline and intramuscular steroid groups. The transforaminal steroid group had concomitant improvements in function and disability. The transforaminal epidural steroid injectate of 2.5 ml was comprised of 70 mg triamcinolone and 0.75 ml of 5% bupivacaine. No variation in dosage or frequency could be determined to affect the outcomes. Patients who did not obtain relief from the first transforaminal epidural steroid injection were offered a second "rescue" transforaminal epidural steroid injection. Among the patients who accepted a rescue transforaminal epidural steroid injection, 50% obtained relief. Transforaminal steroid injection was found to be more effective than intramuscular steroid injection for the treatment of lumbar radiculopathy secondary to lumbar disc herniation. No discrete complications from the injections were identified.

The authors concluded that transforaminal epidural steroid injection is a viable alternative to surgery for lumbar radicular pain due to disc herniation. Its immediate yield is modest, but substantial, and not a placebo effect. For long-term efficacy, proof beyond a reasonable doubt would require prohibitively

large studies. This study provides Level I therapeutic evidence that transforaminal epidural steroid injection is an effective treatment for a proportion of patients with symptomatic lumbar disc herniations and is superior to intramuscular saline, intramuscular steroids, transforaminal saline, and transforaminal local anesthetics for short-term (30 days) pain relief and functional improvement.

Karppinen et al (May 2001)<sup>2</sup> and (December 2001)<sup>3</sup> performed a randomized controlled trial to test the efficacy of periradicular corticosteroid injection for sciatica. Of the 160 consecutively assigned patients included in the study, 80 patients received a single transforaminal epidural steroid injection and 80 received a single transforaminal injection of normal saline. Outcomes were assessed at two and 12 months using VAS (leg pain), ODI and Nottingham Health Profile. Cost effectiveness was assessed at 12-month follow-up. The study published in December 2001 provided subgroup analyses by type of herniation. For bulging discs, there were no known significant differences between the treatments. For extrusions, there was significant improvement with transforaminal normal saline at six months. For contained disc herniations, leg pain at four weeks and Nottingham Health Profile emotional scores at three months were significantly better for the transforaminal epidural steroid injections compared to transforaminal normal saline. The authors concluded that transforaminal epidural steroid injection is superior to transforaminal normal saline injection for treatment of leg pain due to most contained disc herniations. For extrusions, steroid appears counter-effective. These two studies provide Level I therapeutic evidence that transforaminal epidural steroid injection is an effective treatment for a proportion of patients with symptomatic lumbar disc herniations, as compared with saline injection, for short-term (four weeks) pain relief.

**Interlaminar epidural steroid injections may be considered in the treatment of patients with lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: C**

Manchikanti et al<sup>4</sup> described a prospective randomized controlled trial to compare interlaminar epidural corticosteroid injection to interlaminar epidural local anesthetic injection. Of the 120 patients included in the study, 60 received interlaminar epidural corticosteroid injection and 60 received interlaminar epidural local anesthetic injection. Outcomes were assessed at three, six and 12 months using the Numeric Rating Scale, ODI and medication use status. At three months and 12 months,

both groups had significant improvement in NRS and ODI. At six months, the steroid group had significantly greater NRS & ODI improvement than the local anesthetic group. There was no significant difference in opioid use, but both groups improved. The authors concluded that both the local anesthetic and steroid groups had significant long- and short-term improvement in VAS and ODI. Because the subgroup analysis did not elaborate on the extent of repeat injections allowed, this potential Level II study provides Level III evidence that interlaminar epidural steroid injection provides better relief of pain and disability at six months than interlaminar epidural local anesthetic in the treatment of patients with lumbar disc herniation with radiculopathy. This paper included many patients with chronic and bilateral pain, and the work group questioned the underlying diagnosis.

Ackerman et al<sup>5</sup> conducted a prospective randomized controlled trial to test the null hypothesis that these three methods of lumbar epidural steroid injections (caudal, interlaminar, transforaminal) are equally effective for the management of radicular pain associated with lumbar disc herniation at L5-S1. Of the 90 consecutively assigned patients included in the study, 30 were treated with each of the following: caudal epidural steroid injection, interlaminar epidural steroid injection and transforaminal epidural steroid injection. Outcomes were assessed at 24 weeks using ODI, Beck Depression Score and Numerical Pain Intensity Score. Pain scores improved in all groups. All groups showed significant improvement in functional and depression outcome measures two weeks following their last treatment. Patients had an average of 1.5, 2.2 and 2.5 injections in the transforaminal, interlaminar, and caudal groups, respectively. Pain scores improved in all groups, but were significantly lower in the transforaminal group. At 24 weeks, the transforaminal epidural steroid group had significantly more patients reporting complete (30%) or partial relief (53%). At 24 weeks, complete or partial pain relief in the transforaminal, interlaminar, and caudal groups was reported in 25, 18, and 17 patients respectively. All groups showed significant improvement in functional and depression outcome measures two weeks after their last injection. However, no differences were noted between groups in depression and functional outcomes. The authors concluded that the transforaminal approach offers the benefit of increased analgesic efficacy compared to the caudal and interlaminar approaches. This study provides Level I therapeutic evidence that transforaminal injections are more effective than caudal or interlaminar injections in the treatment of patients with lumbar disc herniation with radiculopathy. The study provides Level IV evidence regarding efficacy of interlaminar epidural steroid injections.

**There is insufficient evidence to make a recommendation for or against the 12 month efficacy of transforaminal epidural steroid injection in the treatment of patients with lumbar disc herniations with radiculopathy.**

**Grade of Recommendation: I (Insufficient Evidence)**



Ghahreman et al<sup>1</sup> reported results from a prospective randomized controlled trial assessing the efficacy of transforaminal injection of steroid and local anesthetic, local anesthetic alone, normal saline alone, intramuscular injection of steroid or normal saline on radicular pain secondary to lumbar disc herniation. Of the 150 consecutively assigned patients, 28 received transforaminal steroid and local anesthetic, 27 had transforaminal local anesthetic, 27 received transforaminal normal saline, 30 had intramuscular steroid and 28 received intramuscular normal saline. Outcomes were assessed at one month and 12 months using Numeric Rating Scale, Roland Morris, SF-36, proportion of patients who underwent each treatment who obtained complete relief or at least 50% relief of pain for at least one month after treatment, Patient-Specified Functional Outcome Scale, use of other healthcare, duration of relief and proportion of patients who required rescue treatment or surgery. Of the transforaminal epidural steroid group, 54% experienced greater than 50% radicular pain relief at one month after treatment (CI, 0.36-0.72). This outcome was statistically significant compared to the transforaminal normal saline, transforaminal local anesthetic, intramuscular normal saline and intramuscular steroid groups. The transforaminal steroid group had concomitant improvements in function and disability. The transforaminal epidural steroid injectate of 2.5 ml was comprised of 70 mg triamcinolone and 0.75 ml of 5% bupivacaine. No variation in dosage or frequency could be determined to affect the outcomes. Patients who did not obtain relief from the first transforaminal epidural steroid injection were offered a second “rescue” transforaminal epidural steroid injection. Among the patients who accepted a rescue transforaminal epidural steroid injection, 50% obtained relief. Transforaminal steroid injection was found to be more effective than intramuscular steroid injection for the treatment of lumbar radiculopathy secondary to lumbar disc herniation. No discrete complications from the injections were identified.

The authors concluded that transforaminal epidural steroid injection is a viable alternative to surgery for lumbar radicular pain due to disc herniation. Its immediate yield is modest, but substantial, and not a placebo effect. For long-term efficacy, proof beyond a reasonable doubt would require prohibitively large studies. This study provides Level I therapeutic evidence that transforaminal epidural steroid injection is an effective treatment for a proportion of patients with symptomatic lumbar disc herniations and is superior to intramuscular saline, intramuscular steroids, transforaminal saline, and transforaminal local anesthetics for short-term (30 days) pain relief and functional improvement.

Vad et al<sup>6</sup> described a prospective randomized controlled trial comparing transforaminal epidural steroid injection with saline trigger point injection used in the treatment of lumbosacral radiculopathy secondary to herniated nucleus pulposus. Of the 50 consecutive patients included in the study, 25 were treated with transforaminal epidural steroid injection and 25 received saline trigger point injection. Outcomes were assessed at 12 months using VAS, Roland Morris and patient satisfaction. Successful outcomes were defined as patient satisfaction scores of good or very good, Roland Morris improvement of at least five and VAS reduced by at least 50% at one year. The success rate was significantly better in the transforaminal epidural steroid group

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(84%) compared to the saline trigger point group (48%). This study provides Level II therapeutic evidence that transforaminal epidural steroid injection is more effective in relieving radicu-

lar pain and improving function than a sham control of trigger point injections with normal saline in patients with lumbar radiculopathy due to lumbar disc herniation.

## Is there an optimal frequency or quantity of injections for the treatment of lumbar disc herniations with radiculopathy?



**No evidence to address this question.**

## Does the approach (interlaminar, transforaminal, caudal) influence the risks or effectiveness of epidural steroid injections in the treatment of lumbar disc herniations with radiculopathy?



**There is insufficient evidence to make a recommendation for or against the effectiveness of one injection approach over another in the delivery of epidural steroids for patients with lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: I (Insufficient Evidence)**

Ackerman et al<sup>5</sup> conducted a prospective randomized controlled trial to test the null hypothesis that these three methods of lumbar epidural steroid injections (caudal, interlaminar, transforaminal) are equally effective for the management of radicular pain associated with lumbar disc herniation at L5-S1. Of the 90 consecutively assigned patients included in the study, 30 were treated with each of the following: caudal epidural steroid injection, interlaminar epidural steroid injection and transforaminal epidural steroid injection. Outcomes were assessed at 24 weeks using ODI, Beck Depression Score and Numerical Pain Intensity Score. Pain scores improved in all groups. All groups showed significant improvement in functional and depression outcome measures two weeks following their last treatment. Patients had an average of 1.5, 2.2 and 2.5 injections in the transforaminal, interlaminar, and caudal groups, respectively. Pain scores improved in all groups, but were significantly lower in the transforaminal group. At 24 weeks, the transforaminal epidural steroid group had significantly more patients reporting complete (30%) or partial relief (53%). At 24 weeks, complete or partial pain relief in the transforaminal, interlaminar, and caudal groups was reported in 25, 18 and 17 patients, respectively. All groups showed significant improvement in functional and depression outcome measures two weeks after their last injection. However,

no differences were noted between groups in depression and functional outcomes. The authors concluded that the transforaminal approach offers the benefit of increased analgesic efficacy compared to the caudal and interlaminar approaches. This study provides Level I therapeutic evidence that transforaminal injections are more effective than caudal or interlaminar injections in the treatment of patients with lumbar disc herniation with radiculopathy.

Kolsi et al<sup>7</sup> described a prospective randomized controlled trial comparing the short-term efficacy on pain and functional impairment of nerve root sheath and interspinous glucocorticoid injection. Of the 30 patients included in the study, 17 were treated with nerve root sheath and 13 received interspinous glucocorticosteroid injection. Outcomes were assessed at 28 days and again at a mean of eight months using VAS, Roland Morris and whether patients proceeded to surgery. Both treatment groups had improvement in their pain and disability with no significant difference between treatment groups. At the eight-month follow-up, three patients in each group had surgery, and the remaining patients were pain free. The authors concluded that it remains to be proven whether nerve root sheath is superior to interspinous glucocorticosteroid injection. Because of the small sample size and improper method of randomization, this

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potential Level II study provides Level III therapeutic evidence that nerve root sheath and interspinous glucocorticoid injection are comparably effective in the treatment of lumbar disc herniation with radiculopathy.

Schaufele et al<sup>8</sup> reported results of a retrospective case-control study to assess whether there is a difference in short-term pain improvement and long-term surgical rates between interlaminar and transforaminal epidural steroid injection techniques. Of the 40 consecutive patients included in the study, 20 received interlaminar and 20 received transforaminal epidural steroid injections. Outcomes were assessed using the Numeric Rating Scale at 18 days, and at one year patients were contacted to determine whether they had proceeded to surgery. There was a statistically significant improvement in the Numeric Rating Scale scores at follow-up for the transforaminal group. The average Numeric Rating Scale improvement was 46% in the transforaminal group and 19% in the interlaminar group. Surgery was performed in 25% of the interlaminar group and 10% of the transforaminal group. The authors concluded that transforaminal epidural steroid injections for treatment of radicular pain due to lumbar disc herniation resulted in better short-term pain improvement and fewer long-term surgeries compared with interlaminar epidural steroid injections. Because of the small sample size and the lack of standardization of follow-up injections, this potential Level III study provides Level IV evidence that transforaminal epidural steroid injection is more effective than interlaminar epidural steroid injection for short-term radicular pain relief, and is associated with fewer surgical interventions for lumbar disc herniation.

### 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 disc herniation with radiculopathy.

#### Recommendation #1:

A large double-blinded, randomized controlled clinical trial with at least one-year follow-up in patients with lumbar disc herniation with radiculopathy treated by fluoroscopically-guided interlaminar or caudal epidural steroid injections in which the control group receives saline placebo injections. Subgroup analyses should be provided for responders and nonresponders.

#### Recommendation #2:

A large double-blinded, randomized controlled clinical trial with at least one-year follow-up comparing patients with lumbar disc herniation with radiculopathy treated by fluoroscopically-guided transforaminal, interlaminar and caudal epidural steroid injections.

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## What is the role of interventional spine procedures such as intradiscal electrothermal annuloplasty (IDEA or IDET) and percutaneous discectomy (chemical or mechanical) in the treatment of lumbar disc herniation with radiculopathy?

**Note:** For the purpose of this guideline, the work group defined the following interventional spine procedures addressed in this clinical question:

- **Percutaneous discectomy is defined as any discectomy procedure that does not require open dissection of the thoracolumbar fascia. This includes endoscopic discectomy.**
- **Endoscopic percutaneous discectomy is defined as a discectomy procedure in which access to the disc herniation is made with a portal, visualization of the discectomy is done with an endoscope, and removal of disc material is done with micro instruments or laser. This is an indirect visualization technique using the endoscope and fluoroscopic guidance.**
- **Automated percutaneous discectomy is defined as a discectomy procedure in which a cannula is inserted into the intervertebral disc space, usually with fluoroscopic guidance, and nuclear material is removed without direct visualization by nucleotome, laser or radiofrequency heat. This is an indirect visualization technique using the endoscope and fluoroscopic guidance.**

**There is insufficient evidence to make a recommendation for or against the use of intradiscal ozone in the treatment of patients with lumbar disc herniation with radiculopathy.**

**Grade of Recommendation I (Insufficient Evidence)**

Gallucci et al<sup>1</sup> conducted a prospective randomized controlled trial to prospectively compare the clinical effectiveness of intraforaminal and intradiscal injections of a mixture of a steroid, a local anaesthetic and oxygen-ozone (O<sub>2</sub>-O<sub>3</sub>) to intraforaminal and intradiscal injections of a steroid and an anesthetic in the management of radicular pain related to acute lumbar disc herniation. Group A, the control group, underwent intraforaminal and intradiscal injections of 2 mL of triamcinolone acetonide (40 mg/mL Kenacort; Bristol-Myers Squibb, Sermoneta, Italy),

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with 1 mL injected in the epidural space and 1 mL injected inside the disc, and 2–4 mL of 2% ropivacaine (Naropina; AstraZeneca, Basiglio, Italy), about 2 mL injected in the epidural space and 1 mL injected inside the disc. Group B, the treatment group, received the same treatment with the addition of an O2-O3 mixture, with an ozone concentration of 28 mcg/mL. Intraforaminal and intradiscal injections of O2-O3 (5–7 mL; mean 6.5 & 5.8 mL, respectively) were injected in Group B. Of the 158 consecutively assigned patients, 77 were included in Group A (control) and 82 were assigned to Group B to receive the O2-O3 mixture. Outcomes were assessed at six months using the ODI.

In Group A, the treatment was a success in 69 (90%) of 77 patients (95% CI, 80.6%, 95.4%) after two weeks, 52 (67%) patients (95% CI, 55.9%, 77.8%) after three months, and 36 (47%) patients (95% CI, 35.3%, 58.5%) after six months. In Group B, the treatment was a success in 72 (88%) of 82 patients (95% CI: 78.8%, 93.4%) after two weeks, 64 (78%) patients (95% CI: 67.5%, 86.4%) after three months, and 61 (74%) patients (95% CI: 63.6%, 83.3%) after six months. There was a statistically significant difference ( $p < .01$ ) in the success rate in favor of Group B: the group treated with O2-O3 injections. The authors concluded that O2-O3 chemodiscolysis should be regarded as a useful treatment for the management of lumbar disc herniation. This study provides Level I therapeutic evidence that intraforaminal and intradiscal local anesthetic, steroid and O2-O3 injections are superior to intraforaminal and intradiscal local anesthetic and steroid injections alone at six months in the treatment of radicular pain caused by lumbar disc herniation. Both treatments yield improved outcomes at two weeks and three months.

**Endoscopic percutaneous discectomy may be considered for the treatment of lumbar disc herniation with radiculopathy.**

### Grade of Recommendation: C

Ahn et al<sup>2</sup> described a retrospective case series of 45 patients assessing the clinical outcome, prognostic factors and the technical pitfalls of percutaneous endoscopic lumbar discectomy for upper lumbar disc herniation. Outcomes were assessed at a mean of 38.8 months (range: 25-52 months) using the VAS and Prolo scale scores (excellent, good, fair and poor). Based on the Prolo scale, the outcomes were excellent in 21 of 45 patients (46.7%), good in 14 patients (31.1%), fair in six patients (13.3%), and poor in four patients (8.9%). The combined rate of excellent or good outcome at the final follow-up was 77.8%. The mean VAS for radicular pain was  $8.38 \pm 1.22$ , and after operation decreased to  $2.36 \pm 1.65$  ( $p < 0.0001$ ). The authors concluded that patient selection and an anatomically modified surgical technique promote a more successful outcome after percutaneous endoscopic discectomy for upper lumbar disc herniation. This study provides Level IV therapeutic evidence that transforaminal endoscopic percutaneous discectomy can be effective for treatment of upper lumbar disc herniations at L1-2 and L2-3.

Ahn et al<sup>3</sup> reported a retrospective case series of 43 patients evaluating the efficacy of endoscopic discectomy for recurrent

disc herniations and to determine the prognostic factors affecting surgical outcome. Outcomes were assessed at a mean follow-up of 31 months (range: 24-39 months) using VAS and MacNab criteria. Based on the MacNab criteria, the surgical outcomes were rated as follows: excellent in 12 patients (27.9%), good in 23 (53.5%), fair in six (13.9%), and poor in two (4.7%). Therefore, the percentage of successful outcomes was 81.4%, whereas the rate of improvement was 95.3%. The preoperative mean VAS was  $8.72 \pm 1.20$ , which decreased to  $2.58 \pm 1.55$  at the final follow up ( $p < 0.0001$ ). The authors concluded that percutaneous endoscopic lumbar discectomy is effective for recurrent disc herniation in selected cases. This study provides Level IV therapeutic evidence that percutaneous endoscopic lumbar discectomy is effective for recurrent disc herniation in selected cases. Patients younger than 40 years, with shorter symptom duration (less than three months) and without concurrent lateral recess stenosis tended to have better outcomes. The work group debated the eligibility of this paper for inclusion in the guideline. Several members opposed its inclusion because the paper evaluated the treatment of recurrent herniations. Proponents pointed out that patients included in the study had a mean pain-free interval after their previous surgery of 63 months, ranging from six to 186 months. Furthermore, the question serving as the basis for the literature review and guideline formulation did not specifically exclude recurrent herniation (although all committee members inferred that the guideline development was intended to address virgin disc herniations).

Cervellini et al<sup>4</sup> described a retrospective case series describing experiences in the treatment of 17 patients with extraforaminal disc herniation via the microendoscopic far lateral approach. Outcomes were assessed at 1-4 years using MacNab criteria. All patients had excellent or good outcomes. The authors concluded that the minimally invasive surgical treatment via the microendoscopic far lateral approach has a high rate of success. This study provides Level IV therapeutic evidence that the minimally invasive surgical treatment, via the microendoscopic far lateral approach, is a viable treatment alternative for far lateral disc herniations.

Hermantin et al<sup>5</sup> performed a prospective comparative study to evaluate the results of endoscopic percutaneous lumbar discectomy compared with open discectomy in patients with lumbar disc herniation and radiculopathy. Of the sixty patients included in the study, 30 were treated with endoscopic discectomy and 30 with open discectomy. Outcomes were assessed at an average of 31 months (range: 19-42 months) for open discectomy and 32 months (range: 21-42 months) for endoscopic discectomy. Measures utilized included the Pain Intensity Scale (0-10) and assessment of outcomes related to patients' perioperative self-evaluation, return to normal activity, findings on physical exam and patient satisfaction using a four point patient satisfaction scale. The mean postoperative pain score was 1.9 and 1.2 in the open discectomy and endoscopic discectomy groups, respectively. There was no difference in satisfactory outcomes between the groups: 93% satisfactory outcome in open discectomy, 97% in endoscopic. A very satisfactory outcome was reported in 67% and 73% of the open discectomy and endoscopic discectomy groups, respectively. Narcotic use was longer (25 days versus seven days) in patients treated with open discectomy. Average post-

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operative disability was 49 and 27 days in the open discectomy and endoscopic discectomy groups, respectively. The authors concluded that in carefully selected patients, endoscopic percutaneous lumbar discectomy is a useful treatment for lumbar disc herniation. Although described by the authors as a randomized controlled trial, randomization was limited to patients not sent for one procedure or another and only performed in select patients who agreed to randomization, who met inclusion criteria for endoscopic percutaneous lumbar discectomy. This study provides Level II therapeutic evidence that compared to open discectomy, select patients with lumbar disc herniation and radiculopathy treated with endoscopic discectomy postoperatively consume less opioids and resume normal activity levels sooner. This study provides Level IV evidence regarding the efficacy of endoscopic percutaneous discectomy.

Jang et al<sup>6</sup> reported a retrospective case series documenting the outcome for 35 consecutive patients with intraforaminal and extraforaminal herniated discs who were surgically treated with transforaminal percutaneous endoscopic lumbar discectomies. Outcomes were assessed at an average of 18 months (range: 10-35 months) using VAS and MacNab criteria. In the immediate postoperative period, six patients (17%) developed burning dysesthesia in the sensory distribution of the operated nerve root. The mean preoperative and postoperative VAS scores went from 8.6 before the surgery to 3.2 after the surgery. These improvements were statistically significant ( $P < 0.01$ ). Overall, excellent or good outcomes were obtained in 30 (85.7%) of the 35 patients as determined at the last follow-up examination according to the MacNab criteria. The authors concluded that the posterolateral endoscopic approach to foraminal and extraforaminal lumbar disc herniations for the decompression of the exiting root contributes a minimally invasive procedure that seems to be safe and effective. This study provides Level IV therapeutic evidence that the posterolateral endoscopic approach to foraminal and extraforaminal lumbar disc herniations for the decompression of the exiting root constitutes a minimally invasive procedure that seems to be effective in the majority of patients. However, 17% of patients experienced postoperative dysesthesias in the distribution of the affected nerve root and 8.6% of patients eventually had open surgery for persistent radiculopathy.

Mayer et al<sup>7</sup> conducted a prospective randomized controlled trial assessing two series of patients with comparable indication criteria treated by either percutaneous endoscopic discectomy or microdiscectomy. Of the 40 patients included in the study, 20 were randomly assigned to each group. Outcomes were assessed at two years using a clinical scoring system, patients' subjective evaluation and postoperative disability assessment. At two years, both the percutaneous endoscopic discectomy and microdiscectomy group had statistically significant improvement over their baseline clinical outcome score. The patient's subjective evaluation of treatment was more favorable in the percutaneous endoscopic discectomy group. Average postoperative disability was 7.7 weeks in the percutaneous endoscopic discectomy group and 22.9 weeks in the microdiscectomy group. Nineteen of the 20 patients in the percutaneous endoscopic discectomy group and 13 of the 20 patients in the microdiscectomy group returned to their previous occupation. The authors concluded that percutaneous endoscopic discectomy can be a surgical alternative

for patients with contained or small subligamentous lumbar disc herniations. Because of the lack of validated outcome measures, small sample size and absence of a description of the randomization process, this potential Level II study provides Level III therapeutic evidence that percutaneous endoscopic discectomy and microdiscectomy provide statistically significant clinical improvement from lumbar radicular symptoms due to contained or small noncontained lumbar disc herniation at two years. At two year follow-up, patient satisfaction is greater in the percutaneous endoscopic discectomy group, and average postoperative disability was markedly less in the percutaneous endoscopic discectomy group compared to the microdiscectomy group. This study provides Level IV evidence regarding the efficacy of full-endoscopic discectomy.

Ruetten et al<sup>8</sup> performed a prospective randomized controlled trial to compare results of lumbar discectomies in full-endoscopic interlaminar and transforaminal technique with conventional microsurgical technique. Of the 200 patients included in the study, 100 were treated with microdiscectomy and 100 received full-endoscopic discectomy. Outcomes were assessed at 24 months using VAS (leg and back), the NASS instrument, ODI and consideration of: whether a second surgical procedure was performed, postoperative pain and pain medication, and postoperative work disability. There was constant and significant improvement in leg pain and daily activities in all groups. There was no significant differences in results between the groups. Of the 184 patients available at follow-up, 17 underwent a second surgical procedure (10 microdiscectomy patients and seven full-endoscopic patients). Postoperative pain and pain medication were significantly reduced in the full-endoscopic group. The mean postoperative work disability was significantly less in the full endoscopy group at 25 days compared with 49 days in the microdiscectomy group. The authors concluded that the clinical results of the full-endoscopic technique are equal to those of the microsurgical technique. Because the full-endoscopic approach blends data on two different technical approaches (38 transforaminal and 53 interlaminar) without subgroup analysis and diagnostic radiology studies are not described, this potential Level I study provides Level II therapeutic evidence that full-endoscopic interlaminar and transforaminal techniques provide statistically equivalent improvements in pain and function over two years compared to conventional microdiscectomy in patients with radicular pain due to lumbar disc herniation. Compared with conventional microdiscectomy, full-endoscopic discectomy is associated with significantly less postoperative work disability and use of pain medication. This study provides Level IV evidence regarding the efficacy of full-endoscopic discectomy.

**Endoscopic percutaneous discectomy is suggested for carefully selected patients to reduce early postoperative disability and reduce opioid use compared with open discectomy in the treatment of patients with lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: B**

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Hermantin et al<sup>5</sup> performed a prospective comparative study to evaluate the results of endoscopic percutaneous lumbar discectomy compared with open discectomy in patients with lumbar disc herniation and radiculopathy. Of the 60 patients included in the study, 30 were treated with endoscopic discectomy and 30 with open discectomy. Outcomes were assessed at an average of 31 months (range: 19-42 months) for open discectomy and 32 months (range: 21-42 months) for endoscopic discectomy. Measures utilized included the Pain Intensity Scale (0-10) and assessment of outcomes related to patients' perioperative self-evaluation, return to normal activity, findings on physical exam and patient satisfaction using a four point patient satisfaction scale. The mean postoperative pain score was 1.9 and 1.2 in the open discectomy and endoscopic discectomy groups, respectively. There was no difference in satisfactory outcomes between the groups: 93% satisfactory outcome in open discectomy, 97% in endoscopic. A very satisfactory outcome was reported in 67% and 73% of the open discectomy and endoscopic discectomy groups, respectively. Narcotic use was longer (25 days versus seven days) in patients treated with open discectomy. Average postoperative disability was 49 and 27 days in the open discectomy and endoscopic discectomy groups, respectively. The authors concluded that in carefully selected patients, endoscopic percutaneous lumbar discectomy is a useful treatment for lumbar disc herniation. Although described by the authors as a randomized controlled trial, randomization was limited to patients not sent for one procedure or another and only performed in select patients who agreed to randomization, who met inclusion criteria for endoscopic percutaneous lumbar discectomy. This study provides Level II therapeutic evidence that compared to open discectomy, select patients with lumbar disc herniation and radiculopathy treated with endoscopic discectomy postoperatively consume less opioids and resume normal activity levels sooner.

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evidence that full-endoscopic interlaminar and transforaminal techniques provide statistically equivalent improvements in pain and function over two years compared to conventional microdiscectomy in patients with radicular pain due to lumbar disc herniation. Compared with conventional microdiscectomy, full-endoscopic discectomy is associated with significantly less postoperative work disability and use of pain medication.

Mayer et al<sup>7</sup> conducted a prospective randomized controlled trial assessing two series of patients with comparable indication criteria treated by either percutaneous endoscopic discectomy or microdiscectomy. Of the 40 patients included in the study, 20 were randomly assigned to each group. Outcomes were assessed at two years using a clinical scoring system, patients' subjective evaluation and postoperative disability assessment. At two years, both the percutaneous endoscopic discectomy and microdiscectomy groups had statistically significant improvement over their baseline clinical outcome score. The patient's subjective evaluation of treatment was more favorable in the percutaneous endoscopic discectomy group. Average postoperative disability was 7.7 weeks in the percutaneous endoscopic discectomy group and 22.9 weeks in the microdiscectomy group. Nineteen of the 20 patients in the percutaneous endoscopic discectomy group and 13 of the 20 patients in the microdiscectomy group returned to their previous occupation. The authors concluded that percutaneous endoscopic discectomy can be a surgical alternative for patients with contained or small subligamentous lumbar disc herniations. Because of the lack of validated outcome measures, small sample size and absence of a description of the randomization process, this potential Level II study provides Level III therapeutic evidence that percutaneous endoscopic discectomy and microdiscectomy provide statistically significant clinical improvement from lumbar radicular symptoms due to contained or small noncontained lumbar disc herniation at two years. At two year follow-up, patient satisfaction is greater in the percutaneous endoscopic discectomy group, and average postoperative disability was markedly less in the percutaneous endoscopic discectomy group compared to the microdiscectomy group.

**Automated percutaneous discectomy may be considered for the treatment of lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: C**

Alo et al<sup>9</sup> reported results from a prospective case series examining outcomes of 50 consecutive patients treated with the Dekompressor<sup>®</sup> 1.5mm percutaneous lumbar discectomy probe at a six month follow-up. Outcomes were assessed using VAS, analgesic consumption, self-reported functional improvement and patient satisfaction. Percutaneous discectomy was completed in 50 patients (62 levels) with an average reduction in preoperative pain score (VAS) of 60.25% ( $p < 0.001$ ). Of the patients included in the study, 74% reported reducing their analgesic intake, 90% reported improvement in post-decompression functional status, and overall satisfaction with therapy was greater than 80%. There were no procedure related complications. The

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authors concluded that this preliminary cohort obtained safe and efficacious disc removal and pain relief without complication at six months. Percutaneous discectomy can be successfully integrated into a conservative treatment algorithm for chronic discogenic leg pain patients. This study provides Level IV therapeutic evidence that satisfactory outcomes can be achieved in patients with radicular pain associated with disc herniations that are less than 6 mm in size and are treated with the Dekompresor® 1.5mm percutaneous lumbar discectomy probe.

Davis et al<sup>10</sup> described a case series reporting the outcomes of 518 consecutive patients treated for disc-related sciatica with automated percutaneous discectomy. Outcomes were assessed at two years with successful outcomes defined as moderate to complete pain relief, no narcotic medication, return to preinjury functional status and patient satisfaction with the procedure. The overall success rate was 85% with an 87% success in non-compensation patients and 74% in compensation patients. The authors concluded that APD should play a valuable role in the treatment of primary and recurrent disc herniation. This study provides Level IV therapeutic evidence that percutaneous discectomy can be used effectively in patients with sciatica caused by small, contained disc herniations.

Faubert et al<sup>11</sup> published a retrospective case series to present the short-term follow-up analysis of 28 patients who underwent a percutaneous discectomy at L4-5 after presenting with an L5 radiculopathy that was refractory to conservative therapy. Outcomes were assessed at a minimum two-month follow-up using subjective measures. Of the 28 patients, 18 (64.3%) were considered to have good or fair outcomes; 10 (35.7%) patients had no leg or back pain relief, experienced a worsening condition, and were unable to resume work or other activities; and nine (32.1%) were later treated with open surgery. There were no major operative complications. Four patients (14.3%) were considered to have had poor indications for percutaneous discectomy because of concomitant spinal stenosis, the presence of a “lateralized foraminal herniation,” or because the predominant symptom was back pain. The authors concluded that percutaneous discectomy is a viable alternative to open surgery as a first step procedure when performed in experienced hands. This study provides Level IV therapeutic evidence that percutaneous lumbar discectomy is a viable treatment alternative for patients presenting with an L5 radiculopathy from an L4-5 disc herniation that is refractory to conservative treatment. The lack of validated outcome measures decreased the value of this retrospective case series.

Haines et al<sup>12</sup> conducted a prospective randomized controlled trial to estimate the success rates of automated or endoscopic percutaneous discectomy and conventional discectomy in comparable patients and to document the resource consumption of patients treated in these ways. Of the 34 consecutive patients included in the study, 21 were treated with automated percutaneous discectomy or endoscopic percutaneous discectomy and 13 received conventional discectomy. Outcomes were assessed at six months using modified Roland Morris scale, SF-36, and a four dimension outcome assessment matrix developed by the authors that incorporated patient assessment of pain frequency and severity, ability to participate in activities of work and leisure, and analgesic use -- factors commonly used in published

studies of treatment for herniated lumbar disc. There was no statistical difference between the two groups for the primary and secondary outcome measures. The success rate for the primary outcome measure was 41% in the automated percutaneous discectomy group and 40% in the conventional discectomy group. Both groups showed significant improvement in the secondary outcome measures at six months. The authors concluded that their trial did not enroll sufficient numbers of patients to reach a definitive conclusion about the efficacy and cost-effectiveness of standard and automated or endoscopic percutaneous discectomy in the treatment of radiculopathy related to lumbar disc herniation. Due to the small sample size, litigation status of subjects, and change in procedures mid-study from automated percutaneous discectomy to endoscopic discectomy with no subgroup analysis, this potential Level II study provides Level III evidence that patients treated with automated or endoscopic discectomy and conventional discectomy have comparable outcomes at six months. This study provides Level IV evidence about the efficacy of automated or endoscopic discectomy.

Lierz et al<sup>13</sup> described a prospective case series of 64 patients assessing the utility of using the Dekompresor® system under CT-control in an attempt to improve postinterventional results and minimize the rate of complications. Outcomes were assessed at one year using VAS, along with assessment of opioid use, activities of daily living and patient satisfaction. The average pain score was significantly improved at two days, and six and 12 months postprocedure. Reduction in analgesic use and improvement in activities of daily living were seen in 80% and 77%, respectively, at 12 months. Patient satisfaction was reported for 77% at 12 months. There was a significant favorable difference in patient satisfaction, analgesic use, and activities of daily living in patients treated at a single level. The authors concluded that when standardized patient selection criteria are used, treatment of patients with radicular pain associated with contained disc herniation using Dekompresor® can be a safe and efficient procedure. This study provides Level IV therapeutic evidence that with standardized selection criteria, single level automated percutaneous lumbar discectomy is associated with rapid and sustained satisfactory relief from radicular pain due to a contained lumbar disc herniation of 6 mm or less.

Revel et al<sup>14</sup> conducted a prospective randomized controlled trial to compare results of automated percutaneous discectomy with those of chemonucleolysis. Of the 165 patients who were initially randomized, 19 were excluded before treatment. Of the 141 treated patients, five were excluded after the first follow-up. This left 69 patients in the automated percutaneous discectomy group and 72 in the chemonucleolysis group. Outcomes were assessed at one, three, six and 12 months using VAS, Waddell Main Functional Outcome, MacNab Criteria and patient self-assessment of treatment outcome (none, moderate, good, very good). A successful outcome occurred if the patient considered their improvement better than moderate. Among the patients who underwent the technical aspect of the procedure, automated percutaneous discectomy was deemed unsatisfactory in 10% of the patients. Twenty-five of the patients withdrew from follow-up and were considered failures. For those who completed the study, successful outcomes at six months were reported in 83% and 68% according to the investigators and patients, re-

spectively. Treatment with automated percutaneous discectomy was considered a success by 44% of the patients at six months. At 12 months, the overall success rate was 37%, and 61% among those followed for one year. The authors concluded that there is no methodologic nuance that can explain away the disappointing results with automated percutaneous discectomy. This study provides Level II therapeutic evidence that automated percutaneous discectomy can be expected to yield favorable outcomes in 44% of patients at six months when compared with chemonucleolysis. It provides Level IV evidence regarding efficacy of automated percutaneous discectomy.

**There is insufficient evidence to make a recommendation for or against the use of automated percutaneous discectomy compared with open discectomy in the treatment of patients with lumbar disc herniation with radiculopathy.**



**Grade of Recommendation: I (Insufficient Evidence)**

Haines et al<sup>12</sup> conducted a prospective randomized controlled trial to estimate the success rates of automated or endoscopic percutaneous discectomy and conventional discectomy in comparable patients and to document the resource consumption of patients treated in these ways. Of the 34 consecutive patients included in the study, 21 were treated with automated percutaneous discectomy or endoscopic percutaneous discectomy and 13 received conventional discectomy. Outcomes were assessed at six months using modified Roland Morris scale, SF-36, and a four dimension outcome assessment matrix developed by the authors that incorporated patient assessment of pain frequency and severity, ability to participate in activities of work and leisure, and analgesic use -- factors commonly used in published studies of treatment for herniated lumbar disc. There was no statistical difference between the two groups for the primary and secondary outcome measures. The success rate for the primary outcome measure was 41% in the automated percutaneous discectomy group and 40% in the conventional discectomy group. Both groups showed significant improvement in the secondary outcome measures at six months. The authors concluded that their trial did not enroll sufficient numbers of patients to reach a definitive conclusion about the efficacy and cost-effectiveness of standard and automated or endoscopic percutaneous discectomy in the treatment of radiculopathy related to lumbar disc herniation. Due to the small sample size, litigation status of subjects, and change in procedures mid-study from automated percutaneous discectomy to endoscopic discectomy with no subgroup analysis, this potential Level II study provides Level III evidence that patients treated with automated or endoscopic discectomy and conventional discectomy have comparable outcomes at six months.

**There is insufficient evidence to make a recommendation for or against the use of plasma disc decompression/nucleoplasty in the treatment of patients with lumbar disc herniation with radiculopathy.**



**Grade of Recommendation: I (Insufficient Evidence)**

Cohen et al<sup>15</sup> reported a retrospective case series to determine the treatment outcomes of 16 consecutive patients with lumbar radicular pain secondary to a herniated disc who underwent nucleoplasty as their primary therapy, with or without intradiscal electrothermal therapy (IDET). Of the 16 patients included in the study, 7 had nucleoplasty alone. Outcomes were assessed at mean follow-up of 8.6 months. The primary indicator of success was a greater than, or equal to, 50% reduction in pain at the latest follow-up visit. Three secondary measures included: reduction in opioid usage, retention on active duty and response to the question: "Given the known outcome, would you repeat the procedure?" Only one of the seven patients in the relevant subgroup reported a greater than, or equal to, 50% reduction in pain, which was the primary outcome measure of success. That patient underwent a two level nucleoplasty procedure. The authors concluded that given their selection criteria, nucleoplasty was not an effective long-term treatment for lumbar radiculopathy. This study provides Level IV therapeutic evidence that nucleoplasty was not an effective treatment option in this small retrospectively reviewed cohort of patients.

Gerszten et al<sup>16</sup> conducted a prospective randomized controlled trial to assess the utility of transforaminal epidural steroid injections versus plasma disc decompression for patients with contained disc herniations who had already failed transforaminal epidural steroid injections. Of the 85 consecutively assigned patients, 45 patients were treated with plasma disc decompression and 40 received transforaminal epidural steroid injections. Outcomes were assessed at six months using VAS, SF-36, ODI, analgesic use, employment status and patient satisfaction. At six months, 29/45 plasma disc decompression patients and 28/40 transforaminal epidural steroid injection patients were available for follow-up. Leg pain VAS scores were significantly reduced from baseline in both treatment groups. Back pain VAS and ODI scores were significantly reduced from baseline in the plasma disc decompression group, while these scores for the transforaminal epidural steroid injection group were not. Leg and back pain VAS scores, and ODI scores differed significantly between the two groups favoring the plasma disc decompression group. The plasma disc decompression group had significantly greater improvement in SF-36 physical function, bodily pain, social function and physical components summary scores compared to the transforaminal epidural steroid injection group. A significantly greater percentage of patients in the plasma disc decompression group were satisfied with care. The number of patients working full- or part-time (69-70%) was similar for both groups. Reduction in the use of analgesics did not differ between the groups.

The authors concluded that patients with radicular pain associated with a contained lumbar disc herniation and treated

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with plasma disc decompression following a failed transforaminal epidural steroid injection receive clinically significant benefits over a repeated course of transforaminal epidural steroid injection. Due to the small sample size, this potential Level II study provides Level III therapeutic evidence that patients with radicular pain associated with a lumbar disc herniation had significantly greater reductions in back and leg pain and improved quality of life scores following treatment with plasma disc decompression compared to a repeated course of failed transforaminal epidural steroid injection. The study provides Level IV therapeutic evidence that select patients with contained disc herniations, not responsive to a transforaminal epidural steroid injection, may experience significant reductions in radicular pain and improved quality of life scores at six months following lumbar plasma disc decompression.



**There is insufficient evidence to make a recommendation for or against the use of plasma disc decompression as compared with transforaminal epidural steroid injections in patients with lumbar disc herniation who have previously failed transforaminal epidural steroid injection therapy.**

**Grade of Recommendation: 0 (Insufficient Evidence)**

Gerszten et al<sup>16</sup> conducted a prospective randomized controlled trial to assess the utility of transforaminal epidural steroid injections versus plasma disc decompression for patients with contained disc herniations who had already failed transforaminal epidural steroid injections. Of the 85 consecutively assigned patients, 45 patients were treated with plasma disc decompression and 40 received transforaminal epidural steroid injections. Outcomes were assessed at six months using VAS, SF-36, ODI, analgesic use, employment status and patient satisfaction. At six months, 29/45 plasma disc decompression patients and 28/40 transforaminal epidural steroid injection patients were available for follow-up. Leg pain VAS scores were significantly reduced from baseline in both treatment groups. Back pain VAS and ODI scores were significantly reduced from baseline in the plasma disc decompression group, while these scores for the transforaminal epidural steroid injection group were not. Leg and back pain VAS scores, and ODI scores differed significantly between the two groups favoring the plasma disc decompression group. The plasma disc decompression group had significantly greater improvement in SF-36 physical function, bodily pain, social function and physical components summary scores compared to the transforaminal epidural steroid injection group. A significantly greater percentage of patients in the plasma disc decompression group were satisfied with care. The number of patients working full- or part-time (69-70%) was similar for both groups. Reduction in the use of analgesics did not differ between the groups.

The authors concluded that patients with radicular pain associated with a contained lumbar disc herniation and treated

with plasma disc decompression following a failed transforaminal epidural steroid injection receive clinically significant benefits over a repeated course of transforaminal epidural steroid injection. Due to the small sample size, this potential Level II study provides Level III therapeutic evidence that patients with radicular pain associated with a lumbar disc herniation had significantly greater reductions in back and leg pain and improved quality of life scores following treatment with plasma disc decompression compared to a repeated course of failed transforaminal epidural steroid injection. The study provides Level IV therapeutic evidence that select patients with contained disc herniations, not responsive to a transforaminal epidural steroid injection, may experience significant reductions in radicular pain and improved quality of life scores at six months following lumbar plasma disc decompression.

**There is insufficient evidence to make a recommendation for or against the use of intradiscal high-pressure saline injection in the treatment of patients with lumbar disc herniation with radiculopathy.**



**Grade of Recommendation: 1 (Insufficient Evidence)**

Kanai et al<sup>17</sup> reported a prospective case series evaluating the efficacy of a modification of minimally invasive percutaneous intradiscal high-pressure injection with saline on persistent pain and disability caused by lumbar disc herniation refractory to conservative care. Of the 25 consecutive patients, 20 had annular tears and 5 did not. MRI was obtained at 3-6 months and clinical outcomes were assessed at six months using VAS and Japanese Orthopaedic Association (JOA) Score. Tear group disc morphology included 100% of the extruded and sequestered discs and 44% of the protruded discs. The tear group had significantly improved VAS and JOA scores at six months compared to the nontear group. The tear group had disappearance of all lumbar disc herniations on follow-up MRI. The nontear group had 56% of the protruded lumbar disc herniations, and no extrusions or sequestrations. The nontear group had a one-month improvement in VAS and JOA scores. There were slight changes in lumbar disc herniation morphology on follow-up MRI between preprocedure and postprocedure images in the nontear group. There were no complications reported in either group. The authors concluded that intradiscal high-pressure injection of saline is associated with good outcomes in patients with lumbar radiculopathy due to lumbar disc herniation. The treatment is more effective in patients with extrusions and sequestrations. This study provides Level IV therapeutic evidence that intradiscal high-pressure injection with saline for the treatment of lumbar radiculopathy due to extruded and sequestered discs reliably provides significant pain relief and recovery at six months follow-up.

**There is insufficient evidence to make a recommendation for or against the use of percutaneous electrothermal disc decompression in the treatment of patients with lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: I (Insufficient Evidence)**

Schafele et al<sup>18</sup> described a prospective case series of 22 patients to determine the effect and magnetic resonance imaging changes of targeted disc decompression using an intradiscal catheter for focal heating of symptomatic lumbar disc herniation resulting in radicular pain. Outcomes were assessed at three, six and 12 months using VAS, SF-36 and patient satisfaction. Disc morphology was assessed at three months. Of the 22 patients included in the study, 16 were available for 12-month follow-up. Significant improvements for back and leg pain scores were present at all follow-up time points. The average VAS back and leg pain improvement was 2.4 and 2.6, respectively. Effect sizes for back and leg pain were 0.9 and 1.0, respectively. Significant improvements for SF-36 bodily pain and physical function domains were present at all follow-up time points. The average improvement in SF-36 bodily pain and physical function scores were 28.8 and 25.4, respectively. Effect sizes for SF-36 bodily pain and physical function were 1.4 and 1.2, respectively. Magnetic resonance imaging follow-up on 15/22 patients at three months showed an average improvement on anteroposterior, transverse and cranio-caudad images of 1.6 mm, 2.6 mm and 2.5 mm, respectively. The authors concluded that targeted disc decompression provided moderate improvement in leg pain and function in the majority of patients with chronic radicular pain. This study provides Level IV therapeutic evidence that the effect size for improvement in pain and function due to disc protrusions is small with this form of treatment.

**Future Directions for Research**

The work group suggests randomized, controlled trials comparing the use of individual interventional spine procedures to a control, preferably blinded, in patients with lumbar disc herniation with radiculopathy. The work group suggests studies be conducted to compare automated percutaneous discectomy and percutaneous endoscopic discectomy with open surgical techniques.

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## What is the role of ancillary treatments such as bracing, electrical stimulation, acupuncture and transcutaneous electrical stimulation (TENS) in the treatment of lumbar disc herniation with radiculopathy?

**There is insufficient evidence to make a recommendation for or against the use of ultrasound or low power laser in the treatment of lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: I (Insufficient Evidence)**

Unlu et al<sup>1</sup> conducted a prospective randomized controlled trial comparing the outcomes of traction, ultrasound (US) and low power laser (LPL) therapies in patients with acute lower back pain and leg pain caused by lumbar disc herniation. Of the 60 consecutive patients included in the study, 20 were assigned to each treatment group: mechanical traction with 35-50% body weight, ultrasound and low power laser. Outcomes were assessed at three months using VAS, ODI, Roland Morris, clinical signs and MRI disc morphology. There were significant reductions in pain and disability scores between baseline and follow-up in all three groups. There was a significant reduction in the size of the disc herniation on MRI after treatment. There was no correlation between clinical findings, pain and disability scores, and change in lumbar disc herniation size. The authors concluded that traction, ultrasound and low power laser therapies were all effective in the treatment of this group of patients with acute lumbar disc herniation. Because the randomization method was not defined, along with the small sample size, this potential Level I study provides Level II evidence that pain and disability due to acute lumbar radiculopathy secondary to lumbar disc herniation may improve over three months in patients treated with low power laser or ultrasound; however, the improvement is equivalent that from mechanical traction with 35-50% body weight. The study provides case series (Level IV) evidence that pain and disability due to acute lumbar radiculopathy secondary to LDH may improve over three months in patients undergoing ultrasound or low power laser treatment. Since the study did not include an untreated control group, the possibility of spontaneous improvement in this group of patients cannot be excluded.

### Future Directions for Research

An RCT with long-term follow-up and validated outcome measures would assist in providing evidence to assess the efficacy of

ancillary treatments in the management of lumbar disc herniation with radiculopathy. When ethically possible, this would be compared to an untreated control group. Other active treatment groups could be substituted as a comparative group.

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## What is the likelihood that a patient with lumbar disc herniation with radiculopathy undergoing medical/interventional treatment would have good/excellent functional outcomes at short (weeks to six months), medium (six months - two years) and long-term (greater than two years)?

**Medical/interventional treatment is suggested to improve functional outcomes in the majority of patients with lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: B**

Saal et al<sup>1</sup> described a retrospective cohort study to determine whether patients with lumbar disc herniation and radiculopathy without stenosis could be treated effectively with aggressive conservative care. Of the 58 patients included in the study, outcomes data were presented on 52 patients at an average follow-up of 31.1 months. Outcomes were assessed using ODI, self-rating scale and whether patients proceeded to surgery. Median Oswestry scores for the excellent and good groups were 16.6 and 20, respectively. Good or excellent long-term outcomes were reported in 50/52 patients (96%). The authors concluded that herniated nucleus pulposus of a lumbar intervertebral disc with radiculopathy can be treated very successfully with aggressive medical/interventional care. This study provides Level II prognostic evidence that patients with lumbar radicular pain due to herniated nucleus pulposus may obtain good or excellent long-term benefits from medical /interventional treatment.

Suri et al<sup>2</sup> reported results from a prospective cohort study including 164 patients to determine whether older adults (aged greater than 60 years) experience less improvement in disability and pain with nonsurgical treatment of lumbar disc herniation than younger adults (less than 60 years). Outcomes were assessed at six months using ODI and VAS. Adjusted mean improvement in older and younger adults was 31 versus 33 ( $p=0.63$ ) for ODI, 4.5 versus 4.5 ( $p=0.99$ ) for leg pain, and 2.4 versus 2.7 for back pain ( $p=0.69$ ). The authors concluded that older adults suffering from subacute radicular pain (less than 12 weeks), demonstrated improvements in disability and pain with nonsurgical treatment that were not significantly different from those seen in younger adults over a six month period. This study provides Level I prognostic evidence that conservative treatment improves pain and disability in the majority of patients regardless of age.

Thomas et al<sup>3</sup> conducted a prospective cohort study to assess health-related quality of life following either lumbar discectomy or medical/interventional care for lumbar disc protrusion causing radiculopathy. Of the 497 patients included in the study, 333

received surgical treatment and 164 were treated with medical/interventional management (excluding injection-based therapy). Outcomes were assessed at 12 months using the North American Spine Society (NASS) Lumbar Spine Follow-Up Questionnaire, Version 2.0; NASS Neurogenic Symptom Score (NSS); and SF-36. The mean baseline score was lower in the surgical group (30.9 medical/interventional versus 25.3 surgical), indicative of greater baseline disability. The scores at follow-up (six months postsurgery for the surgical group compared with 12 months postbaseline for the medical/interventional group) were approximately equivalent (44.6 medical/interventional, 43.8 surgical), suggesting that both groups of patients improved over time. Within the timeframe of the study, however, neither group returned to an age-matched normative NSS (51.6). While the surgical group improved a mean of 4.77 points more (95% CI, 2.08–7.46,  $p=0.001$ ) than the medical/interventional group, this difference was reduced to 0.95 points and became nonsignificant after adjustment for confounders. From the NASS instrument, the outcome “change in pain and disability score (PDS)” was significantly associated with treatment group, with the surgical group experiencing an average score change of 3.46 points greater than the medical/interventional group ( $p=0.04$ ; 95% CI, 0.17–6.75). From the SF-36, the outcomes “change in mental health (MH) score” and “change in mental component score (MCS)” were also significantly associated with treatment group, with the surgical group experiencing an average posttreatment score improvement of 3.01 and 3.52 points greater, respectively, than the medical/interventional group (MH:  $p=0.04$ ; 95% CI, 0.19–5.83; MCS  $p=0.02$ ; 95% CI, 0.48–6.56). Although three secondary outcomes, the NASS PDS, the MH domain of the SF-36, and the MCS of the SF-36 showed statistically significant differences favoring surgical treatment, in each case, the effect sizes were small and were not felt to be clinically significant.

The authors concluded that patients treated either surgically or nonsurgically for lumbar disc protrusion causing radiculop-

athy showed no significant difference in change in NASS NSS scores at follow-up. Clinical outcome of delayed surgery and nonsurgical care may be no different within one year of baseline assessment. This study provides Level II prognostic evidence that change in the neurogenic symptom score, from baseline to follow-up, is not associated with type of treatment received, medical/interventional care or delayed surgery, in this cohort of patients.

**Transforaminal epidural steroid injections are suggested to improve functional outcomes in the majority of patients with lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: B**

Ng et al<sup>4</sup> performed a prospective cohort study assessing the outcome of periradicular infiltration for radicular pain in patients with either spinal stenosis or lumbar disc herniation. Of the patients included in the study, 55 were diagnosed with lumbar disc herniation. Outcomes were assessed at 12 weeks using ODI and Low Back Outcome Score. Of the patients with radicular pain due to lumbar disc herniation, 58% had at least a 10% decrease in their ODI at three months. The average change in ODI at three months was 12%. The authors concluded that periradicular infiltration is a safe procedure that produces short to intermediate term benefit in a significant proportion of patients with radiculopathy. This study provides Level I evidence that there is short- to medium-term functional improvement in patients with radicular pain due to lumbar disc herniation.

Lutz et al<sup>5</sup> described a prospective cohort study to determine the therapeutic value and long-term effects of fluoroscopic transforaminal epidural steroid injections in patients with refractory radicular leg pain due to herniated nucleus pulposus. The study included 69 patients treated with transforaminal epidural steroids injections and followed for an average of 20 months (range: six months – 2.77 years). Outcomes were assessed using the Numeric Rating Scale, patient reported functional level (excellent, good, fair) and patient satisfaction. Successful outcomes were defined as good/excellent self-reported functional outcome and greater than 50% reduction in preinjection Numeric Rating Scale score. Successful outcomes were reported in 75.4% of patients in the medium- to long-term after receiving an average of 1.8 TFESI for the treatment of radicular pain due to lumbar disc herniation. Patient satisfaction with final outcome was 78.3%. A larger proportion of patients who experienced a successful outcome had a baseline duration of symptoms less than 36 weeks as compared to patients with symptoms greater than 36 weeks. The authors concluded that fluoroscopic transforaminal epidural steroid injection is an effective nonsurgical treatment for patients with lumbar disc herniation and radiculopathy in whom more conservative treatment has failed. Because no validated functional outcome measures were utilized, this potential Level I study provides Level II prognostic evidence that transforaminal epidural steroid injections provide good/excellent pain relief and improved level of function by patient report in the medium- and

long-term. Successful outcome occurred after an average of 1.8 injections.

**There is insufficient evidence to make a recommendation for or against the use of spinal manipulation to improve functional outcomes in patients with lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: I (Insufficient Evidence)**

Murphy et al<sup>6</sup> reported results of a prospective cohort study presenting the outcomes of patients with lumbar radiculopathy secondary to lumbar disc herniation treated after a diagnosis-based clinical decision rule. Of the 60 patients included in the study, data of interest were available for a subset of 37 patients. Outcomes were assessed at an average of 14.5 months using the Numeric Rating Scale, Bournemouth Disability Questionnaire and patient self-rating of outcome (excellent, good, fair, poor, none). Good or excellent medium-term results were reported in 80% of patients. The average improvement in Bournemouth Disability Questionnaire scores was 67.4%. Clinically meaningful improvements in disability were seen in 73% of patients. The authors concluded that patients with lumbar radiculopathy due to disc herniation may be treated with integrated chiropractic care and physical therapy using a diagnosis-based clinical decision rule. This study provides Level II prognostic evidence that integrated chiropractic care and physical therapy using a diagnosis-based clinical decision rule achieves favorable long-term outcomes.

#### 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/interventional treatment for lumbar disc herniation with radiculopathy.

#### Recommendation #1:

Future long-term studies of the effects of medical, noninvasive interventions for lumbar disc herniation with radiculopathy should include an untreated control group.

#### Recommendation #2:

Future long-term outcome studies of lumbar disc herniation with radiculopathy should include results specific to each of the medical/interventional treatment methods and present results at multiple follow-up points throughout the study.

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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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**Are there prognostic factors (eg, age, duration or severity of symptoms) that make it more likely that a patient with lumbar disc herniation with radiculopathy will have good/excellent functional outcomes at short (weeks to six months), medium (six months - two years) and long-term (greater than two years) following medical/interventional treatment?**

**Patient age (under 40 years of age) and a shorter duration of symptoms (less than three months) are associated with better outcomes in patients undergoing percutaneous endoscopic lumbar discectomy.**

**Level of Evidence: II**

Ahn et al<sup>1</sup> described a retrospective case series of 45 patients assessing the clinical outcome, prognostic factors and the technical pitfalls of percutaneous endoscopic lumbar discectomy for upper lumbar disc herniation. Outcomes were assessed at a mean of 38.8 months (range: 25-52 months) using the VAS and Prolo scale scores (excellent, good, fair and poor). Based on the Prolo scale, the outcomes were excellent in 21 of 45 patients (46.7%), good in 14 patients (31.1%), fair in six patients (13.3%), and poor in four patients (8.9%). The combined rate of excellent or good outcome at the final follow-up was 77.8%. The mean VAS for radicular pain was  $8.38 \pm 1.22$ , and after operation decreased

to  $2.36 \pm 1.65$  ( $p < 0.0001$ ). The age of the patient and the duration of symptoms were found to be related to outcome. Patients younger than 45 years old tended to obtain better outcomes than older patients (75% vs. 36.4%,  $p < 0.05$ ). An excellent outcome was seen in 65% of patients with shorter symptom durations (less than six months) but was less at 32% (six months or longer) ( $p < 0.05$ ). Age younger than 45 and a lateral disc herniation were significantly related to the outcome. After multivariate analysis, the shorter symptom duration was not associated with outcome because of a strong association with a lateral disc herniation. The authors concluded that patient selection and an anatomically modified surgical technique promote a more successful outcome after percutaneous endoscopic discectomy for upper lumbar disc herniation. This study provides Level II prognostic evidence that transforaminal endoscopic percutaneous discectomy can be effective for treatment of upper lumbar disc herniations at L1-2 and L2-3, and that a younger age (less than 45 years) correlates with a higher likelihood of excellent outcome. Patients with shorter symptom durations (less than six months) may have a better outcome.

Ahn et al<sup>2</sup> reported a retrospective case series of 43 patients

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evaluating the efficacy of endoscopic discectomy for recurrent disc herniations and to determine the prognostic factors affecting surgical outcome. Outcomes were assessed at a mean follow-up of 31 months (range: 24-39 months) using VAS and MacNab criteria. Based on the MacNab criteria, the surgical outcomes were rated as follows: excellent in 12 patients (27.9%), good in 23 (53.5%), fair in six (13.9%) and poor in two (4.7%). Therefore, the percentage of successful outcomes was 81.4%, whereas the rate of improvement was 95.3%. The preoperative mean VAS was 8.72 +/- 1.20, which decreased to 2.58 +/- 1.55 at the final follow up ( $p < 0.0001$ ). Patients' age and duration of symptoms were strongly related with surgical outcome. Patients younger than 40 years showed better outcomes ( $p = 0.036$ ). Cases with duration of symptoms of less than months also had a tendency to have successful outcomes ( $p = 0.028$ ). In consideration of the radiologic findings, the presence of concurrent lateral recess stenosis was the only factor affecting the outcome (lateral recess stenosis was defined as a lateral recess measurement of less than 3 mm). Among six patients with lateral recess stenosis, only two (33.3%) had successful outcomes, whereas 33 (89.2%) of the remaining 37 without lateral recess stenosis had successful outcomes ( $p = 0.007$ ). The authors concluded that percutaneous endoscopic lumbar discectomy is effective for recurrent disc herniation in selected cases. Patients younger than 40 years, patients with duration of symptoms of less than three months, and patients without concurrent lateral recess stenosis tended to have better outcomes. This study provides Level II prognostic evidence that percutaneous endoscopic lumbar discectomy is effective for recurrent disc herniation in selected cases. Patients younger than 40 years, with shorter symptom duration (less than three months) and without concurrent lateral recess stenosis tended to have better outcomes. The work group debated the eligibility of this paper for inclusion in the guideline. Several members opposed its inclusion because the paper evaluated the treatment of recurrent herniations. Proponents pointed out that patients included in the study had a mean pain-free interval after their previous surgery of 63 months, ranging from six to 186 months. Furthermore, the question serving as the basis for the literature review and guideline formulation did not specifically exclude recurrent herniation (although all committee members inferred that the guideline development was intended to address virgin disc herniations).

**It is suggested that the type of lumbar disc herniation does not influence outcomes associated with transforaminal epidural steroid injections in patients with lumbar disc herniation with radiculopathy.**

### Level of Evidence: II/III

Ghahreman et al<sup>3</sup> reported results from a retrospective case series to identify clinical and radiographic features predictive of a

favorable response to transforaminal injection of steroids. Of the 71 patients included in the study, 38 experienced favorable response to transforaminal epidural steroid injection; 33 had no response to transforaminal epidural steroid injection. Outcomes were assessed using the VAS at one month. Favorable response was defined as a reduction of at least 50% in VAS score lasting longer than one month after treatment. No clinical feature was predictive of outcome: duration of symptoms, neurologic symptoms or abnormal neurologic exam. The morphology of the disc herniation was of no significance. The MRI grade of nerve root compression was a significant prognostic factor for the treatment of paracentral and foraminal disc herniations. Pooling the paracentral and foraminal nerve root compression patients into a single group, a favorable response occurred for 75% of the patients with low grade root compression compared to 26% of patients with high grade nerve root compression. The authors concluded that in patients with low grade nerve root compression, there is a 75% favorable response rate to a transforaminal lumbar epidural steroid injection. This study provides Level II prognostic evidence that transforaminal epidural steroid injection is more likely to be successful in patients with MRI evidence of low grade nerve root compression. The clinical features and disc morphology are insignificant.

Choi et al<sup>4</sup> performed a retrospective case-control study of 68 patients to compare MRI findings in patients who responded to transforaminal epidural steroid injections with those who did not. Of the 68 patients, 41 were designated responders and 27 were nonresponders. Outcomes were assessed at a mean follow-up of 3.6 months (range: seven days to 24 months) using the Visual Numeric Scale and patient satisfaction (0-poor, 1-fair, 2-good, 3-very good, 4-excellent). Successful outcome (responders) was defined as patient satisfaction score greater than two and a pain reduction score greater than 50% on the last visit. There was no significant difference between the responders and nonresponders in terms of type, hydration and size of the herniated disc or an association with spinal stenosis. There was a significant difference among nonresponders in terms of the location of the herniated disc and grade of nerve compression. Nonresponders included all six patients with a subarticular disc herniation and two-thirds of the patients with Grade 3 nerve root compression. Grade 3 nerve root compression showed more unsatisfactory results than Grade 1 nerve root compression. The authors concluded that magnetic resonance imaging may have a role in predicting response to transforaminal epidural steroid injections in patients with lumbar disc herniation. Because no functional outcomes were used and the follow-up ranged from seven days to 24 months, this potential Level II study provides Level III prognostic evidence that there was no significant difference between responders and nonresponders with regard to size of disc herniation, association with spinal stenosis, and type of herniation: extrusion, protrusion or sequestration. Radicular leg pain due to a herniated disc in the subarticular region and Grade 3 nerve root compression may not respond to transforaminal epidural steroid injections.

**It is suggested that a higher degree of nerve root compression negatively affects outcomes associated with transforaminal epidural steroid injections in patients with lumbar disc herniation with radiculopathy.**

### Level of Evidence: II/III

Ghahreman et al<sup>3</sup> reported results from a retrospective case series to identify clinical and radiographic features predictive of a favorable response to transforaminal injection of steroids. Of the 71 patients included in the study, 38 experienced favorable response to transforaminal epidural steroid injection; 33 had no response to transforaminal epidural steroid injection. Outcomes were assessed using the VAS at one month. Favorable response was defined as a reduction of at least 50% in VAS score lasting longer than one month after treatment. No clinical feature was predictive of outcome: duration of symptoms, neurologic symptoms or abnormal neurologic exam. The morphology of the disc herniation was of no significance. The MRI grade of nerve root compression was a significant prognostic factor for the treatment of paracentral and foraminal disc herniations. Pooling the paracentral and foraminal nerve root compression patients into a single group, a favorable response occurred for 75% of the patients with low grade root compression compared to 26% of patients with high grade nerve root compression. The authors concluded that in patients with low grade nerve root compression, there is a 75% favorable response rate to a transforaminal lumbar epidural steroid injection. This study provides Level II prognostic evidence that transforaminal epidural steroid injection is more likely to be successful in patients with MRI evidence of low grade nerve root compression. The clinical features and disc morphology are insignificant.

Choi et al<sup>4</sup> performed a retrospective case-control study of 68 patients to compare MRI findings in patients who responded to transforaminal epidural steroid injections with those who did not. Of the 68 patients, 41 were designated responders and 27 were nonresponders. Outcomes were assessed at a mean follow-up of 3.6 months (range: seven days to 24 months) using the Visual Numeric Scale and patient satisfaction (0-poor, 1-fair, 2-good, 3-very good, 4-excellent). Successful outcome (responders) was defined as patient satisfaction score greater than two and a pain reduction score greater than 50% on the last visit. There was no significant difference between the responders and nonresponders in terms of type, hydration and size of the herniated disc or an association with spinal stenosis. There was a significant difference among nonresponders in terms of the location of the herniated disc and grade of nerve compression. Nonresponders included all six patients with a subarticular disc herniation and two-thirds of the patients with Grade 3 nerve root compression. Grade 3 nerve root compression showed more unsatisfactory results than Grade 1 nerve root compression. The authors concluded that magnetic resonance imaging may have a role in predicting response to transforaminal epidural steroid injections in patients with lumbar disc herniation. Because no functional outcomes were used and the follow-up ranged from seven days to 24 months, this potential Level II study provides

Level III prognostic evidence that there was no significant difference between responders and nonresponders with regard to size of disc herniation, association with spinal stenosis, and type of herniation: extrusion, protrusion or sequestration. Radicular leg pain due to a herniated disc in the subarticular region and Grade 3 nerve root compression may not respond to transforaminal epidural steroid injections.

**There is insufficient evidence to make a recommendation regarding the influence of patient age on outcomes associated with medical/interventional treatment for patients with lumbar disc herniation with radiculopathy.**

### Grade of Recommendation: I (Insufficient Evidence)

Choi et al<sup>4</sup> performed a retrospective case-control study of 68 patients to compare MRI findings in patients who responded to transforaminal epidural steroid injections with those who did not. Of the 68 patients, 41 were designated responders and 27 were nonresponders. Outcomes were assessed at a mean follow-up of 3.6 months (range: seven days to 24 months) using the Visual Numeric Scale and patient satisfaction (0-poor, 1-fair, 2-good, 3-very good, 4-excellent). Successful outcome (responders) was defined as patient satisfaction score greater than two and a pain reduction score greater than 50% on the last visit. There was no significant difference between the responders and nonresponders in terms of type, hydration and size of the herniated disc or an association with spinal stenosis. There was a significant difference among nonresponders in terms of the location of the herniated disc and grade of nerve compression. Nonresponders included all six patients with a subarticular disc herniation and two-thirds of the patients with Grade 3 nerve root compression. Grade 3 nerve root compression showed more unsatisfactory results than Grade 1 nerve root compression. The authors concluded that magnetic resonance imaging may have a role in predicting response to transforaminal epidural steroid injections in patients with lumbar disc herniation. Because no functional outcomes were used and the follow-up ranged from seven days to 24 months, this potential Level II study provides Level III prognostic evidence that there was no significant difference between responders and nonresponders with regard to size of disc herniation, association with spinal stenosis, and type of herniation: extrusion, protrusion or sequestration. Radicular leg pain due to a herniated disc in the subarticular region and Grade 3 nerve root compression may not respond to transforaminal epidural steroid injections.

Suri et al<sup>5</sup> described a prospective cohort study examining whether older adults (aged 60 or older) experience less improvement in disability and pain with medical/interventional treatment of lumbar disc herniation than younger adults (under 60 years). Of the 133 patients included in the study, 89 were under 60 years of age, and 44 were aged 60 or older. Outcomes were assessed at six months using ODI, Numeric Pain Scale (Leg) and Numeric Pain Scale (Back). There was no significant difference

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in six month Oswestry Disability Index and back and leg Numeric Pain Scale outcome measures among those younger or older than 60 years who received medical/interventional treatment for radicular pain due to a lumbar disc herniation. Multivariate analysis of sex, race, employment status, prior low back pain, tobacco history, comorbidity, symptom duration of less than 12 weeks, baseline Oswestry score, herniation level, herniation type, herniation location, herniation morphology, adjusted baseline leg pain and adjusted baseline back pain were not significantly related to outcome at six months. The authors concluded that age greater than 60 versus less than 60 did not have an effect on outcomes at six months in patients with lumbar disc herniation who received medical/interventional treatment. This study provides Level I evidence that age has no impact on pain relief from medical/interventional treatment outcomes. Race, sex, employment status, prior low back pain, tobacco history, comorbidity, symptom duration of less than 12 weeks, baseline Oswestry, herniation level, herniation location and herniation morphology are not significantly related to outcome.

### Future Directions for Research

#### General Recommendation:

Future studies assessing medical/interventional treatments for patients with lumbar disc herniation with radiculopathy should include results specific to potential prognostic factors (eg, age, duration or severity of symptoms, clinical exam features, radiographic findings) that may influence medical/interventional treatment outcomes.

#### Specific Recommendation:

Studies examining whether prognosis is affected by the performance of a second or third transforaminal epidural steroid injection.

### Prognostic Factors for Medical/Interventional Treatment Functional Outcomes References

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## What is the cost-effectiveness of medical/interventional treatment options in the management of lumbar disc herniation with radiculopathy?



**The methodology for assessing level of evidence for studies of cost-effectiveness is not well-defined.**

### Medical/Interventional Treatment: Transforaminal Epidural Steroid Injections

Karppinen et al<sup>1,2</sup> performed a randomized controlled trial to test the efficacy of periradicular corticosteroid injection for sciatica. Of the 160 consecutively assigned patients included in the study, 80 patients received a single transforaminal epidural steroid injection and 80 received a single transforaminal injection of normal saline. Outcomes were assessed at two and 12 months using VAS (leg pain), ODI and Nottingham Health Profile. Cost effectiveness was assessed at 12-month follow-up. The study published in December 2001 provided subgroup analyses by type of herniation. For bulging discs, there were no known significant differences between the treatments. For extrusions, there was significant improvement with transforaminal normal saline at six months. For contained disc herniations, leg pain at four weeks and Nottingham Health Profile emotional scores at three months were significantly better for the transforaminal epidural steroid injections compared to transforaminal normal saline. Compared to transforaminal epidural steroid injection at 12 months, it costs \$12,666 more per patient to obtain one painless patient in the transforaminal saline injection group. Conversely, for lumbar disc extrusions, costs in the transforaminal epidural steroid group were \$4,445 more per painless patient. The additional cost at 12 months was the result of the higher rate of surgical treatment.

The authors concluded that transforaminal epidural steroid injection is cost effective for contained herniations, seemingly by preventing surgery, which results in savings at one year of \$12,666 per responder. For extrusions the treatment seems to be counter-effective. In this study there was an increase in surgery for this patient group. The work group concluded that these two studies provide evidence that transforaminal epidural steroid injection is an effective treatment for a proportion of patients with symptomatic lumbar disc herniations, as compared with saline injection, for short-term (four weeks) pain relief. At one year, a single transforaminal epidural steroid injection prevented operations for contained lumbar disc herniations saving \$12,666 per patient responder.

### Future Directions for Research

Participation in long-term outcome registries could provide meaningful data regarding the cost effectiveness of treatment option for patients with radiculopathy from lumbar disc herniation.

### Cost-Effectiveness of Medical/Interventional Treatments References

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## D. Surgical Treatment

### Are there signs or symptoms associated with lumbar radiculopathy that predict a favorable surgical outcome?

It is suggested that patients be assessed preoperatively for signs of psychological distress, such as somatization and/or depression, prior to surgery for lumbar disc herniation with radiculopathy. Patients with signs of psychological distress have worse outcomes than patients without such signs.

**Grade of Recommendation: B**

Chaichana et al<sup>1</sup> performed a prospective cohort study assessing the role of depression and somatization in predicting outcomes following surgery for lumbar disc herniation. Outcomes were assessed for 67 patients at one year using the SF-36, VAS pain scale and Oswestry Disability Index. Patients with preoperative evidence of depression or somatization did poorly compared to the remainder of cohort. The authors concluded that depression and somatization are negative prognostic factors for good outcomes following lumbar discectomy. This study provides Level I prognostic evidence that despite similar improvements in leg pain, patients with preoperative depression or somatization have poorer outcomes as measured by quality of life indices or functional disability scales compared with similar patients without depression or somatization.

Kohlbeck et al<sup>2</sup> conducted a prospective cohort study evaluating the influence of patient-related factors on surgical outcomes. Six-month outcomes were assessed in 48 patients using the SF-36, Hannover Mobility Questionnaire and VAS pain score, in addition to return to work and number of pain locations. The authors concluded that psychosocial variables influence outcomes following discectomy as do examination findings. A positive preoperative straight leg raising sign is a good prognostic sign whereas depression is associated with worse outcomes. With less than 80% follow-up, this potential Level I study provides Level II prognostic evidence that a preoperative straight leg raising sign is associated with better outcomes following decompression for radiculopathy, while preoperative depression is associated with worse outcomes. Outcomes are also affected by work status. Preoperative medical, psychological, educational and economic variables can predict outcomes in many patients.

There is insufficient evidence to make a recommendation for or against the duration of symptoms prior to surgery affecting the prognosis for patients with cauda equina syndrome caused by lumbar disc herniation with radiculopathy.

**Grade of Recommendation: 0 (Insufficient Evidence)**

Ahn et al<sup>3</sup> performed a meta-analysis assessing risk factors for poor outcomes following decompressive surgery for cauda equina syndrome including the influence of timing of decompression. The meta-analysis included 322 patients, primarily from case series, and reported outcomes related to resolution of deficits in bowel or bladder function, motor strength, sensory disturbance and ongoing pain. There was no significant difference in outcomes among patients that had decompression performed at more than 48 hours after onset. There was a significant improvement in resolution of sensory deficit, motor deficit, urinary incontinence and rectal dysfunction when decompression was performed within 48 hours compared with after 48 hours. Specifically, patients who underwent surgery 48 hours or more after onset of cauda equina syndrome, when compared with patients who underwent surgery within 48 hours, were at 2.5 times the risk of continuing to have a urinary deficit ( $p = 0.01$ , CI, 1.19–5.26); 9.1 times the risk of continuing to have a motor deficit ( $p=0.01$ , CI, 2.56–33.33); 9.1 times the risk of continuing to have rectal dysfunction ( $p=0.003$ , CI, 2.13–33.3); and 3.5 times the risk of continuing to have a sensory deficit ( $p=0.005$ , CI, 1.45–8.33). There was no statistically significant difference in outcomes related to continuing pain ( $p=0.338$ ). The authors concluded that there is a significant advantage to treating patients within 48 hours as opposed to later than 48 hours, with improved outcomes in resolution of sensory deficit, motor deficit, urinary function and rectal function. The presence of preoperative chronic low back pain is associated with poorer outcomes in urinary and rectal function. Preoperative rectal dysfunction is associated with a worsened outcome in urinary continence. In addition, older patients are less likely to fully regain sexual function after surgery. This study provides Level IV therapeutic evidence that treating patients with cauda equina syndrome within 48 hours of the onset of symptoms improves outcomes in

resolution of sensory deficit, motor deficit, urinary function and rectal function, but not pain.

Buchner et al<sup>4</sup> described a retrospective case series examining the incidence of urinary functional recovery related to the variables of preoperative symptoms and timing of treatment for cauda equina syndrome. Outcomes for 22 patients were assessed at a mean of three years and nine months relative to recovery of neurological deficits, in particular bladder function. Of 22 patients, 10 had “excellent” results and regained full subjective urinary capacity within the immediate postoperative period. Seven patients had good results and regained urinary continence within the follow-up period. Four patients had “fair” results (not further explained), only one patient had incomplete recovery of bladder function during follow-up with a persisting stress incontinence. No patient underwent urodynamic testing preoperatively, and only seven of 22 had studies postoperatively. In 13 of 17 patients with preoperative motor deficits, recovery was noted during follow-up. Fourteen of 21 patients with preoperative sensory deficits recovered. Thirteen of 15 patients with complete perianal and saddle anesthesia regained perianal sensation postoperatively. A statistically better postoperative outcome was correlated with: female sex ( $p=.03$ ), absence of preoperative complete perianal or saddle anesthesia ( $p=.03$ ) and absence of preoperative radicular motor deficit ( $p=.05$ ). Age, previous lumbar surgery, preoperative sciatica of over six months duration, acute or chronic onset of symptoms, preoperative fecal incontinence or reflex deficit, preoperative uni- or bilateral sciatic pain, time of postoperative recovery of sensory function and time between onset of urinary symptoms and surgery did not have a statistically significant correlation with postoperative outcomes. The authors concluded that there was no difference in clinical outcome of urinary, motor or sensory function relative to the time of the onset of symptoms of cauda equina syndrome and time to surgical decompression. This study provides Level IV therapeutic evidence that the time between the onset of symptoms of cauda equina syndrome and surgical decompression does not affect the subsequent outcome of urinary, motor or sensory function.

McCarthy et al<sup>5</sup> reported results of a retrospective case series identifying factors affecting long-term results in cauda equina syndrome. Outcomes were assessed in 56 patients at a mean of two years using the ODI, SF-36, Low Back Outcome Score and VAS, along with neurological examination and assessment of bladder and sexual dysfunction. There are very little data regarding the 24- to 48-hour window. Five (12%) of the cases were operated within 24 hours of onset, 21 (50%) between 24 and 48 hours, and 16 (38%) were after 48 hours. Of the latter group, three were due to a delay in diagnosis. No significant difference was found in outcome between the three groups. There may be a trend toward improved sphincteric control if decompression is performed within 48 hours. This was not significant after Bonferroni correction and may indicate a Type 2 error. The authors concluded that the symptom duration before operation and the speed of onset do not affect the outcome more than two years after surgery. This study provides Level IV therapeutic evidence that timing of surgery does not influence outcome following decompression for cauda equina syndrome.

Olivero et al<sup>6</sup> described a retrospective case series assess-

ing outcomes of patients operated upon for cauda equina syndrome, focusing on sphincter and motor disturbances. Of the 29 patients participating in a survey regarding motor strength and bladder function at a mean follow-up of five years, 93% regained continence without urinary complaints. The only patient performing intermittent catheterization at follow-up had been operated on within 24 hours after onset of symptoms. There was no statistically significant difference as far as return of bladder function comparing patients operated on less than 48 hours after onset of symptoms versus those operated on after 48 hours ( $p<0.85$ ). Long-term follow-up was available for motor function in 29 patients. Eighty percent of the patients regained normal motor function. There was no difference between patients operated on less than 48 hours versus those operated on greater than 48 hours after onset of symptoms ( $p<0.76$ ). Long-term sensory follow-up was available on 29 patients. Fifty percent regained normal sensory function. No significant difference was observed between the two time periods ( $p<0.7$ ). The authors concluded that over 90%, subjectively, regained normal bladder function. There was no correlation between time-to-surgery and return of bladder, motor, or sensory function. Unilateral exposure was frequently all that was needed to adequately and safely remove these large disc herniations. The authors feel that the data support the practice of continuing to operate on these patients as an emergency as soon as they are diagnosed, unless there are medical or anesthesia contradictions for emergency surgery. This study provides Level IV therapeutic evidence that the vast majority of patients improve following decompression for cauda equina syndrome, with no difference in outcomes between patients operated upon within 24 hours, between 24 and 48 hours, and greater than 48 hours.

**It is suggested that patients be assessed using the preoperative straight leg raising test prior to surgery, as the presence of a positive straight leg raise test correlates with better outcomes from surgery for lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: B**

Kohlbeck et al<sup>2</sup> conducted a prospective cohort study evaluating the influence of patient-related factors on surgical outcomes. Six-month outcomes were assessed in 48 patients using the SF-36, Hannover Mobility Questionnaire and VAS pain score, in addition to return to work and number of pain locations. The authors concluded that psychosocial variables influence outcomes following discectomy as do examination findings. A positive preoperative straight leg raising sign is a good prognostic sign whereas depression is associated with worse outcomes. With less than 80% follow-up, this potential Level I study provides Level II prognostic evidence that a preoperative straight leg raising sign is associated with better outcomes following decompression for radiculopathy, while preoperative depression is associated with worse outcomes. Outcomes are also affected by work status. Preoperative medical, psychological, educational and economic variables can predict outcomes in most patients.

Abramovitz et al<sup>7</sup> performed a prospective comparative study evaluating the indications for and efficacy of lumbar discectomy with or without facetectomy, stratified by preoperative risk factors. Outcomes were assessed at 12 months for the 740 patients included in the study, with three-month data available and presented for 533 patients. Outcomes were defined as either poor or good as defined by the authors. The authors concluded that risk factors based on clinical examination and history can predict outcomes following lumbar discectomy. Facetectomy may lead to a higher incidence of chronic low back pain. Because diagnostic criteria were not provided, this potential Level II study provides Level III prognostic evidence that patients with an absence of back pain, an absence of a work-related injury, presence of a straight leg raising test, distribution of radicular pain including the foot, reflex asymmetry and absence of back pain with straight leg raising have a better prognosis for good outcomes following lumbar discectomy. The use of the operating microscope may decrease the need for facetectomy and improve outcomes in patients at risk for chronic low back pain.

### 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 signs or symptoms associated with lumbar radiculopathy that predict a favorable outcome in surgically treated patients with lumbar disc herniation with radiculopathy.

#### Recommendation #1:

Due to the lack of clinical equipoise regarding the timing of surgical intervention for cauda equina syndrome, a randomized trial is not possible. Currently, the literature is limited to retrospective case series, which are highly subject to bias. Prospective collection of information related to pre-operative functional status and postoperative functional outcomes through the use of a multicenter prospective registry will allow the collection of information that can potentially provide Level II evidence regarding the efficacy of early intervention on improving outcomes in patients with cauda equine syndrome.

#### Recommendation #2:

Collecting data regarding the preoperative characteristics and postoperative outcomes of patients undergoing surgical intervention for lumbar disc herniation using validated outcomes measures would potentially provide Level I. This information could be collected using a prospective national registry.

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## What is the role of epidural steroid injections or selective nerve root blocks in diagnosis or patient selection for subsequent surgical treatment of a lumbar disc herniation with radiculopathy?

No studies were available to directly address this question.

### Future Directions for Research

A prospective study is needed evaluating the relationship between diagnostic nerve root block and the results of surgery in patients with radiculopathy due to lumbar disc herniation.

### Role of ESI or SNRB in Patient Selection for Subsequent Surgery Bibliography

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## When is the optimal timing for surgical intervention?

Surgical intervention prior to six months is suggested in patients with symptomatic lumbar disc herniation whose symptoms are severe enough to warrant surgery. **Earlier surgery (within six months to one year) is associated with faster recovery and improved long-term outcomes.**

Grade of Recommendation: B

Fisher et al<sup>1</sup> performed a prospective comparative study assessing health related quality of life (HRQOL) and the appropriateness of surgery in patients who have undergone elective lumbar discectomy. Of the 82 patients included in the study, 77 were available for follow-up at six months and 71 were available at one year. Outcomes were assessed using the NASS Lumbar Spine Instrument, SF-36 and HRQOL. There was little change between the six month and one year HRQOL scores. Clinically significant improvement (greater than 20%) occurred in 77% of patients according to the neurogenic symptom score (NSS) and 82% according to the pain/disability score (PDS), whereas in 10% of patients the NSS declined, and in 3% the PDS declined. Both of the NASS scores were significantly lower than normative values after six months and one year ( $p=0.001$ ). The SF-36 mental component scale (MCS) at one year was not significantly different from the normative data, which indicated that the MCS had recovered to normal. The mean PCS at six months and one year was significantly less than normative data (both  $p<0.001$ ). Individual scores related to pain and physical status were significantly lower than normative scores. Adjusted for age, when time between symptom onset and surgery was greater than 6.1-9 months, 9.1-12 months and greater than 12 months, the PDS was significantly worse at one year compared with when this period was zero to three months ( $p=0.04$ ,  $0.024$ , and  $0.029$ , respectively). The authors concluded that NSS and PDS showed very significant improvement at six months, with little change between six months and one year after surgery. Scores on the SF-36 scales demonstrated the greatest improvement. Prolonged duration of preoperative symptoms appears to impact negatively on patient outcome. This study provides Level II therapeutic evidence that duration of symptoms greater than six months is associated with less improvement following microdiscectomy when compared to patients with symptom duration less than six months when patients are managed with usual care prior to surgery.

Ng et al<sup>2</sup> reported a prospective case series examining the association between the duration of sciatica and the outcome of lumbar discectomy. Of the 113 patients included in the study, 103 were available for follow-up at one year. Outcomes were assessed using the ODI, Low Back Outcome Score (LBOS), and VAS, along with patients' subjective evaluation of the surgery (excellent, good, fair or poor). The duration of sciatica was related to the change in the ODI score ( $p = 0.005$ ) and the LBOS ( $p = 0.03$ ). If the result was expressed as a coefficient, an increase over one month in the duration of symptoms was associated with a reduction in the change of the ODI score of 0.6%. There was also a weak negative correlation between the duration of the sciatica and the change in the ODI score (Spearman rank correlation coefficient,  $-0.2$ ). No association was found between the VAS score and the duration of sciatica ( $p = 0.09$ ). The authors concluded that patients with sciatica for more than 12 months have a less favorable outcome. No variation was detected in the results for patients operated on in whom the duration of sciatica was less than 12 months. This study provides Level IV therapeutic evidence that the duration of symptoms of sciatic pain (less than four months versus greater than 12 months) prior to surgery significantly and negatively affects outcomes after lumbar discectomy.

Nygaard et al<sup>3</sup> described a prospective case series includ-

ing 132 patients investigating different variables in the duration of symptoms that can be used to predict outcome after lumbar microdiscectomy. Outcomes were assessed at one year using the ODI, VAS and Clinical Overall Score (COS). In patients for whom duration of leg pain was the shortest (less than four months) a significantly lower COS was demonstrated at the follow-up examination compared with patients in whom duration of leg pain was longer ( $> eight months$ ). The authors concluded that the optimal time for surgical treatment of lumbar disc herniation may be two to eight months. There are weak indications for surgery before two months of sustained leg pain, and after eight months the risk of a less favorable clinical result is probably increased. This study provides Level IV therapeutic evidence that delaying surgery for radiculopathy due to lumbar disc herniation for more than eight months is associated with poor outcomes.

Peul et al<sup>4</sup> conducted a prospective study including 283 patients comparing the efficacy of early surgical intervention with a strategy of prolonged conservative care. Outcomes were assessed at 52 weeks using the Roland Morris Disability Questionnaire and the VAS. There was no significant overall difference in disability scores during the first year ( $p = 0.13$ ). Relief of leg pain was faster for patients assigned to early surgery ( $p<0.001$ ). Patients assigned to early surgery also reported a faster rate of perceived recovery (hazard ratio, 1.97; 95% CI, 1.72 to 2.22;  $p<0.001$ ). In both groups, however, the probability of perceived recovery after one year of follow-up was 95%. The authors concluded that the one-year outcomes were similar for patients assigned to early surgery and those assigned to conservative treatment with eventual surgery if needed, but the rates of pain relief and of perceived recovery were faster for those assigned to early surgery. Because of the high crossover rate, with 11% in the early surgery group and 39% in the conservative group, this potential Level II study provides Level III therapeutic evidence that early surgery (6-12 weeks) for lumbar disc herniation provides faster recovery and better pain relief than prolonged conservative measures. There were no long-term outcome differences.

**There is insufficient evidence to make a recommendation for or against urgent surgery for patients with motor deficits due to lumbar disc herniation with radiculopathy.**

**Grade of Recommendation: ⓪ (Insufficient Evidence)**

Ghahreman et al<sup>9</sup> reported a retrospective case series assessing the rate and extent of the recovery of ankle dorsiflexion weakness in patients treated with surgical decompression at various intervals [urgent ( $<10$  days), expeditious ( $<30$  days) and routine ( $>30$  days)]. Outcomes were assessed in 56 patients at 24 months using the Medical Research Council Scale (MRCs). Ankle dorsiflexion power at the long-term follow-up significantly correlated with the preoperative ankle dorsiflexion power ( $p < 0.001$ ). Patients aged 25 to 40 years made a better recovery in the first six weeks after surgery. The authors concluded that the duration of ankle dorsiflexion weakness did not correlate with

the recovery from weakness. This study provides Level IV therapeutic evidence that timing of surgery does not affect recovery of ankle dorsiflexion.

### Future Directions for Research

Future prospective studies should include appropriate subgroup analyses of patients with motor deficits to provide information on the importance of timing of surgery on recovery from motor deficits.

### Surgical Timing References

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## Does discectomy (with or without preoperative medical/interventional treatment) result in better outcomes (clinical or radiographic) than medical/interventional treatment for lumbar disc herniation with radiculopathy?

**Discectomy is suggested to provide more effective symptom relief than medical/interventional care for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgical intervention. In patients with less severe symptoms, surgery or medical/interventional care appear to be effective for both short- and long-term relief.**

### Grade of Recommendation: B

Butterman et al<sup>1</sup> conducted a prospective randomized controlled trial comparing microdiscectomy to epidural steroid injection in a select population of patients with large lumbar disc herniations. Of the 100 patients included in the study, 50 were assigned to each treatment group. Outcomes were assessed at three years using the VAS, Oswestry Disability Index (ODI) and patient satisfaction as determined by patient questionnaire. At one and three months the surgically treated patients had a significant increase in motor function compared to the patients treated with epidural steroid injection. At two years the motor function was not significantly different. The ODI and pain were similar at all time points. The surgical group reported a statistically significant decrease in pain medication usage at one and three months. The surgically treated group expressed 92%-98% satisfaction versus 42%-56% for the epidural steroid injection group. There were 27 patients that failed epidural steroid injections and crossed over to the surgical treatment group. The authors concluded that epidural steroid injection was not as effective as discectomy with regard to reducing symptoms associated with a large herniation of the lumbar disc. This potential Level I study provides Level II therapeutic evidence that patients with large disc herniations, occupying more than 25% of the spinal canal, with symptoms that do not resolve in six weeks, do better with surgery than epidural injections. However, about 50% of patients who have injections will improve.

Weinstein et al<sup>2</sup> reported results of both a prospective comparative study including 743 patients comparing surgical and medical/interventional treatment of lumbar intervertebral disc herniation. The surgically treated group consisted of 528 patients and the medical/interventional group consisted of 191 patients. Outcomes were assessed for up to two years using the SF-36, ODI, patient self-reported improvement, work status and satisfaction. At three months, patients in the surgical group had statistically significant improvement in measures of bodily pain, physical function and Oswestry Disability Index, which narrowed at two years but remained statistically significant. The authors concluded that patients with persistent sciatica from lumbar disc herniation improved in both surgical and medical/interventional treatment groups. This study provides Level

II therapeutic evidence that at up to two years, patients whose symptoms are severe enough to warrant surgery enjoy substantial benefits compared to medical/interventional patients.

Weinstein et al<sup>3,4</sup> conducted a prospective randomized controlled trial including 1244 patients to assess the efficacy of surgery and medical/interventional treatment for lumbar intervertebral disc herniation. In the randomized group there were 245 surgically treated patients and 256 medical/interventional patients. In the observational cohort 521 patients were treated surgically and 222 patients were treated medically/interventionally. Outcomes were assessed at two years and four years using the SF-36, ODI, patient self-reported improvement, work status and satisfaction. There was 30% crossover from the medical/interventional group to the surgical group. At three months, one year, two years and four years the treatment effect in the intent-to-treat analysis favored surgery. Patients in both groups improved over the four-year period. Because of the large numbers of crossover patients, conclusions about the superiority or equivalence of treatments are not warranted based on the intent-to-treat analysis. With less than 80% follow-up and significant crossover, this potential Level I study provides Level II therapeutic evidence that at up to four years, patients whose symptoms are severe enough to warrant surgery enjoy substantial benefits compared to medical/interventional patients.

Osterman et al<sup>5</sup> described a prospective randomized controlled trial assessing outcomes of microdiscectomy compared to conservative treatment for lumbar disc herniation in patients with six to 12 weeks of symptoms. Of the 56 patients included in the study, 28 were assigned to each treatment group and assessed at two years using the ODI and VAS. There were no clinically significant differences between the groups at two-year follow-up. Discectomy was associated with a more rapid recovery. The authors concluded that lumbar microdiscectomy provided only modest short-term benefit over conservative treatment. Due to the small sample size and less than 80% follow-up, this potential Level II study provides Level III therapeutic evidence that lumbar microdiscectomy provides only modest short-term benefit over conservative treatment.

Thomas et al<sup>6</sup> reported results of a prospective study com-

paring surgical and nonoperative management (excluding injection-based therapy) of lumbar disc herniation. Of the 497 patients included in the study, 333 were treated surgically and 164 received “usual care.” Outcomes were assessed at two years using the North American Spine Society Lumbar Spine Follow-Up Questionnaire, Version 2.0 and the SF-36. Improvement in health related quality of life outcomes was the same in both medical and surgical patients, but improvement did not achieve normative population scores. The authors concluded that medical and surgical management produce similar outcomes. With less than 80% follow-up and significant differences in the cohort populations with regard to previous surgery, degree of disability and level of education, this potential Level II study provides Level III therapeutic evidence that patients who choose surgery tend to have greater degrees of disability and pain than those who choose not to have surgery. Patients who choose surgery have a statistically significant and durable improvement in pain and health related quality of life, while functional outcome is similar between the two groups.

**In a select group of patients automated percutaneous lumbar discectomy (APLD) may achieve equivalent results to open discectomy, however, this equivalence is not felt to be generalizable to all patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.**

#### Level of Evidence: II/III

Hermantin et al<sup>7</sup> performed a prospective randomized controlled trial to evaluate the results of endoscopic percutaneous lumbar discectomy compared with open discectomy in patients with lumbar disc herniation and radiculopathy. Thirty patients were assigned to each treatment group, and outcomes were assessed at an average of 30 months based on patient self-evaluation and return to work. There was no difference in outcomes between the groups (93% satisfactory outcome in open discectomy, 97% in endoscopic groups). Mean return to work was 49 days in open patients and 27 days in endoscopically-treated patients. Narcotic use was longer (25 days versus seven days) in patients treated with open discectomy. The authors concluded that in carefully selected patients, endoscopic percutaneous lumbar discectomy is a useful treatment for lumbar disc herniation. Randomization was limited to select patients referred for an operative procedure after non-standardized preoperative conservative care, and only performed in patients who agreed to randomization. The study also failed to utilize validated outcome measures. Because of these limitations, this potential Level I study provides Level II therapeutic evidence that in select patients with lumbar disc herniation and radiculopathy, there is no significant difference in outcome for patients treated with endoscopic discectomy or open discectomy. Patients treated with open discectomy may require longer narcotic use and have a longer period of inability to work.

Haines et al<sup>8</sup> described a prospective randomized controlled trial comparing the efficacy and cost effectiveness of automated

percutaneous lumbar discectomy (APLD) and conventional discectomy. Of the 36 patients included in the study, 21 were treated with APLD and 13 received conventional discectomy. Outcomes were assessed at one year using the Roland Morris Disability Index, SF-36 and the authors’ own matrix. At six months, 41% of APLD patients and 40% of conventional discectomy patients (total 27 patients) achieved successful outcomes. The authors concluded that they had insufficient enrollment to draw conclusions. The patients were not consecutively assigned in this small study, which also had less than 80% follow-up. Because of these limitations, this potential Level II study provides Level III therapeutic evidence that there is no difference in efficacy or cost effectiveness between automated percutaneous lumbar discectomy and open discectomy. However, based on the small sample size, this study lacks statistical significance.

Van Alphen et al<sup>9</sup> reported results from a prospective randomized controlled trial comparing chymopapain and surgery in the treatment of single level disc herniation which failed previous surgery. Of the 151 patients included in the study, 78 were treated with discectomy and 73 with chemonucleolysis. Outcomes were assessed at one year based upon reoperation rate, along with patient- and physician-reported outcomes scales. Based upon reoperation rates, microdiscectomy fared better than chymopapain, with 3% and 25% respectively. There were better patient and doctor reported outcomes following microdiscectomy, with a 25% crossover from chemonucleolysis to the surgical group within one year. The overall success rate in an intent-to-treat analysis showed 73% success with chemonucleolysis and 78% with surgery. The authors concluded that chemonucleolysis is an option in patients who failed conservative treatment. Because there were no validated outcome measures used (with the exception of reoperation rate), this potential Level II study provides Level III therapeutic evidence that microdiscectomy is associated with better outcomes than chymopapain.

**There is insufficient evidence to make a recommendation for or against the use of spinal manipulation as an alternative to discectomy in patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.**

#### Grade of Recommendation: I (Insufficient Evidence)

McMorland et al<sup>10</sup> described a prospective randomized controlled trial comparing manipulation with discectomy in patients with herniated nucleus pulposus with lumbar radiculopathy. Twenty patients were assigned to each treatment group, and outcomes were assessed at one year using the Roland-Morris Disability Index, SF-36, McGill Pain Questionnaire and Aberdeen Back Pain Scale. Sixty percent of patients treated with manipulation and 85% of surgically treated patients improved at 12 weeks. Eight patients who crossed over to surgery had improvements comparable to those treated initially with surgery. There was no difference in the intent-to-treat analysis at one year. The authors concluded that 60% of medically managed patients (ma-

nipulation) responded as well to treatment as surgically treated patients at 12 weeks. Because of the small sample size, along with the significant crossover and lack of as-treated analysis, this potential Level I study provides Level II therapeutic evidence that short-term outcomes in patients with lumbar disc herniation with radiculopathy may be superior in surgically treated patients compared to patients treated with manipulation.

### Future Directions for Research

In the absence of clinical equipoise, it is impractical to demand additional randomized controlled trials comparing surgical intervention to “usual nonoperative care.” Randomized controlled trials focusing on specific alternative treatments may be useful to identify effective alternatives to surgical intervention.

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## Are there clinical circumstances in which lumbar fusion is appropriate in the treatment of lumbar disc herniation with radiculopathy?



**There is insufficient evidence to make a recommendation for or against fusion for specific patient populations with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.**

### Grade of Recommendation: I (Insufficient Evidence)

The best evidence available suggests that outcomes are equivalent in patients with radiculopathy due to lumbar disc herniation whether or not a fusion is performed.

Takehima et al<sup>1</sup> performed a prospective study comparing the clinical and radiographic results of simple disc excision with and without posterolateral fusion in lumbar disc herniation patients. Of the 95 patients included in the study, 44 were treated with simple discectomy and 51 had discectomy with posterolateral fusion. Outcomes were assessed at a mean of 6.6 years for the discectomy group and 7.4 years for the fusion group using the Japanese Orthopedic Association (JOA) Score along with measurement of disc height. Although better results were seen in JOA for the fusion group, this was not statistically significant. Postoperative low back pain was statistically greater in the fusion group when JOA scores were evaluated. When asked, less patients in the fusion group had low back pain than the discectomy group. More patients had recurrent disc herniations in the non-fusion group. Fusion was a longer surgery with more associated blood loss and longer hospital stay. There was statistically more loss of disc height at five years in the non-fusion group and statistically less motion in the fusion group. The authors concluded that there is seldom an indication for primary fusion in the treatment of lumbar disc herniation. This study provides Level III therapeutic evidence that primary fusion is rarely indicated in the treatment of lumbar disc herniation.

Donceel et al<sup>2</sup> reported results of a retrospective comparative study comparing fitness for work after surgery for discectomy, percutaneous discectomy and fusion. Of the 3956 patients included in the study, 3544 were treated with standard discectomy, 126 with percutaneous discectomy and 286 with fusion. Outcomes were assessed at one to three years based upon fitness to work (in the first six months to return to their own work and after six months to any job), as determined by the health care provider. Discectomy combined with fusion was significantly related to poor outcomes, whereas standard discectomy and percutaneous nucleotomy did not differ in their impact on fitness for work. The authors made no recommendations regarding which procedures to perform. Because of the lack of validated outcome measures and the fact that functional groups were not equivalent, this potential Level III study provides Level IV therapeutic evidence that discectomy with fusion is associated with a poor outcome compared to discectomy alone in the treatment of lumbar disc herniation with radiculopathy.

Eie et al<sup>3</sup> described a retrospective comparative study comparing results of discectomy with and without fusion in the treatment of lumbar disc herniation. Of the 259 patients included in the study, 191 were treated with discectomy alone and 68 received discectomy and fusion. Outcomes were assessed at six to seven years based on reports of whether results were satisfactory. At six month follow-up, there was statistically less recurrence of pain in the fusion group. The main source of pain in the discectomy group was recurrent herniations and pseudoarthrosis in the fusion group. At final follow-up the results were slightly better in the fusion group, but the differences were not statistically significant. No statistical difference was found in return work. The authors concluded that fusion is recommended for young patients and discectomy for older patients. Because of the lack of validated outcome measures, this potential Level III study provides Level IV therapeutic evidence that long-term outcomes may be improved with fusion.

Matsunaga et al<sup>4</sup> presented results from a retrospective study comparing results of percutaneous discectomy, discectomy and fusion for patients with simple disc herniations who were manual laborers and athletes. The study included 82 manual laborers and 28 athletes, of which 30 patients were treated with discectomy, 51 with percutaneous discectomy and 29 with discectomy and fusion. Duration of follow-up varied from two years and nine months to seven years and three months, with the percutaneous group having the shortest follow-up and simple discectomy and fusion had similar follow-up profiles. Outcomes were assessed based upon return to work. Only two patients in the athlete group had fusions. For manual laborers there was a higher return to work with a fusion as opposed to discectomy. Time of return to work was shorter in the discectomy group than the fusion group. Lumbar fatigue was the main reason why people did not return to work and that was more commonly found in the simple discectomy patients. The authors concluded that manual laborers should undergo fusion for disc herniations to provide the best chance of return to work. Because there were no validated outcome measures used and the treatment groups were substantially different, this potential Level III study provides Level IV therapeutic evidence that simple discectomy is associated with earlier return to work and competitive sports, however, long-term back pain is improved with fusion in manual laborers.

### Future Directions for Research

Further research is required to identify subgroups of patients who may benefit from the addition of fusion to decompression as a primary procedure.

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**Is there a difference in outcome (clinical or radiographic) or complications between different surgical approaches in the treatment of a lumbar disc herniation with radiculopathy?**

**When surgery is indicated, performance of sequestrectomy or aggressive discectomy is recommended for decompression in patients with lumbar disc herniation with radiculopathy since there is no difference in rates of reherniation.**

**Grade of Recommendation: B**

Barth et al<sup>1,2</sup> reported results of a prospective study comparing microdiscectomy with sequestrectomy in patients with lumbar disc herniation and radiculopathy. Of the 84 patients included in the study, 42 were treated with microdiscectomy and 42 with sequestrectomy. Outcomes were assessed at two years using the SF-36 and VAS, along with reherniation rate, self-rated sensory and motor deficit, and impairment in activities of daily living. Reherniation rates did not differ significantly (discectomy: 12.5%, sequestrectomy: 12.5%). Self-rated assessment de-

teriorated over two years in discectomy patients but improved in sequestrectomy patients. Sequestrectomy yielded superior results in physical and social functioning, use of analgesics and overall outcome at two years. The authors concluded that reherniation rates were similar two years after microdiscectomy or sequestrectomy. However, sequestrectomy was associated with a better functional outcome over time. This study provides Level II therapeutic evidence that there is no significant difference in reherniation rates after microdiscectomy or sequestrectomy, but long-term functional outcome after sequestrectomy is superior. Outcome after microdiscectomy worsens with time.

Schick et al<sup>3</sup> described a prospective comparative study assessing clinical differences between sequestrectomy and microdiscectomy. Of the 200 patients included in the study, 100 were assigned to each treatment group. Outcomes were assessed at an average of 34 months using the ODI and VAS low back and leg pain. At follow-up, 46 sequestrectomy and 45 microdiscectomy patients completed the ODI. At final follow-up, there was no difference in leg or back pain, ODI or recurrence rate between groups. The authors concluded that sequestrectomy was safe with no higher rate of recurrent symptoms. They recommended the technique especially in young people where preservation of disc height is important. With more than 50% of patients lost to follow-up, this potential Level II study provides Level III therapeutic evidence that there is no significant difference between aggressive discectomy and sequestrectomy.

**There is insufficient evidence to make a recommendation for or against the performance of aggressive discectomy or sequestrectomy for the avoidance of chronic low back pain in patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.**

**Grade of Recommendation: I (Insufficient Evidence)**

Barth et al<sup>1,2</sup> reported results of a prospective study comparing microdiscectomy with sequestrectomy in patients with lumbar disc herniation and radiculopathy. Of the 84 patients included in the study, 42 were treated with microdiscectomy and 42 with sequestrectomy. Outcomes were assessed at two years using the SF-36 and VAS, along with reherniation rate, self-rated sensory and motor deficit, and impairment in activities of daily living. Reherniation rates did not differ significantly (discectomy: 12.5%, sequestrectomy: 12.5%). Self-rated assessment deteriorated over two years in discectomy patients but improved in sequestrectomy patients. Sequestrectomy yielded superior results in physical and social functioning, use of analgesics and overall outcome at two years. The authors concluded that reherniation rates were similar two years after microdiscectomy or sequestrectomy. However, sequestrectomy was associated with a better functional outcome over time. This study provides Level II therapeutic evidence that there is no significant difference in

reherniation rates after microdiscectomy or sequestrectomy, but long-term functional outcome after sequestrectomy is superior. Outcome after microdiscectomy worsens with time.

Schick et al<sup>3</sup> described a prospective comparative study assessing clinical differences between sequestrectomy and microdiscectomy. Of the 200 patients included in the study, 100 were assigned to each treatment group. Outcomes were assessed at an average of 34 months using the ODI and VAS low back and leg pain. At follow-up, 46 sequestrectomy and 45 microdiscectomy patients completed the ODI. At final follow-up, there was no difference in leg or back pain, ODI or recurrence rate between groups. The authors concluded that sequestrectomy was safe with no higher rate of recurrent symptoms. They recommended the technique especially in young people where preservation of disc height is important. With more than 50% of patients lost to follow-up, this potential Level II study provides Level III therapeutic evidence that there is no significant difference between aggressive discectomy and sequestrectomy.


**Use of an operative microscope is suggested to obtain comparable outcomes to open discectomy for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.**

**Grade of Recommendation: B**

Henrikson et al<sup>4</sup> conducted a prospective randomized controlled trial evaluating whether microdiscectomy compared with standard discectomy would reduce the length of stay or postoperative morbidity in patients with lumbar disc herniation. Of the 79 patients included in the study, 40 were assigned to receive microdiscectomy and 39 to standard discectomy. Outcomes were assessed at six weeks using the VAS along with consideration of length of hospital stay. No difference was seen in VAS at any time between the two treatments. Operative time was longer in the microdiscectomy patients (48 minutes versus 35 minutes,  $p < .0001$ ). There was no difference in length of stay (5.2 days for microdiscectomy, 4.6 days for standard discectomy). The authors concluded that microdiscectomy does not shorten length of stay or influence postoperative morbidity. This study provides Level I therapeutic evidence that outcomes are similar between microdiscectomy and standard discectomy in patients with lumbar disc herniation.

Tureyen et al<sup>5</sup> described a prospective randomized controlled trial assessing outcomes of microdiscectomy versus macrodiscectomy. Microdiscectomy was defined as a small incision with flavum excision, use of scope and minimal bony removal. Macrodiscectomy consisted of hemilaminectomy with a large incision. Of the 114 patients included in the study, 63 were treated with microdiscectomies and 51 received macrodiscectomies. Outcomes were assessed at 10 days, one month and one year using the VAS along with a neurological examination. VAS improved significantly in both groups. Patients treated with microdiscectomy had smaller incisions and showed a statistically significantly greater improvement in muscle power, lower nar-

cotic use and more returned to work within four weeks than the open discectomy group. Open discectomy took less time. The authors concluded that microdiscectomy allows more return to work and function with less narcotic use than open surgery. Due to concerns about the randomization process, this potential Level I study provides Level II therapeutic evidence that microdiscectomy allows more return to work and function with less narcotic use than open surgery; however, no difference between groups was observed relative to the primary outcome of VAS.

**There is insufficient evidence to make a recommendation for or against the use of medial facetectomy to improve the outcomes for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.** 

**Grade of Recommendation: I (Insufficient Evidence)**

Abramovitz et al<sup>6</sup> performed a prospective comparative study evaluating the indications for and efficacy of lumbar discectomy with or without facetectomy, stratified by preoperative risk factors. Outcomes were assessed at 12 months for the 740 patients included in the study, with three-month data available and presented for 533 patients. Outcomes were defined as either poor or good as defined by the authors. Facetectomy resulted in a 5.8 times greater risk of a “nonradicular” failure. Use of the operating microscope improved outcome in patients with one to two predictors of favorable outcome but worsened outcome in patients with five to six predictors. The authors concluded that risk factors based on clinical examination and history can predict outcomes following lumbar discectomy. Facetectomy may lead to a higher incidence of chronic low back pain. The meaning of these findings relative to the use of the operating microscope is speculative. Because diagnostic criteria were not provided, this potential Level II study provides Level III therapeutic evidence that facetectomy for lumbar disc disease is associated with increased risk of postoperative back pain in comparison to patients treated without facetectomy.




**There is insufficient evidence to make a recommendation for or against the specific surgical approach for far lateral disc herniations in patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.**

**Grade of Recommendation: I (Insufficient Evidence)**

Epstein et al<sup>7</sup> performed a retrospective comparative study to determine and compare indications and benefits of varying surgical approaches to far lateral lumbar disc herniation. Of the 174 patients included in the study, 73 were treated with complete facetectomy, 39 with laminotomy with medial facetectomy and 58 with intertransverse discectomy. Outcomes were assessed at an average of five years using the authors’ own criteria (poor – excellent). No difference in outcomes, defined as the percentage of patients with good or excellent results, was seen between the surgical treatment subgroups. The authors concluded that the three surgical procedures yielded near comparable outcomes in patients with far lateral disc herniations. Because the study did not utilize validated outcome measures and included significant comorbid pathology in addition to disc herniation, this potential Level III study provides Level IV therapeutic evidence that in patients with far lateral disc herniations, differing surgical approaches produce similar outcomes when applied based on individual patient anatomy and comorbidity.

Ryang et al<sup>8</sup> described a retrospective comparative study comparing the efficacy of lateral transmuscular and combined interlaminar/paraisthmic approach to treat lateral lumbar disc herniation. Of the 48 patients included in the study, 28 were treated with a combined interlaminar/paraisthmic approach and 20 with a lateral transmuscular approach. Outcomes were assessed between 18 and 37 months using Ebling criteria and assessing pain in the lower back, along with consideration of radicular, sensory or motor deficits. There was a statistically significant improvement in overall excellent outcomes in the lateral transmuscular group. Even though 100% of back pain resolved in both groups, the patients treated with the combined approach had a 21% incidence of new back pain. The authors concluded that a lateral transmuscular approach leads to overall better outcomes and is the preferred choice at their institution. Because the small study did not utilize validated outcome measures, this potential Level III study provides Level IV therapeutic evidence that a lateral alone approach results in better outcomes than a combined medial and lateral approach in the treatment of far lateral disc herniations.

**There is insufficient evidence to make a recommendation for or against the use of tubular discectomy compared with open discectomy to improve the outcomes for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.** 

**Grade of Recommendation: I (Insufficient Evidence)**

**Note:** For purposes of this guideline, the work group defined tubular discectomy as a discectomy procedure in which a tubular retractor is used to access the herniation. This usually involves making a smaller incision than with a traditional open microdiscectomy procedure and involves direct visualization of the disc and or nerve roots by naked eye and or microscope/loupe magnification.

Arts et al<sup>9</sup> reported results of a prospective randomized controlled trial evaluating tubular versus open discectomy. Of the 328 patients included in the study, 167 were treated with tubular discectomy and 161 with conventional discectomy. Outcomes were assessed at one year using the Roland Morris Disability Questionnaire, VAS and a Likert scale for patient satisfaction. During the entire follow-up period, no statistical difference was found in the Roland Morris Disability scores between the two surgical treatment groups. VAS scores for back and leg pain were statistically superior in the patients treated with conventional discectomy. The authors concluded that the expected treatment benefit of faster recovery after tubular discectomy could not be demonstrated in this study. Pain and recovery rates were superior in the patients treated with conventional discectomy. This study provides Level I therapeutic evidence that conventional discectomy produces similar results to tubular discectomy in functional outcome as assessed by the Roland Morris Disability score. Recovery rate and improvement in back and leg pain are superior in patients treated with conventional discectomy with no differences in hospital stay or blood loss.

**There is insufficient evidence to make a recommendation for or against the application of glucocorticoids, with or without fentanyl for short-term perioperative pain relief following decompression for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.**

#### **Grade of Recommendation: I (Insufficient Evidence)**

Debi et al<sup>10</sup> conducted a prospective randomized controlled trial evaluating the efficacy of topical steroid application to reduce pain following lumbar discectomy. Of the 61 patients included in the study, 26 received application of a methylprednisolone collagen sponge to the decompressed nerve root and 35 received a saline collagen sponge. Outcomes were assessed at one year using the VAS pain scale. Application of the methylprednisolone sponge produces statistically superior pain reduction compared to the saline soaked sponge in the immediate postoperative period but no difference was found at one year. The authors concluded that local application of steroid to the decompressed nerve root produced short-term benefit but no long-term effect. This study provides Level I therapeutic evidence that application of steroids on a collagen sponge to the decompressed nerve root results in short-term (14 day) improvement in back pain, but not leg pain, which may not be clinically relevant. There was no effect at one year.

Masopust et al<sup>11</sup> performed a prospective randomized controlled trial to assess the effectiveness of use of steroids and fentanyl (direct application post decompression) following discectomy. Of the 200 patients included in the study, follow-up data were available for 167 patients. Of these 167 patients, 82 were treated with discectomy alone and 85 received an additional steroid plus fentanyl sponge. Thirty-three patients were lost to

follow-up at 12 months. Outcomes were assessed using the VAS, MRI, assessment of surgical outcome during postoperative days one through seven and assessment of capacity for work. Patients who received steroids tended to have more epidural fibrosis on MRI. There were no differences between patient groups with regard to functional outcome measures in medium and long term outcomes although there were some trends for improved pain control in the first few days after surgery in the group in the steroid group. The authors concluded that there was a correlation between scar and pain postoperatively. Addition of steroid and fentanyl sponge helps towards the end of the first postoperative week, with no significance in the clinical picture, but strong correlation to better outcomes with steroid mix. Because there was no power analysis performed, this potential Level I study provides Level II therapeutic evidence that addition of steroid and fentanyl sponge to the nerve root does not appear to improve outcomes with regard to VAS or work status.

**The application of glucocorticoids, with or without fentanyl, is not suggested to provide long-term relief of symptoms following decompression for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.**

#### **Grade of Recommendation: B**

Debi et al<sup>10</sup> conducted a prospective randomized controlled trial evaluating the efficacy of topical steroid application to reduce pain following lumbar discectomy. Of the 61 patients included in the study, 26 received application of a methylprednisolone collagen sponge to the decompressed nerve root and 35 received a saline collagen sponge. Outcomes were assessed at one year using the VAS pain scale. Application of the methylprednisolone sponge produces statistically superior pain reduction compared to the saline soaked sponge in the immediate postoperative period but no difference was found at one year. The authors concluded that local application of steroid to the decompressed nerve root produced short-term benefit but no long-term effect. This study provides Level I therapeutic evidence that application of steroids on a collagen sponge to the decompressed nerve root results in short-term (14 day) improvement in back pain, but not leg pain, which may not be clinically relevant. There was no effect at one year.

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outcomes although there were some trends for improved pain control in the first few days after surgery in the group in the steroid group. The authors concluded that there was a correlation between scar and pain postoperatively. Addition of steroid and fentanyl sponge helps towards the end of the first postoperative week, with no significance in the clinical picture, but strong correlation to better outcomes with steroid mix. Because there was no power analysis performed, this potential Level I study provides Level II therapeutic evidence that addition of steroid and fentanyl sponge to the nerve root does not appear to improve outcomes with regard to VAS or work status.



**There is insufficient evidence to make a recommendation for or against the application of a fat graft following open discectomy for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.**

### Grade of Recommendation: I (Insufficient Evidence)

Jensen et al<sup>12</sup> performed a prospective randomized controlled trial to evaluate whether a free fat graft at the time of open lumbar discectomy affects clinical outcome or scar formation. Of the 99 patients included in the study, 50 received a free fat graft and 49 did not. Outcomes were assessed at an average of 376 days using the Low Back Pain Rating Scale along with postoperative CT assessment of scar and fat graft and patient global self-assessment. No differences were found in clinical outcomes between the two groups. Patients treated with fat graft had less dural scar but no difference in radicular scarring. Fat graft was visible in 66% of patients. The authors concluded that free fat graft can reduce the degree of dural scarring, but doesn't result in an improved clinical outcome. This study provides Level I therapeutic evidence that adding a fat graft following open discectomy does not improve clinical outcome.

Gambardella et al<sup>13</sup> conducted a prospective randomized controlled trial evaluating the effect of an adipose tissue graft on postoperative scarring and clinical outcomes. Of the 74 patients included in the study, 37 received an adipose graft and 37 did not. Outcomes were assessed at one year using the authors' own postoperative symptoms and fibrosis scores. Clinical and radiologic outcomes were superior in patients treated with the adipose graft. The authors concluded that adipose tissue autograft has a positive effect in preventing postoperative scarring and failed back syndrome. Because of the lack of validated outcomes measures in combination with less than 80% follow-up, this potential Level II study provides Level III therapeutic evidence that placing a fat graft may reduce epidural fibrosis and improve clinical outcome in patients undergoing lumbar discectomy.

**There is insufficient evidence to make a recommendation for or against the addition of Oxiplex/SP gel or ADCON-L to discectomy for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.**

### Grade of Recommendation: I (Insufficient Evidence)

Kim et al<sup>14,15</sup> reported results of a prospective randomized controlled trial comparing discectomy to discectomy plus Oxiplex/SP gel. Of the 34 patients included in the study, 23 received Oxiplex/SP gel. Outcomes were assessed at six months and again at one year using the Lumbar Spine Outcome Questionnaire, along with assessments of leg pain, physical symptoms and function self-assessment scores, MRI and postoperative assessment of scar. MRI showed no difference and no statistical difference was found at any time point. There was a trend towards improvement in leg weakness and radiculopathy scores in the gel group only at the 30-day follow-up. When a post hoc analysis was performed in patients with significant leg pain scores and weakness preoperatively, there was a statistically significant difference in several scores at 30 days. At 12 months, data were available only for 18 patients (11 Oxiplex/SP gel and seven discectomy only). Gel treated patients had less leg pain symptoms ( $p < 0.038$ ) and weakness ( $p < 0.023$ ) than non-gel treated patients. No difference in MRI appearance was found. The authors concluded that patients with a herniated lumbar disc, significant pain and lower extremity weakness reported clinical benefit with the use of Oxiplex/SP Gel. These improvements were maintained over the one-year study. Because of the small sample size, this potential Level I study provides Level II therapeutic evidence that the application of Oxiplex/SP gel results in no significant benefit to the overall patient population. Some select patients with significant leg pain scores and preoperative weakness may experience some short-term (30 day) benefits. Due to the significant (50%) loss to follow-up in this small study, it is impossible to draw any conclusions regarding the one-year results of the study.

Ronnberg et al<sup>16</sup> conducted a prospective randomized controlled trial to assess effectiveness of the addition of ADCON-L to discectomy in reducing scar and improving clinical outcomes. Of the 119 patients included in the study, 60 received ADCON-L. Outcomes were assessed at two years using the VAS, MacNab criteria and review of postoperative MRI. No relationships were found between scar and pain, between ADCON-L use and scar formation, or between ADCON-L use and clinical outcomes. The authors concluded that ADCON-L does not influence scar production and has no impact on scar or pain. This study provides Level I therapeutic evidence that the addition of ADCON-L does not improve outcomes following discectomy.

Petrie et al<sup>17</sup> described a prospective randomized controlled trial assessing whether ADCON-L, when added to single level discectomy, leads to decreased scarring postoperatively on MRI and better clinical outcomes. Of the 213 patients included in the study, 100 received ADCON-L. Outcomes were assessed at six months using the Hopkins scale, along with the degree of

fibrosis as determined on MRI and subjectively by the surgeon in reoperation. Patients treated with ADCON-L showed 23% less extensive scarring and 120% more minimal scarring (although the authors failed to state overall scarring numbers when comparing both groups). Scarring was associated with increased pain, and at reoperation, there was more scarring in the control group. The ADCON-L group did clinically better at follow-up. The authors concluded that ADCON-L is safe and effective in reducing scar and leads to better clinical outcomes. Because the study failed to utilize validated outcome measures or present actual data to support the results and conclusions, this potential Level I study provides Level II therapeutic evidence that suggests that ADCON-L may be safe and effective in reducing scar and leading to better clinical outcomes.

### Future Directions for Research

High quality prospective comparative studies are needed to clarify the utility of the above procedures in patients with radiculopathy due to lumbar disc herniation for which the evidence is insufficient, specifically the:

- application of glucocorticoids, with or without fentanyl, for short term pain relief following decompression;
- performance of aggressive discectomy or sequestrectomy for the avoidance of chronic low back pain;
- use of an operative microscope or medial facetectomy to improve the outcomes;
- use of tubular discectomy compared with open discectomy to improve the outcomes;
- specific surgical approach for far lateral disc herniations;
- application of a fat graft following open discectomy;
- addition of Oxiplex/SP gel application to discectomy; and
- addition of ADCON-L to discectomy.

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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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## What are the medium-term (one to four years) and long-term (greater than four years) results of surgical management of lumbar disc herniation with radiculopathy?

The performance of surgical decompression is suggested to provide better medium-term (one to four years) symptom relief as compared with medical/interventional management of patients with radiculopathy from lumbar disc herniation whose symptoms are severe enough to warrant surgery.

### Grade of Recommendation: B

Butterman et al<sup>1</sup> conducted a prospective randomized controlled trial comparing microdiscectomy to epidural steroid injection in a select population of patients with large lumbar disc herniations. Of the 100 patients included in the study, 50 were assigned to each treatment group. Outcomes were assessed at three years using the VAS, Oswestry Disability Index (ODI) and patient satisfaction as determined by patient questionnaire. At one and three months, the surgically treated patients had a significant increase in motor function compared to the patients treated with epidural steroid injection. At two years the motor function was not significantly different. The ODI and pain were similar at all time points. The surgical group reported a statistically significant decrease in pain medication usage at one and three months. The surgically treated group expressed 92%-98% satisfaction versus 42%-56% for the epidural steroid injection group. There were 27 patients that failed epidural steroid injections and crossed over to the surgical treatment group. The authors concluded that epidural steroid injection was not as effective as discectomy with regard to reducing symptoms associated with a large herniation of the lumbar disc. This potential level I study provides Level II therapeutic evidence that patients with large disc herniations, occupying more than 25% of the spinal canal, with symptoms

that do not resolve in six weeks, do better with surgery than epidural injections. However, about 50% of patients who have injections will improve.

Weinstein et al<sup>2</sup> reported results of a prospective comparative study including 743 patients comparing surgical and medical/interventional treatment of lumbar intervertebral disc herniation. The surgically treated group consisted of 528 patients and the medical/interventional group consisted of 191 patients. Outcomes were assessed for up to two years using the SF-36, ODI, patient self-reported improvement, work status and satisfaction. At three months, patients in the surgical group had statistically significant improvement in measures of bodily pain, physical function and Oswestry Disability Index, which narrowed at two years but remained statistically significant. The authors concluded that patients with persistent sciatica from lumbar disc herniation improved in both surgical and medical/interventional treatment groups. Those who chose operative intervention reported greater improvements than patients who elected nonoperative care. The effects of surgery persisted at two-year follow-up. This study provides Level II therapeutic evidence that surgical treatment of lumbar disc herniation may result in earlier and greater improvement of symptoms compared to medical/interventional treatment.

Weinstein et al<sup>34</sup> conducted a prospective randomized controlled trial including 472 patients to assess the efficacy of surgery and medical/interventional treatment for lumbar intervertebral disc herniation. In the randomized group, there were 232 surgically treated patients. Outcomes were assessed at two years and four years using the SF-36, ODI, patient self-reported improvement, work status and satisfaction. Because of significant crossover, the intent to treat analysis was inconclusive. Recognizing this, the authors presented the “as treated” analysis, which changed the study to a prospective cohort design (as patients were largely able to choose their treatments). In the “as treated analysis,” patients who chose surgery enjoyed clinically and statistically significant benefits in every measure at every time point out to two years. This study provides level II evidence as a prospective cohort study supporting the efficacy of microdiscectomy for patients with symptomatic lumbar disc herniations.

Peul et al<sup>5</sup> conducted a prospective study including 283 patients comparing the efficacy of early surgical intervention with a strategy of prolonged conservative care followed by surgery if necessary. Outcomes were assessed at 52 weeks using the Roland Morris Disability Questionnaire and the VAS. There was no significant overall difference in disability scores during the first year ( $p = 0.13$ ). Relief of leg pain was faster for patients assigned to early surgery ( $p < 0.001$ ). Patients assigned to early surgery also reported a faster rate of perceived recovery (hazard ratio, 1.97; 95% CI, 1.72 to 2.22;  $p < 0.001$ ). In both groups, however, the probability of perceived recovery after one year of follow-up was 95%. The authors concluded that the one-year outcomes were similar for patients assigned to early surgery and those assigned to conservative treatment with eventual surgery if needed, but the rates of pain relief and of perceived recovery were faster for those assigned to early surgery. Because of the high crossover rate, with 11% in the early surgery group and 39% in the conservative group, this potential Level II study provides Level III therapeutic evidence that early surgery (6-12 weeks) for lumbar disc herniation provides faster recovery and better pain relief than prolonged conservative measures. There were no long-term outcome differences.



**Surgical decompression provides long-term (greater than four years) symptom relief for patients with radiculopathy from lumbar disc herniation whose symptoms warrant surgery. It should be noted that a substantial portion (23-28%) of patients will have chronic back or leg pain.**

### Level of Evidence: IV

Bakhsh et al<sup>6</sup> described a retrospective case series assessing the long-term outcome of lumbar disc surgery on relief of sciatic leg pain. Of the 68 patients treated with surgical decompression including curettage, 54 were pain free in the immediate postoperative period. Outcomes were assessed by a single physician specifically evaluating sciatic pain at 10 years for those 54 pa-

tients. Though a large percentage (79%) of patients were “pain free” initially postoperatively, five of the 54 had recurrence of their pain within one year, an additional 14 had recurrent sciatic pain by five years, and an additional 20 by 10 years. Only 27% had relief of their original pain lasting 10 years. The authors concluded that significant pain relief from surgery was obtained in a majority of patients but for a substantial portion of these, symptoms did recur. This study provides Level IV therapeutic evidence that significant pain relief from surgery can be obtained in a majority of patients but for a substantial portion of these, symptoms do recur.

Findlay et al<sup>7</sup> reported results of a retrospective case series evaluating long-term outcome of lumbar microdiscectomy for herniated nucleus pulposus with sciatica. Of the 88 patients included in the study, 90% (79/88) were followed for 10 years. Outcomes were assessed using MacNab criteria and the Roland Morris Disability Questionnaire, along with a measurement of patient satisfaction. Using MacNab’s definition of “success and/or failure,” in comparing six month results versus results at 10 years, 75% of patients were “unchanged,” 18% deteriorated one grade (of 4), and 7% improved a grade or more. Success was 91% at six months and 83% at 10 years. Four patients (6%) required additional surgery. Results from the MacNab and Roland Morris studies were equivalent. The authors concluded that there is no significant deterioration of the high success rate of lumbar microdiscectomy at long-term follow-up. This study provides Level IV therapeutic evidence that early microdiscectomy results hold up quite well at 10 years with only 17% unsatisfactory (fair and poor) results versus 9% (fair, poor) at six months.

Loupasis et al<sup>8</sup> described a retrospective case series of 109 patients assessing the effects of conventional discectomy surgery for lumbar disc herniation over an extended period of time to examine factors that might correlate with unsatisfactory results. Outcomes were assessed at an average of 12.2 years using the ODI and modified Stauffer–Coventry’s evaluating criteria. Late results were satisfactory in 64% of patients. The mean ODI score was 18.9. Of the 101 patients who had primary procedures, 28% still complained of significant back or leg pain. Sixty-five percent of patients were very satisfied with their results, 29% were satisfied, and six percent were dissatisfied. The reoperation rate was 7.3% (eight patients), about one-third of which was due to recurrent disc herniation. Socio-demographic factors predisposing to unsatisfactory outcome included female gender, low vocational education and jobs that were significantly physically strenuous. Disc space narrowing was common at the level of discectomy, but was without prognostic significance. This study provides Level IV therapeutic evidence that the majority of patients treated with discectomy have satisfactory long-term results, however, 28% still had significant low back and leg pain for the long term.

Padua et al<sup>9</sup> presented a retrospective case series evaluating the outcome of standard discectomy surgery for disc herniation by means of an analysis of long-term results in a large number of treated patients. Of the 150 patients included in the study, long-term data were available on 120 patients. Outcomes were assessed at an average 12.1 years using the Roland Morris Disability Questionnaire along with patient satisfaction with surgery and presence of peripheral pain. The overall results of the Roland Morris Disability Questionnaire showed a score of less

than 5 in 107 of the 120 patients. All but 23.4% of the patients were entirely satisfied, while only 4.2% were unsatisfied. Leg pain also was considered a rare condition. The authors concluded that the standard procedure for disc herniation is still a good treatment, given its safety and simplicity, unless there are elective indications for microinvasive techniques. Furthermore, the authors concluded that one of the most important predictors for a good outcome in disc herniation is the indication for surgery, and further studies must be conducted in order to define indications. This study provides Level IV therapeutic evidence that discectomy yields good long-term (10-15 years) results in the treatment of lumbar disc herniation with radiculopathy. However, the results are difficult to interpret.

Porchet et al<sup>10</sup> reported results of a retrospective comparative study evaluating long term outcomes for surgery for foraminal and extraforaminal lumbar disc herniation. There were 202 patients included in the study with one patient having surgery at L1-2, 9 patients at L2-3, 48 patients at L3-4, 86 patients at L4-5 and 58 patients at L5-S1. Outcomes were assessed at 50 months using MacNab criteria, along with reported complications and recurrent herniation. Good to excellent results were achieved in 73% and fair and poor results in 27% of patients. There were 11 recurrent lumbar disc herniations. The authors concluded that far lateral discectomy is a good option for foraminal and extraforaminal lumbar disc herniation. Due to the lack of adequate subgroup analysis, this potential Level III study provides Level IV therapeutic evidence that far lateral discectomy has relatively good long-term (50 months) results.

Wenger et al<sup>11</sup> described a retrospective case series reporting the late outcome of 104 consecutive patients after Williams' sequestrectomy. Outcomes were assessed at an average of 5.3 years comparing pre- and postoperative patient reported symptoms, classifying outcomes in one of five categories (excellent, good, fair, unchanged, worse). Success rates, including excellent, good, and fair results, were 92.5%, 94.7%, and 93.3% for lumbalgia, radicular pain, and neurological dysfunction, respectively. The authors concluded that sequestrectomy alone is a safe operative modality and should be used whenever possible. As demonstrated in this series with a long follow-up time, the results are as favorable as or better than results after standard microsurgical lumbar discectomy with curettement of the interspace. This study provides Level IV therapeutic evidence that sequestrectomy is effective treatment for lumbar disc herniation at five-year follow-up.

### 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 medium- and long-term results for surgical management of lumbar disc herniation with radiculopathy.

#### Recommendation #1:

Follow-up of patients included in the studies describing medium-term outcomes would provide information on long-term treatment.

#### Recommendation #2:

Future long-term studies of the effects of surgical interventions

for lumbar disc herniation with radiculopathy should include an untreated control group, when ethically feasible.

#### Recommendation #3:

Future long-term outcome studies of lumbar disc herniation with radiculopathy should include results specific to each of the surgical treatment methods.

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**Is there a difference in outcome or complications between different sites of service for the surgical management of a lumbar disc herniation with radiculopathy?**



**No studies were available to address this question.**

#### **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 outcomes or complications between different sites of service for the surgical management of lumbar disc herniation with radiculopathy.

#### **Recommendation #1:**

Participation in surgical registries would allow for comparison of clinical outcomes across sites of service.

#### **Recommendation #2:**

Assuming that the surgical procedure performed is the same, administrative data could be examined to assess complication and readmission rates.

#### **Comparison of Surgical Outcomes/Complications by Site-of-Service Bibliography**

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## E. Value of Spine Care

### What is the cost-effectiveness of surgical treatment options in the management of lumbar disc herniation with radiculopathy?



The cost effectiveness of microdiscectomy for lumbar disc herniation has been evaluated by several authors using different methodologies and from different perspectives (patient, payer, society). Overall, the committee felt that there was strong and consistent evidence supporting the cost effectiveness of microdiscectomy for patients with symptomatic lumbar disc herniation who desired surgical treatment. While criteria for judging the methodological quality of cost effectiveness studies have been suggested, the committee had great difficulty in applying these criteria to the available literature regarding lumbar disc herniation. This difficulty was a result of a combination of factors including the relative immaturity of the rating methodology, the relative inexperience of the committee members in evaluating cost effectiveness studies, and the different methodologies employed by the authors of the primary studies.

Tosteson et al<sup>1</sup> have performed cost effectiveness studies using the SPORT cohort at two and four years. They estimated treatment costs based on both hospital charges as well as Medicare reimbursement information for hospitals and medical staff. Ongoing costs were assessed using surveys at follow-up visits regarding medication use, physical therapy, injections, and other interventions. Indirect costs were estimated using a standard human capital approach based on patient recall of time missed from work, patient estimated wage loss, and caretaker expense. While this analysis captured expenses from the payer and from the patient, and captured the expenses associated with lost productivity from the patient's perspective, it did not account for the societal cost of lost productivity. This is a feature of the human capital approach and is not unique to these studies. Changes in health status were measured using the EQ5D health utility measure. At two years, lumbar discectomy compared to non-surgical management was felt to be cost effective with a cost per QALY of between \$35,000 and \$70,000 depending upon the payer. The same cohort of patients was followed for an additional two years, and because the benefits of surgery were durable, the cost per QALY of surgical intervention dropped to approximately \$20,000 per QALY.

Hansson et al<sup>2</sup> performed a similar analysis using a prospective registry of 1822 workers who were on medical disability for at least 28 days. Ninety-two of these workers were treated with surgery for sciatica due to lumbar disc herniation and the authors compared this group to a closely matched comparison cohort based on demographic as well as pain diagram and pain severity ratings. They followed both cohorts for a two year period and documented change in health status using a variety of

metrics including the EQ5D. They were able to track all health care costs for the study duration and used a standard human capital approach to estimate indirect costs. While the costs for the surgical cohort were significantly higher than in the nonsurgical cohort, improvement in symptoms following surgery was dramatic and resulted in a large change on the measured QALY. These authors estimated the cost per QALY of surgical intervention to be \$4,648.00 and reported that surgical treatment had better cost utility than nonsurgical treatment.

Malter et al<sup>3</sup> used previously published outcomes information concerning lumbar disc surgery from several studies looking at microdiscectomy as well as chemonucleolysis and calculated costs based on hospital reimbursements (a payer perspective analysis). This group found that even when indirect costs of persistent disability are ignored, microdiscectomy was cost effective with an estimated cost per QALY of \$12,000-\$30,000 depending upon the payer.

#### Future Directions for Research

Participation in long-term outcome registries could provide meaningful data regarding the cost effectiveness of treatment option for patients with radiculopathy from lumbar disc herniation.

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## Does the surgical approach for lumbar disc herniation with radiculopathy have an effect on the value of treatment?



**No studies were available to address this question.**

### Future Directions for Research

Participation in long-term outcome registries could provide meaningful data regarding the effect of surgical approach on the value of treatment.

## Does the site-of-service chosen for surgical management of lumbar disc herniation with radiculopathy affect the value of treatment?



**No studies were available to address this question.**

### Future Directions for Research

Participation in long-term outcome registries could provide meaningful data regarding the effect of site-of-service on the value of surgical treatment.

# V. Appendices

## A. Acronyms

ADL	activities of daily living
APLD	automated percutaneous lumbar discectomy
CI	confidence interval
COS	clinical outcome score
CT	computed tomography
DISQ	low back disability questionnaire
EBM	evidence-based medicine
EDBR	extensor digitorum brevis reflex
EHL	extensor hallucis longus
EMG	electromyography
ESI	epidural steroid injection
GROC	Global Rating of Change
HRQOL	health-related quality of life
IDET	intradiscal electrothermal therapy
JOA	Japanese Orthopaedic Association
LBOS	low back outcome score
LPL	low power laser
LR	likelihood ratio
MCS	mental component score
MEP	motor evoked potentials
MH	mental health
MR	magnetic resonance
MRCS	Medical Research Council Scale
MRI	magnetic resonance imaging
NASS	North American Spine Society
NPV	negative predictive value
NSAIDs	nonsteroidal anti-inflammatory drugs
NSS	neurogenic symptom score
ODI	Oswestry Disability Index
PDS	pain and disability score
PPV	positive predictive value
QALY	quality adjusted life years
QST	quantitative sensory testing
RCT	randomized controlled trial
SLR	straight leg raise
SEP	somatosensory evoked potentials
SNRB	selective nerve root block
TENS	transcutaneous electrical nerve stimulation
TNF	tumor necrosis factor
US	ultrasound
VAS	visual analog scale

## B. Levels of Evidence for Primary Research Questions<sup>1</sup>

Types of Studies				
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	<ul style="list-style-type: none"> <li>High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals</li> <li>Systematic review<sup>2</sup> of Level I RCTs (and study results were homogenous<sup>3</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>High quality prospective study<sup>4</sup> (all patients were enrolled at the same point in their disease with <math>\geq 80\%</math> follow-up of enrolled patients)</li> <li>Systematic review<sup>2</sup> of Level I studies</li> </ul>	<ul style="list-style-type: none"> <li>Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard)</li> <li>Systematic review<sup>2</sup> of Level I studies</li> </ul>	<ul style="list-style-type: none"> <li>Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses</li> <li>Systematic review<sup>2</sup> of Level I studies</li> </ul>
Level II	<ul style="list-style-type: none"> <li>Lesser quality RCT (eg, <math>&lt; 80\%</math> follow-up, no blinding, or improper randomization)</li> <li>Prospective<sup>4</sup> comparative study<sup>5</sup></li> <li>Systematic review<sup>2</sup> of Level II studies or Level I studies with inconsistent results</li> </ul>	<ul style="list-style-type: none"> <li>Retrospective<sup>6</sup> study</li> <li>Untreated controls from an RCT</li> <li>Lesser quality prospective study (eg, patients enrolled at different points in their disease or <math>&lt; 80\%</math> follow-up)</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>	<ul style="list-style-type: none"> <li>Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard)</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>	<ul style="list-style-type: none"> <li>Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>
Level III	<ul style="list-style-type: none"> <li>Case control study<sup>7</sup></li> <li>Retrospective<sup>6</sup> comparative study<sup>5</sup></li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>	Case control study <sup>7</sup>	<ul style="list-style-type: none"> <li>Study of non-consecutive patients; without consistently applied reference “gold” standard</li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>	<ul style="list-style-type: none"> <li>Analyses based on limited alternatives and costs; and poor estimates</li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>
Level IV	Case series <sup>8</sup>	Case series	<ul style="list-style-type: none"> <li>Case-control study</li> <li>Poor reference standard</li> </ul>	Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (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.

*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*

## 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.

## D. Linking Levels of Evidence to Grades of Recommendation

Grade of Recommendation	Standard Language	Levels of Evidence	
A	Recommended	Two or more consistent Level I studies	
B	Suggested	One Level I study with additional supporting Level II or III studies	Two or more consistent Level II or III studies
C	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 consistent studies.			

## 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 research 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 Science. 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 medical 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 current best research evidence available. Research staff will maintain a search history in EndNote for future use or reference.

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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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