

Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain

An Evidence-Based Clinical Practice Guideline From the American Pain Society

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Study Design. Clinical practice guideline.

Objective. To develop evidence-based recommendations on use of interventional diagnostic tests and therapies, surgeries, and interdisciplinary rehabilitation for low back pain of any duration, with or without leg pain.

Summary of Background Data. Management of patients with persistent and disabling low back pain remains a clinical challenge. A number of interventional diagnostic tests and therapies and surgery are available and their use is increasing, but in some cases their utility remains uncertain or controversial. Interdisciplinary rehabilitation has also been proposed as a potentially effective noninvasive intervention for persistent and disabling low back pain.

Methods. A multidisciplinary panel was convened by the American Pain Society. Its recommendations were based on a systematic review that focused on evidence from randomized controlled trials. Recommendations were graded using methods adapted from the US Preventive Services Task Force and the Grading of Recommendations, Assessment, Development, and Evaluation Working Group.

Results. Investigators reviewed 3348 abstracts. A total of 161 randomized trials were deemed relevant to the recommendations in this guideline. The panel developed a total of 8 recommendations.

Conclusion. Recommendations on use of interventional diagnostic tests and therapies, surgery, and interdisciplinary rehabilitation are presented. Due to important trade-offs between potential benefits, harms, costs, and burdens of alternative therapies, shared decision-making is an important component of a number of the recommendations.

Key words: low back pain, guideline, evidence-based, surgery, fusion, laminectomy, discectomy, injection, radiofrequency denervation, intradiscal electrothermal therapy, botulinum toxin, interdisciplinary therapy, multidisciplinary therapy, spinal cord stimulation. **Spine 2009; 34:1066–1077**

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Low back pain is extremely common.^{1,2} Most patients with acute low back pain improve substantially over the first month.³ After the first month, improvements are less pronounced and eventually taper off. In a small minority of patients, back pain is persistent and disabling. Among patients who seek medical care for their low back pain, up to one-third report back pain of at least moderate intensity 1 year after an acute episode, and 1 in 5 reports substantial limitations in activity.⁴ Five percent of the people with back pain disability are estimated to account for 75% of the costs associated with low back pain.⁵

A previous guideline sponsored by the American Pain Society (APS) and the American College of Physicians (ACP) focused on the evaluation and management of low back pain in primary care settings.⁶ It recommends several pharmacologic and nonpharmacologic therapies (spinal manipulation, exercise therapy, cognitive-behavioral therapy, progressive relaxation, yoga, massage, and acupuncture) as moderately effective treatment options.

Management of patients with persistent and disabling back pain despite use of recommended therapies remains a challenge. A number of injections, other interventional therapies, and surgeries were not addressed in the previous APS/ACP guideline, but are also available for treatment of back pain. In general, these therapies are considered to be more invasive and attempt to target specific back structures or spinal abnormalities thought to be the source of back pain, such as back muscles or soft tissues, degenerated facet or sacroiliac joints, spinal canal stenosis, and degenerated or herniated intervertebral discs. Several invasive diagnostic tests are also available. The purpose of such tests is to evaluate potential anatomic sources for back pain, which could theoretically identify patients more likely to benefit from various interventions.

Rates of certain interventional and surgical procedures for back pain are rising.⁷⁻⁹ However, it is unclear if methods for identifying specific anatomic sources of back pain are accurate, and effectiveness of some interventional therapies and surgery remains uncertain or controversial. In addition, interventional and surgical therapies do not address the psychological and environmental factors that are often associated with chronic low back pain (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>).^{10,11} Interdisciplinary rehabilitation (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>), on the other hand, does not target a specific anatomic source of back pain, but incorporates psychological interventions and exercise therapy, and could be an alternative treatment option for persistent and disabling symptoms.

The purpose of this guideline is to present evidence-based recommendations for use of invasive diagnostic tests, interventional therapies, surgery, and interdisciplinary rehabilitation for nonradicular low back pain, radiculopathy with herniated disc, and symptomatic spinal stenosis (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>).

■ Materials and Methods

Panel Composition

In 2004, the APS convened a multidisciplinary panel of 23 experts to formulate low back pain recommendations (panel members are listed at the end of this manuscript). Three co-chairs (J.L., R.R., and D.O.) were selected to lead the panel. In 2007, 3 additional experts in the areas of interventional therapies or surgery were invited to participate in development of recommendations (M.B., D.R., and W.S.).

Target Audience and Scope

The target audience for this guideline is all clinicians caring for patients with low (lumbar) back pain of any duration, either with or without leg pain. Although the target patient population is adults with persistent (at least subacute in duration) low back pain, we included trials of any of the interventions of interest for low back pain of any duration. The guideline is not intended to guide evaluation or management of patients with

back pain associated with major trauma, tumor, metabolic disease, inflammatory back disease, fracture, dislocation, major instability, or major deformity; patients with progressive or severe neurologic deficits; children or adolescents with low back pain; pregnant women, patients with low back pain from sources outside the back (nonspinal low back pain), and thoracic or cervical spine pain.

Funding and Conflicts of Interest

The guideline was sponsored by APS. Funding was provided by APS. The guideline was approved by APS, but the content and publication of the guideline is solely the responsibility of the authors and panel members. All panelists were required to disclose all potential conflicts of interest within the preceding 5 years at all face-to-face meetings and before submission of the guideline for publication, and to recuse themselves from votes if significant conflicts were present. Potential conflicts of interest of the authors and panel members are listed at the end of the guideline.

Evidence Review

This guideline is based on a systematic review¹² summarized in 2 background papers by Chou *et al*^{13,14} in this issue that were conducted at the Oregon Evidence-Based Practice Center and commissioned by APS to inform the guideline. The panel developed the key questions, scope, and inclusion criteria used to guide the evidence review. Literature searches were conducted through July 2008. The evidence report discusses the evidence for invasive diagnostic tests, interdisciplinary therapy, and intrathecal therapy,¹² and the 2 background papers summarize the evidence for other interventional therapies and surgery addressed in the guideline.^{13,14}

The background papers provide details about the methods used for the systematic evidence review.^{13,14} Briefly, for recommendations on use of different therapies, the guideline is based on evidence from all English-language randomized controlled trials of nonpregnant adults (age >18 years) with low back pain (alone or with leg pain) of any duration that evaluated a target interventional therapy or surgery, and reported at least one of the following outcomes: back-specific function, general health status, pain, work disability, patient satisfaction, or an overall assessment of treatment benefit. For invasive diagnostic tests, studies assessing diagnostic accuracy are difficult to interpret because there is no reference standard for reliably identifying specific anatomic sources of low back pain. Therefore, the guideline based its recommendations for invasive diagnostic tests on studies that assessed rates of positive tests in persons without low back pain and studies that evaluated effects of invasive diagnostic tests on clinical outcomes.¹⁵

Investigators reviewed 3348 abstracts identified from searches on electronic databases, reference lists, and suggestions from expert reviewers.¹² A total of 161 randomized trials relevant to the recommendations in this guideline were included in the full evidence report.¹²

Grading of the Evidence and Recommendations

The evidence for individual diagnostic tests and interventions was first evaluated by the APS panel using a system adopted from the US Preventive Services Task Force for grading strength of evidence (Table 1), estimating magnitude of benefits (Table 2), and assigning summary ratings (Table 1).¹⁶ After formulating the recommendations, which encompassed evidence from multiple bodies of evidence and interventions, the

Table 1. Criteria for Grading the Strength of Evidence and Making Treatment Recommendations*

Recommendation		Strength of Evidence	
A	The panel strongly recommends that clinicians consider offering the intervention to eligible patients. The panel found good evidence that the intervention improves health outcomes and concludes that benefits substantially outweigh harms.	Good	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality trials).
B	The panel recommends that clinicians consider offering the intervention to eligible patients. The panel found at least fair evidence that the intervention improves health outcomes and concludes that benefits moderately outweigh harms, or that benefits are small but there are no significant harms, costs, or burdens associated with the intervention.	Fair	Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the No. quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least 1 higher-quality trial of sufficient sample size; 2 or more higher-quality trials with some inconsistency; at least 2 consistent, lower-quality trials, or multiple consistent observational studies with no significant methodologic flaws).
C	The panel makes no recommendation for or against the intervention. The panel found at least fair evidence that the intervention can improve health outcomes, but concludes that benefits only slightly outweigh harms, or the balance of benefits and harms is too close to justify a general recommendation.		
D	The panel recommends against offering the intervention. The panel found at least fair evidence that the intervention is ineffective or that harms outweighs benefits.	Poor	Evidence is insufficient to assess effects on health outcomes because of limited no. or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.
I	The panel found insufficient evidence to recommend for or against the intervention. Evidence that the intervention is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.		

*Adapted from methods developed by the US Preventive Services Task Force.¹⁶

APS panel assigned an overall grade using methods adapted by the ACP from the Grading of Recommendations, Assessment, Development, and Evaluation Working Group (Table 3).¹⁷ Each recommendation received a separate grade for the strength of the recommendation (strong or weak) and for the quality of evidence (high, moderate, or poor). In general, a strong recommendation is based on the panel’s assessment that potential benefits of following the recommendation clearly outweigh potential harms and burdens. Given the available evidence, clinicians and patients would generally choose to follow a strong recommendation. A weak rating is based on more closely balanced benefits to harms or burdens, or weaker evidence. Decisions to follow a weak recommendation could vary depending on specific clinical circumstances or patient prefer-

ences and values. For grading the quality of a body of evidence that supports a recommendation, we considered the type, number, size, and quality of studies; strength of associations or effects; and consistency of results between studies.¹⁷ This guideline considered interventions to have “proven” benefits only when they were supported by at least fair-quality evidence from randomized trials and were associated with at least moderate benefits. The ratings for individual interventions discussed in this guideline are summarized in Tables 4 and 5.

Guideline Development Process

The guideline panel met in person on 3 occasions between July 2005 and January 2007 to develop the scope and key questions used to guide the systematic evidence review, examine and discuss the results of the evidence review, and draft and revise recommendation statements. Following the last panel meeting, the guideline panel finalized and voted on the recommendation statements through a series of conference calls and electronic

Table 2. Definitions for Estimating Magnitude of Effects

Size of Effect	Definition
Small/slight	Pain scales: Mean 5- to 10-point improvement on a 100-point VAS or equivalent Back-specific functional status: Mean 5- to 10-point improvement on the ODI, 1–2 points on the RDQ, or equivalent All outcomes: SMD, 0.2–0.5
Moderate	Pain scales: Mean 10- to 20-point improvement on a 100-point VAS or equivalent Back-specific functional status: Mean 10- to 20-point improvement on the ODI, 2–5 points on the RDQ, or equivalent All outcomes: SMD, 0.5–0.8
Large/substantial	Pain scales: Mean >20-point improvement on a 100-point VAS or equivalent Back-specific functional status: Mean >20-point improvement on the ODI, >5 points on the RDQ, or equivalent All outcomes: SMD, >0.8

ODI indicates Oswestry Disability Index; RDQ, Roland-Morris Disability Questionnaire; SMD, standardized mean difference; VAS, visual analogue scale.

Table 3. The American College of Physicians Clinical Practice Guidelines Grading System*

Quality of Evidence	Strength of Recommendation	
	Benefits Do or Do Not Clearly Outweigh Risks	Benefits and Risks and Burdens Are Finely Balanced
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak
Insufficient evidence to determine net benefits or harms		I

*From the system developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) workgroup and adapted by the American College of Physicians.

Table 4. Level of Evidence and Summary Grades for Interdisciplinary Rehabilitation, Injections, Other Interventional Therapies, and Surgery for Patients With Nonradicular Low Back Pain*

Intervention	Condition	Level of Evidence	Net Benefit	Grade
Interdisciplinary rehabilitation	Nonspecific low back pain	Good	Moderate	B
Prolotherapy	Nonspecific low back pain	Good	No benefit	D
Intradiscal steroid injection	Presumed discogenic pain	Good	No benefit	D
Fusion surgery	Nonradicular low back pain with common degenerative changes	Fair	Moderate vs. standard nonsurgical therapy, no difference vs. intensive rehabilitation	B
Facet joint steroid injection	Presumed facet joint pain	Fair	No benefit	D
Artificial disc replacement	Single-level degenerative disc disease	Fair	No difference vs. fusion through 2 yr, unable to estimate for long-term outcomes	B (through 2 yr), I (long-term outcomes)
Botulinum toxin injection	Nonspecific low back pain	Poor	Unable to estimate	I
Local injections	Nonspecific low back pain	Poor	Unable to estimate	I
Epidural steroid injection	Nonspecific low back pain	Poor	Unable to estimate	I
Medial branch block (therapeutic)	Presumed facet joint pain	Poor	Unable to estimate	I
Sacroiliac joint steroid injection	Presumed sacroiliac joint pain	Poor	Unable to estimate	I
Radiofrequency denervation	Presumed facet joint pain	Poor	Unable to estimate	I
Radiofrequency denervation	Presumed discogenic pain	Poor	Unable to estimate	I
Intradiscal electrothermal therapy	Presumed facet joint pain	Poor	Unable to estimate	I
Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)	Presumed facet joint pain	Poor	Unable to estimate	I
Coblation nucleoplasty	Presumed discogenic back pain	No trials	Unable to estimate	I
Spinal cord stimulation	Nonspecific low back pain	No trials	Unable to estimate	I
Intrathecal therapy	Nonspecific low back pain	No trials	Unable to estimate	I

*Please refer to Table 1 for explanation of grades.

Table 5. Level of Evidence and Summary Grades for Interdisciplinary Rehabilitation, Injections, Other Interventional Therapies, and Surgery for Patients With Radiculopathy or Symptomatic Spinal Stenosis*

Intervention	Condition	Level of Evidence	Net Benefit	Grade
Open discectomy or microdiscectomy	Radiculopathy with prolapsed lumbar disc	Good	Moderate for short-term (through 3 mo) outcomes only	B
Laminectomy with or without fusion	Symptomatic spinal stenosis with or without degenerative spondylolisthesis	Good	Moderate through 1–2 yr	B
Chemoneurololysis	Radiculopathy with prolapsed lumbar disc	Good	Moderate vs. placebo, inferior vs. surgery	B
Epidural steroid injection	Radiculopathy with prolapsed lumbar disc	Fair	Moderate for short-term (through 3 mo) outcomes only	B
Spinal cord stimulation	Failed back surgery syndrome with persistent radiculopathy	Fair	Moderate	B
Interspinous spacer device	One- to 2-level symptomatic spinal stenosis relieved with forward flexion	Fair	Moderate through 2 yr, unable to estimate for long-term outcomes	B
Intradiscal steroid injection	Radiculopathy with prolapsed lumbar disc	Fair	No effect vs. chemoneurololysis (no trials vs. placebo)	C
Epidural steroid injection	Symptomatic spinal stenosis	Poor	Unable to estimate	I
Radiofrequency denervation	Radiculopathy	Poor	Unable to estimate	I
Coblation nucleoplasty	Radiculopathy with prolapsed lumbar disc	No trials	Unable to estimate	I
Spinal cord stimulation	Radiculopathy with prolapsed lumbar disc	No trials	Unable to estimate	I

*Please refer to Table 1 for explanation of grades.

communications. Although a two-third majority was required for a recommendation to be approved, unanimous agreement was achieved on all recommendations except 1, 2, and 3; each had 1 panel member voting against. After approval of the recommendations, a guideline draft was written and distributed to the panel for feedback and revisions. Thirty-one external peer reviewers were solicited for additional comments. After another round of revisions and panel approval, the guideline was submitted to the APS Executive Committee for approval.

APS intends to update its clinical practice guidelines regularly. This guideline and the evidence report used to develop it will be reviewed and updated by 2012.

■ Results

Recommendation 1

In patients with chronic nonradicular low back pain, provocative discography is not recommended as a procedure for diagnosing discogenic low back pain (strong recommendation, moderate-quality evidence). There is insufficient evidence to evaluate validity or utility of diagnostic selective nerve root block, intra-articular facet joint block, medial branch block, or sacroiliac joint block as diagnostic procedures for low back pain with or without radiculopathy.

Although many studies show strong correlation between results of provocative discography (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>) and degenerative disc disease on imaging studies,^{18,19} diagnostic accuracy for identifying “discogenic” pain is uncertain. Degenerative disc disease is common in asymptomatic persons,²⁰ and no reliable reference standard exists for distinguishing symptomatic from asymptomatic imaging findings. In addition, even though positive pain responses with provocative discography are unlikely in healthy, asymptomatic patients without back pain,²¹ false-positive responses are common in persons without significant back pain but with somatization, other pain conditions, unresolved worker’s compensation claims, or previous back surgery,^{22–24} and can occur even after incorporating low pressure threshold criteria.²⁵ One study calculated a positive predictive value for provocative discography of 55% to 57%, though this estimate is based on critical assumptions regarding the comparability of outcomes for different surgical procedures for different underlying conditions in patients without risk factors for poor surgical outcomes.²⁶ There is no evidence that use of provocative discography to select patients for fusion improves clinical outcomes.^{27,28} Discitis is the most serious complication following provocative discography, but appears rare either with or without prophylactic antibiotics (mean: 0.24% based on number of patients and 0.09% based on number of disc injections).²⁹ One small study found that 20% to 67% of patients previously without back pain but with somatization or chronic pain at other sites reported persistent back pain 1 year after provocative discography.²³

No reliable data exist on the diagnostic accuracy or clinical utility of diagnostic facet joint, medial branch, sacroiliac joint, or selective nerve root blocks. Correlation with imaging findings is variable and difficult to

interpret in the absence of reliable reference standards for identifying “true” facet joint pain (see glossary, supplemental Digital Content 1, <http://links.lww.com/A840>), sacroiliac joint pain and radiculopathy. Although positive responses are less frequent with controlled rather than uncontrolled facet joint and sacroiliac joint blocks,^{30,31} it is not possible to determine whether this finding is due to fewer true- or false-positive cases. Some studies have evaluated the association between findings on invasive diagnostic tests and surgical outcomes,³² but no studies have investigated the effects of using facet joint, medial branch, sacroiliac joint, or selective nerve root block to guide choice of therapy or how use of these tests affects subsequent patient outcomes, compared with selecting therapy without using the invasive diagnostic test.¹⁵

Recommendation 2

In patients with nonradicular low back pain who do not respond to usual, noninterdisciplinary interventions, it is recommended that clinicians consider intensive interdisciplinary rehabilitation with a cognitive/behavioral emphasis (strong recommendation, high-quality evidence). Chronic back pain is a complex condition that involves biologic, psychological, and environmental factors.^{10,11,33,34} For patients with persistent and disabling back pain despite recommended noninterdisciplinary therapies,⁶ clinicians should counsel patients about interdisciplinary rehabilitation (defined as an integrated intervention with rehabilitation plus a psychological and/or social/occupational component) as a treatment option.

For chronic low back pain, interdisciplinary rehabilitation is moderately superior to noninterdisciplinary rehabilitation or usual care for improving short- and long-term (through up to 60 months) functional status.^{35–37} Interdisciplinary rehabilitation is also similar in effectiveness to fusion surgery (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>), for nonradicular low back pain.^{38–40} Interdisciplinary rehabilitation is likely to be more effective in patients who are more engaged and able to participate in it, as the intensity and time commitment are substantial. Although the composition of interdisciplinary rehabilitation programs varies, the most effective programs generally involve cognitive/behavioral and supervised exercise components with at least several sessions a week, with over 100 total hours of treatment.^{35,36} Barriers to use of intensive interdisciplinary rehabilitation include relatively high cost, unavailability in some areas, and limited insurance coverage. In workers disabled due to low back pain, some studies suggest that costs of interdisciplinary rehabilitation may be offset by fewer lost wages or days off of work.^{41–43} Interdisciplinary rehabilitation may be a treatment option for patients with persistent low back pain (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>) following back surgery (*i.e.*, “failed back surgery syndrome”), though evidence is limited to a small number of observational studies that

show similar outcomes following interdisciplinary therapy for chronic low back pain either with or without previous back surgery.^{44,45} Insufficient evidence exists to guide recommendations for interdisciplinary rehabilitation for persistent radiculopathy or symptomatic spinal stenosis.

Recommendation 3

In patients with persistent nonradicular low back pain, facet joint corticosteroid injection, prolotherapy, and intradiscal corticosteroid injection are not recommended (strong recommendation, moderate-quality evidence). There is insufficient evidence to adequately evaluate benefits of local injections, botulinum toxin injection, epidural steroid injection, intradiscal electrothermal therapy (IDET), therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, or intrathecal therapy with opioids or other medications for nonradicular low back pain.

Injections and most interventional therapies for nonradicular low back pain target specific areas of the back that are potential sources of pain, including the muscles and soft tissues (botulinum toxin injection, prolotherapy, and local injections [see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>]), facet joints (facet joint steroid injection, therapeutic medial branch block, and radiofrequency denervation [see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>]), degenerated intervertebral discs (intradiscal steroid injection, IDET, [see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>] and related procedures), and sacroiliac joints (sacroiliac joint injection). Intrathecal therapy does not target a specific anatomic source of pain, but involves the delivery of medication (usually an opioid) directly into the intrathecal space.

There is no convincing evidence from randomized trials that injections and other interventional therapies are effective for nonradicular low back pain. Facet joint steroid injection,^{46,47} prolotherapy,⁴⁸ and intradiscal steroid injections^{49,50} are not recommended because randomized trials consistently found them to be no more effective than sham therapies. For local injections, there is insufficient evidence to accurately judge benefits because available trials are small, lower-quality, and evaluate heterogeneous populations and interventions.^{51–54} Trials of IDET^{55,56} and radiofrequency denervation^{57–60} reported inconsistent results between small numbers of higher quality trials and (in the case of radiofrequency denervation) technical or methodologic shortcomings,⁶¹ making it difficult to reach conclusions about benefits. For other interventional therapies, data are limited to either 1 small placebo-controlled trial randomized trial (botulinum toxin injection,⁶² epidural steroid injection for nonradicular low back pain,⁶³ and sacroiliac joint steroid injection [see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>]⁶⁴), or there are no placebo-controlled randomized trials (therapeutic medial

branch block and intrathecal therapy with opioids or other medications).

Recommendation 4

In patients with nonradicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, it is recommended that clinicians discuss risks and benefits of surgery as an option (weak recommendation, moderate-quality evidence). It is recommended that shared decision-making regarding surgery for nonspecific low back pain include a specific discussion about intensive interdisciplinary rehabilitation as a similarly effective option, the small to moderate average benefit from surgery versus noninterdisciplinary nonsurgical therapy, and the fact that the majority of such patients who undergo surgery do not experience an optimal outcome (defined as minimum or no pain, discontinuation of or occasional pain medication use, and return of high-level function).

For persistent nonradicular low back pain with common degenerative changes (most frequently degenerative disc disease with presumed discogenic back pain), fusion surgery is superior to nonsurgical therapy without interdisciplinary rehabilitation in 1 trial,⁶⁵ but no more effective than intensive interdisciplinary rehabilitation in 3 trials^{38–40} (recommendation 2). Compared with noninterdisciplinary, nonsurgical therapy, average benefits are small for function (5–10 points on a 100-point scale) and moderate for improvement in pain (10–20 points on a 100-point scale).⁶⁵ More than half of the patients who undergo surgery do not experience an “excellent” or “good” outcome (defined as no more than sporadic pain, slight restriction of function, and occasional analgesics).⁶⁵ Although operative deaths are uncommon, early complications occur in up to 18% of patients who undergo fusion surgery in randomized trials.^{39,65} Instrumented fusion is associated with enhanced fusion rates compared with noninstrumented fusion, but insufficient evidence exists to determine whether instrumented fusion improves clinical outcomes, and additional costs are substantial.^{66,67} In addition, there is insufficient evidence to recommend a specific fusion method (anterior, posterolateral, or circumferential), though more technically difficult procedures may be associated with higher rates of complications.⁶⁵

Decisions regarding surgery for persistent nonradicular pain should be based on a shared decision-making process⁶⁸ that includes a discussion about alternative treatment options (including interdisciplinary rehabilitation if available), average benefits associated with surgery, potential harms, and costs. Appropriate patient selection is also important, as benefits of fusion *versus* nonsurgical therapy have only been demonstrated in a relatively narrow group of patients with at least moderately severe pain or disability unresponsive to nonsurgical therapies for at least 1 year and without serious psychiatric or medical comorbidities or other risk factors for poor surgical outcomes.

Recommendation 5

In patients with nonradicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, there is insufficient evidence to adequately evaluate long-term benefits and harms of vertebral disc replacement (insufficient evidence).

For persistent nonradicular low back pain, artificial disc replacement (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>) with the CHARITÉ artificial disc⁶⁹ or Prodisc-II⁷⁰ is associated with similar outcomes compared to fusion. However, trial results are only applicable to a narrowly defined subset of patients with single level degenerative disc disease, and all trials have been funded by the manufacturer of the relevant artificial disc. Furthermore, in the case of the CHARITÉ artificial disc, interpretation of results is challenging because the type of fusion surgery evaluated is no longer widely used due to frequent poor outcomes.⁷¹

Data on long-term (beyond 2 years) benefits and harms following artificial disc replacement are limited. Although a potential long-term advantage of artificial disc replacement over fusion is preservation of spinal mobility, observational studies report cases of adjacent level disc degeneration and facet joint arthritis, device-related complications such as migration and subsidence (settling or sinking into bone), and some patients subsequently undergo fusion.⁷²⁻⁷⁴

Recommendation 6

In patients with persistent radiculopathy due to herniated lumbar disc, it is recommended that clinicians discuss risks and benefits of epidural steroid injection as an option (weak recommendation, moderate-quality evidence). It is recommended that shared decision-making regarding epidural steroid injection include a specific discussion about inconsistent evidence showing moderate short-term benefits, and lack of long-term benefits. There is insufficient evidence to adequately evaluate benefits and harms of epidural steroid injection for spinal stenosis.

For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed. Although some higher-quality trials⁷⁵⁻⁷⁸ found epidural steroid injection associated with moderate short-term (through up to 6 weeks) benefits in pain or function, others⁷⁹⁻⁸¹ found no differences *versus* placebo injection. Reasons for the discrepancies between trials is uncertain, but could be related to the type of comparator treatment, as trials^{76,79-88} that compared an epidural steroid injection to an epidural saline or local anesthetic injection tended to report poorer results than trials^{75,77,78,89-91} that compared an epidural steroid injection to a soft-tissue (usually interspinous ligament) placebo injection. Regardless of the comparator intervention, there is no convincing evidence that epidural steroids are associated with long-term benefits and most trials^{75,78,79,92} found no reduction in rates of subsequent surgery. Although serious complications follow-

ing epidural steroid injection are rare in clinical trials,^{75,80,81,93,94} there are case reports of paralysis and infections.⁹⁵⁻⁹⁷ There is insufficient evidence on clinical outcomes to recommend a specific approach for performing epidural steroid injection^{93,94,98-100} or on use of fluoroscopic guidance. In addition, insufficient evidence exists to recommend how many epidural injections to perform, though 1 higher-quality trial found that if an initial epidural steroid injection did not result in benefits, additional injections over a 6-week period did not improve outcomes.⁷⁵

Decisions regarding use of epidural steroid injection should be based on a shared decision-making process that includes a discussion of the inconsistent evidence for short-term benefit, lack of long-term benefit, potential risks, and costs. Patient preferences and individual factors should also be considered. For example, epidural steroid injection may be a reasonable option for short-term pain relief in patients who are less optimal surgery candidates due to comorbidities. There is insufficient evidence to guide specific recommendations for timing of epidural steroid injection, though most trials enrolled patients with at least subacute (greater than 4 weeks) symptoms.

Evidence on efficacy of epidural steroid injection for spinal stenosis is sparse and shows no clear benefit, though more trials are needed to clarify effects.^{84,88,101} Although chymopapain chemonucleolysis (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>) is effective for radiculopathy due to herniated lumbar disc,^{102,103} it is less effective than discectomy (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>) and is no longer widely available in the United States, in part due to risk of severe allergic reactions.

Recommendation 7

In patients with persistent and disabling radiculopathy due to herniated lumbar disc or persistent and disabling leg pain due to spinal stenosis, it is recommended that clinicians discuss risks and benefits of surgery as an option (strong recommendation, high-quality evidence). It is recommended that shared decision-making regarding surgery include a specific discussion about moderate average benefits, which appear to decrease over time in patients who undergo surgery.

For persistent and disabling radiculopathy due to herniated lumbar disc, standard open discectomy and microdiscectomy are associated with moderate short-term (through 6 to 12 weeks) benefits compared to nonsurgical therapy, though differences in outcomes in some trials are diminished or no longer present after 1 to 2 years.¹⁰⁴⁻¹⁰⁸ In addition, patients tend to improve substantially either with or without discectomy, and continued nonsurgical therapy in patients who have had symptoms for at least 6 weeks does not appear to increase risk for *cauda equina* syndrome or paralysis.¹⁰⁸ Serious complications following discectomy are uncommon. There is insufficient evidence to determine whether standard open discectomy or microdiscectomy is associated with superior out-

comes.^{109–112} In addition, insufficient evidence exists to evaluate alternative surgical methods including laser- or endoscopic-assisted techniques, various percutaneous techniques, Coblation nucleoplasty (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>), or the Disc Decompressor.^{113–117}

For persistent and disabling leg pain due to spinal stenosis, either with or without degenerative spondylolisthesis, decompressive laminectomy (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>) is associated with moderate benefits compared to nonsurgical therapy through 1 to 2 years, though effects appear to diminish with long-term follow-up.^{118–121} Although patients on average do not worsen without surgery, improvements are less than those observed in patients with radiculopathy due to herniated lumbar disc.^{120,121} There is insufficient evidence to determine if laminectomy with fusion is more effective than laminectomy without fusion.^{66,67,122–124} Although an interspinous spacer device (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>) is more effective than nonsurgical therapy for symptomatic spinal stenosis, results are only applicable to patients with 1- or 2-level stenosis and symptoms relieved by forward flexion, data on long-term (beyond 2 years) follow-up are lacking, and all trials were funded by the manufacturer of the device.^{125–127} Dural tears occur in around 10% of patients undergoing laminectomy, and neurologic injuries may occur in about 2.5%.^{119–121}

Decisions regarding surgery for radiculopathy due to herniated lumbar disc or leg pain due to spinal stenosis should be based on a shared decision-making approach that includes a discussion of moderate average benefits that diminish over time, likelihood of improvement either with or without surgery, potential risks, and costs. Duration of symptoms should also be considered, as trials of surgery for radiculopathy due to herniated lumbar disc generally enrolled patients with at least 6 weeks of symptoms, and trials of surgery for spinal stenosis enrolled patients with symptoms present for more than 6 months.

Recommendation 8

In patients with persistent and disabling radicular pain following surgery for herniated disc and no evidence of a persistently compressed nerve root, it is recommended that clinicians discuss risks and benefits of spinal cord stimulation as an option (weak recommendation, moderate-quality evidence). It is recommended that shared decision-making regarding spinal cord stimulation include a discussion about the high rate of complications following spinal cord stimulator placement.

Failed back surgery syndrome encompasses a broad range of patients with persistent low back pain following back surgery. In a more narrowly defined group of patients with persistent radicular pain following surgery for herniated disc and no imaging evidence of a persistent compressed nerve root, spinal cord stimula-

tion (see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>) is associated with moderate benefits compared with repeat surgery¹²⁸ or continued medical management.¹²⁹ However, over one-quarter of patients experience complications following spinal cord stimulator placement, including electrode migration, infection or wound breakdown, generator pocket-related complications, and lead problems.^{128,129} No trial has compared spinal cord stimulation to intensive interdisciplinary rehabilitation. Decisions regarding use of spinal cord stimulation should be based on a shared decision-making approach that includes a discussion of potential benefits, risk of complications, and costs. There is insufficient evidence (no randomized trials) to guide recommendations on spinal cord stimulation for other types of failed back surgery syndrome or for low back pain (with or without leg pain) without previous surgery.^{130–133} Published case series of spinal cord stimulation for low back pain not related to previous back surgery provide very weak evidence because they used an uncontrolled study design and were of very low methodologic quality.¹³¹

Discussion

This guideline was developed by a multidisciplinary panel of experts based on a systematic review of the literature. The panel found sufficient evidence from randomized controlled trials to recommend that interdisciplinary rehabilitation, surgery, epidural steroid injection, and spinal cord stimulation be considered in certain clinical circumstances. Benefits are moderate, however, and often do not result in complete resolution of pain or functional limitations. These therapies are typically performed on an elective basis and decisions about their use require consideration of important trade-offs between potential benefits, harms, costs, and burdens of alternative therapies, both invasive and noninvasive. Treatment choices are likely to vary between individuals because patients value such trade-offs differently. For example, a patient with a herniated disc and lumbar radiculopathy who places a high priority on faster improvement of symptoms is more likely to choose surgery. A patient with similar symptoms who places a high value on avoiding surgery is more likely to select nonsurgical therapy. The use of some of the interventions recommended in this guideline may also be influenced by external factors. For example, decisions regarding intensive interdisciplinary rehabilitation are not only affected by patient preferences regarding the substantial time commitment required for this therapy, but also by factors such as its limited availability and frequent noncovered status in the United States.

A shared decision-making approach is appropriate when 2 or more medically reasonable choices exist, and is a key component of several of the recommendations in this guideline.¹³⁴ The goal of shared decision-making is to engage the patient as an active participant in the decision-making process by providing clear information regarding trade-offs and uncertainties, so that decisions are consistent

with his or her preferences, values, and goals. Several recommendations include specific guidance on minimum information that the panel deemed necessary to enable patients to make well-informed decisions. Use of formal decision aids also could be helpful, as such tools have been shown to improve knowledge, make expectations more realistic, enhance active participation in decision-making, decrease the proportion of people remaining undecided, and improve agreement between values and choices.¹³⁵ Formal shared decision-making aids have been shown to decrease the proportion of patients who choose spine surgery without adversely affecting clinical outcomes, but more studies are needed to understand how to best implement shared decision-making.^{136,137}

The panel recommended against use of lumbar discography, prolotherapy, intradiscal steroid injection, and facet joint steroid injection. These interventions are not shown by the best currently available evidence to improve patient outcomes, though future research that demonstrates benefits could change these recommendations. For other interventions or specific clinical circumstances (e.g., epidural steroid injection for spinal stenosis), the panel found insufficient evidence from randomized controlled trials to reliably judge benefits or harms. In such cases, the panel did not issue specific recommendations. In general, clinicians should routinely prioritize therapies supported by higher-quality evidence over those supported by only weak evidence. Not offering therapies supported by weak evidence is consistent with the principle that clinicians should only recommend interventions with proven benefits. Clinicians who do choose to use such interventions should reserve them for patients with at least moderately severe symptoms despite trials of alternative therapies supported by stronger evidence. In such cases, patients always need to be clearly informed about the substantial uncertainties regarding potential benefits and harms.

Although numerous positive observational studies have been published on various interventional therapies and surgeries for low back pain, the panel did not base its recommendations on such evidence. Conclusions of observational studies can be very misleading for evaluating benefits of therapy for low back pain due to important placebo effects,^{138–140} a strong psychological component in some patients, substantial confounding, and fewer safeguards against bias compared with well-conducted randomized trials.¹⁴¹ For example, a nonrandomized, controlled clinical trial¹⁴² of IDET for low back pain reported results that were substantially superior to results from subsequent randomized trials.^{55,56} Moreover, most observational studies are uncontrolled case series (one of the weakest forms of evidence for evaluating benefits), often with serious methodologic shortcomings.¹³¹ Results from such studies are too unreliable and difficult to interpret to serve as the primary basis of evidence-based recommendations, resolve important discrepancies between higher-quality randomized trials, or overturn results from negative randomized

trials. Given the increasing use of invasive diagnostic tests, interventional therapies, and surgery for low back pain, more high-quality randomized trials are urgently needed to reduce uncertainties about the use of these interventions and improve the care of patients with low back pain.

Note

Clinical practice guidelines are “guides” only and may not apply to all patients and all clinical situations. As part of a shared decision-making approach, it may be appropriate for the clinician to inform a patient that a particular recommendation may not be applicable, after considering all circumstances pertinent to that individual.

■ Key Points

- Provocative discography is not recommended because its diagnostic accuracy remains uncertain, false-positives can occur in persons without low back pain, and its use has not been shown to improve clinical outcomes.
- It is recommended that interdisciplinary rehabilitation be considered as a treatment option for persistent, disabling low back pain that does not respond to usual, noninterdisciplinary therapies.
- For persistent nonradicular low back pain, facet joint corticosteroid injection, prolotherapy, and intradiscal corticosteroid injection are not recommended, and there is insufficient evidence to reliably guide recommendations on use of other interventional therapies. A shared decision-making process including a detailed discussion of risks, moderate average benefits, and treatment alternatives is recommended to guide decisions regarding surgery.
- For radicular low back pain, a shared decision-making process including a detailed discussion of risks and inconsistent evidence regarding short-term benefits is recommended to guide decisions regarding epidural steroid injection. A shared decision-making process is also recommended to guide decisions regarding surgery for spinal stenosis and prolapsed lumbar disc, though supporting evidence is stronger than for surgery for nonradicular low back pain.
- In patients with persistent pain following surgery for herniated disc, a shared decision-making process including a detailed discussion of risks including frequent device-related complications and benefits is recommended to guide decisions regarding spinal cord stimulation.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in the HTML text of this article on the journal’s Web site (www.spinejournal.com).

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