



Degenerative lumbar spinal stenosis is a common problem among older adults. Stenotic compression of spinal nerves can result in low back pain, disabling leg pain, and greatly restricted walking capacity. Conservative therapies are usually prescribed for mild symptoms and surgery is prescribed for severe symptoms, while patients with moderate symptoms may not have an obvious treatment choice. The clinical evidence supporting these treatment options has been criticized because of problems with study design and quality that complicate their assessment. Despite the poor quality of most of the literature, recent studies provide better information and a means of starting to judge the effectiveness of treatment.

**Key words:** lumbar spinal stenosis, neurogenic claudication, conservative therapy, surgical intervention

## Lumbar Spinal Stenosis: Evidence for Treatment

*David L. Snyder, PhD, Senior Research Analyst, Evidence-Based Practice Center, ECRI, Plymouth Meeting, PA, USA.*

*David Doggett, PhD, Senior Research Analyst, Evidence-Based Practice Center, ECRI, Plymouth Meeting, PA, USA.*

*Charles Turkelson, PhD, Chief Research Analyst and Director, Evidence-Based Practice Center, ECRI, Plymouth Meeting, PA, USA.*

### Lumbar Spinal Stenosis and Its Impact on Older Adults

Degenerative lumbar spinal stenosis (LSS) is a narrowing of the vertebral canal caused by bony overgrowth and ligament enlargement, intervertebral disc herniation, or vertebral slippage (spondylolisthesis).<sup>1-3</sup> The narrowing can cause spinal nerve entrapment and compression resulting in low back pain, leg fatigue and pain, and reduced physical activity (Figure 1). Neurogenic claudication, characterized by severe disabling leg pain that greatly reduces walking ability, is a common symptom in LSS. Symptoms start or intensify upon standing or walking and are eased by sitting or lying down. In contrast, lower leg pain associated with vascular claudication starts with any leg exercise, not just walking or standing, and is relieved by rest, even in the standing position. Patients with severe symptoms of neurogenic claudication have greatly restricted walking capacity and exercise intolerance.<sup>2,4</sup> Still, not all patients with LSS are symptomatic.

LSS typically affects individuals older than 50 years of age and especially those over 65 years of age.<sup>5-7</sup> In the Maine Lumbar Spine Study, the average age of the 148 patients treated for LSS was 67 years with a range of 22 to 89 years.<sup>8</sup> Two systematic reviews of surgery for LSS have also reported mean ages of over 50.<sup>9,10</sup> LSS is the most common reason for spinal surgery in patients

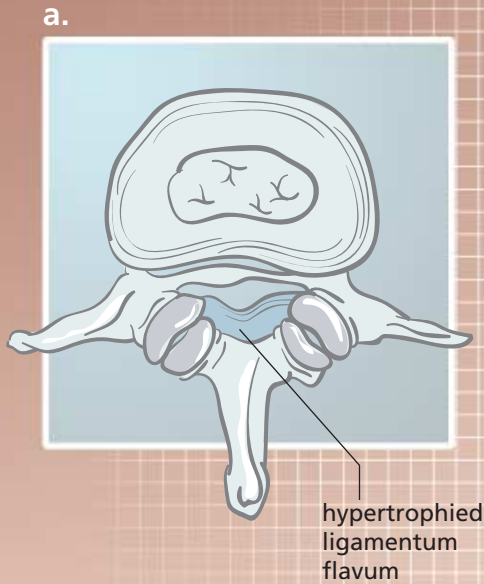
older than 65 years.<sup>11</sup> However, there are increased risks of morbidity and potentially poorer outcomes after spinal surgery in older adults.<sup>12-16</sup>

Symptoms of LSS may be categorized as mild, moderate, or severe based on the extent of leg pain and pain-related disability.<sup>8,17</sup> Conservative therapies seem to be the usual choice when symptoms are mild.<sup>2,8,11,17</sup> Decompressive laminectomy, involving removal of the bone and ligaments around the stenosis, is typically recommended for patients with severe symptoms in whom conservative treatments have not provided pain relief.<sup>2,3,8,11,17</sup> Other surgical procedures may also be used. Patients with moderate symptoms fall into a middle area in which the most appropriate treatment may not be obvious.<sup>8,18</sup> What evidence is available to suggest that these recommendations are correct, and that conservative therapies work for individuals with mild symptoms while surgical procedures work for individuals with severe symptoms? Is evidence available to suggest how individuals with moderate symptoms should be treated?

### The Quality of Available Medical Evidence

In 2001, we prepared a systematic review and analysis of the clinical literature on treatments for degenerative LSS for the United States Agency for Healthcare Research and Quality (AHRQ).<sup>19</sup> In this report, we addressed the questions posed

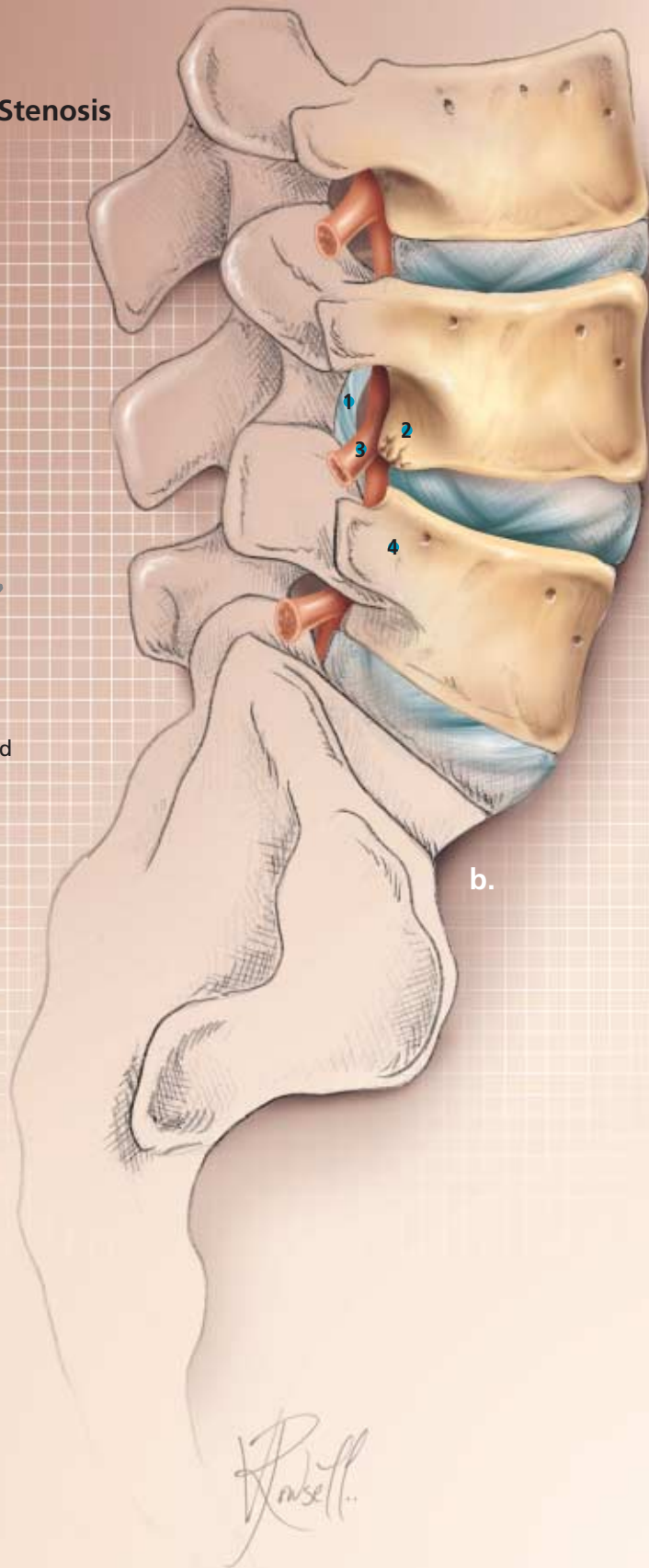
**Figure 1:**  
**The Pathophysiology of**  
**Degenerative Lumbar Spine Stenosis**



**Pathophysiology**

Abnormal narrowing of the lumbar spinal canal – **lumbar stenosis** – can be due to both a bulging disc and infolding of the thick elastic ligament called the ligamentum flavum. An alteration in shape of either the disc or the ligament results in a reduction of space available for the exiting nerve root in the L4-L5 neural foramen.

- 1. Ligamentum flavum (inflamed)
- 2. Osteophytes
- 3. Nerve root (pinched)
- 4. Disc



above. Our examination of the literature up to the year 2000 revealed problems with study design and quality that complicated the assessment of this literature for both conservative (all nonsurgical approaches including analgesic medications and devices) and surgical interventions.<sup>20</sup>

Our analysis, as well as several other reviews of treatments for LSS, noted methodological flaws in most of the available studies, such as poorly defined outcome measures, lack of blinded outcome assessment, failure to provide adequate patient demographic information, and lack of stratification of outcomes by diagnosis.<sup>9,10,21–24</sup> In particular, the use of nonstandardized outcome rating scales—usually involving vague terms such as excellent, good, fair, and poor—led to widely differing conclusions about treatment effectiveness.<sup>25</sup> These deficiencies in the clinical data underlying spine surgery have led to proposals for better designed and conducted studies into the efficacy of nonsurgical and surgical treatments for LSS.<sup>20,21,26</sup>

Despite the poor quality of most of the literature, several studies from the AHRQ report and several newer studies published after the report may provide useful findings (Table 1).

## The Evidence for Conservative Treatment

### Mild to Moderate Symptoms

Of the 178 conservative treatment studies we reviewed, only four met the inclusion criteria for the AHRQ report (controlled study, data for LSS patients reported separately, and at least 10 patients). Only one study was of sufficient quality to merit mention in our analysis, but this study examined patients with severe symptoms. Therefore, we were unable to provide an evidence base that could be used to judge the efficacy of specific conservative treatment approaches in patients with mild to moderate symptoms.

The Maine Lumbar Spine Study, a prospective, observational cohort study, did examine the collective effect of conservative treatments in patients with mild to moderate symptoms.<sup>8</sup> After one year few patients showed a worsening of their condition, but only about one-third of patients reported any symptom improvement. At four years, half of the patients reported symptom improvement and 14 percent reported worsening symptoms.<sup>27</sup> In a similar study performed in Norway, 50 patients with symptoms that were consid-

ered to be too mild for surgery were given conservative therapy with follow-up conducted for 10 years.<sup>17</sup> In 10 patients, symptoms became severe enough to warrant surgery during the first four years, 25 patients showed symptom improvement, and the remaining patients showed no change in condition.

Because the previous two studies were uncontrolled, they provide no convincing evidence that the conservative therapies were actually responsible for patient improvement. Controlled trials are needed to limit the influence of nonspecific effects and of regression to the mean on pain-related outcome measures.<sup>28–32</sup> Nonspecific effects refer to changes in pain levels not related to treatment, and are also called placebo effects. A nonspecific response rate of 35% is often cited, but nonspecific effects may be capable of reducing pain in all patients in a study.<sup>28</sup> Regression to the mean occurs when patients seek treatment when their pain is the most severe, and the subsequent improvement in pain after treatment is actually a return to the patient's typical state.

### Severe Symptoms

In the AHRQ report, one RCT examined the effects of epidural steroid injections

**Table 1:** Evidence of the Effectiveness of Conservative Therapies and Surgical Interventions for the Treatment of Lumbar Spinal Stenosis

Symptoms	Treatment	Evidence of Effectiveness
Mild to Moderate	Specific conservative therapies	No evidence is available to judge the efficacy of specific conservative treatment approaches in patients with mild to moderate symptoms.
Mild to Moderate	Nonspecific collective conservative therapies	A small evidence base from uncontrolled studies suggests that few patients will experience worsening symptoms, but only about half of patients will show improvement. <sup>8,17,27</sup>
Moderate	Surgical intervention	The available evidence suggests that among patients with moderate pain surgery may be more beneficial than conservative treatment in providing symptom relief. <sup>17,18,27,36</sup>
Severe	Epidural steroid injections	Evidence from one controlled trial suggests that local anesthetic block can reduce symptoms for no more than one month; epidural steroid offered no additional benefit. Uncontrolled studies indicate that fluoroscopically guided epidural steroid injections may help. <sup>33–35</sup>
Severe	Surgical interventions	Evidence from uncontrolled studies suggests that patients with severe symptoms and greatly limited walking capacity regain mobility after surgery. <sup>4,37–41</sup>

and a local anesthetic on neurogenic claudication.<sup>33</sup> This study examined patients with severe symptoms characterized by neurogenic claudication when fewer than 20 metres of walking distance caused intolerable leg pain. The local anesthetic mepivacaine reduced symptoms and increased walking distance for up to one month. Epidural steroids offered no additional benefit to the effects of the anesthetic block. Two recent uncontrolled studies of fluoroscopically guided epidural steroid injections, one prospective<sup>34</sup> and one retrospective,<sup>35</sup> reported sustained pain relief in some patients. However, the effectiveness of fluoroscopically guided epidural steroid injections must be confirmed in an RCT because of the potential for nonspecific effects and regression to the mean.

### The Evidence for Surgical Treatment

#### Moderate Symptoms

The Maine Lumbar Spine Study contained a subgroup of 31 surgical patients and 23 nonsurgical patients with moderate symptoms.<sup>8</sup> The surgery patients showed more improvement, suggesting that among patients with moderate pain surgery may be more beneficial than conservative treatment. After four years, outcomes continued to be better among patients who initially had moderate pain and received surgery.<sup>27</sup>

Three trials have considered randomization to surgical or conservative treatment appropriate for LSS patients with moderate symptoms. In the first two trials, patients receiving decompressive surgery showed more improvement than conservatively treated patients.<sup>17,18</sup> In the third trial, patients were randomly assigned to an interspinous implant designed to restrict spinal extension and allow flexion or to epidural steroids plus other conservative therapy.<sup>36</sup> Half of the surgery patients showed improvement compared to 10% of conservatively treated patients. The second and third trials appeared after the AHRQ report.

#### Severe Symptoms

Evidence from six prospective, uncontrolled trials that measured pre- and post-

surgery walking ability suggests that walking significantly improves after surgery. Patients in these studies had severe LSS resulting in greatly limited walking capacity, and prior conservative therapy had failed to relieve their condition.<sup>4,37-41</sup> The average age in all six studies was more than 68 years with a range of 40 to 90 years. Although these studies were uncontrolled, the severe symptoms and the lack of response to prior therapy suggest that surgery was responsible for pain relief and increased walking capacity in these older patients. The value of walking ability as an outcome measure is limited by the extent of comorbidities present in older patients, but it provides an objective outcome measure to complement subjective pain measurements.

### Comments

Our evaluation of the treatments discussed here is based on only a few of the many studies reviewed for the AHRQ report plus studies published since that report was completed. Drawing conclusions from so few trials is problematic, and the aim of this article is not to provide a detailed discussion of the benefits and the potential complications that may arise from spinal surgery. Rather, our findings should be viewed as showing potential relationships among treatments, patient characteristics, and treatment outcomes. As emphasized in our original report, definitive evidence-based conclusions about the efficacy of conservative or surgical treatments for lumbar spinal stenosis await the results of multiple well-designed clinical trials.

The Spine Patient Outcomes Research Trial (SPORT) may represent one such trial.<sup>26,42</sup> SPORT was designed to assess the relative efficacy and cost-effectiveness of surgical and nonsurgical approaches to the treatment of common conditions associated with low back and leg pain, including LSS. The study design involved 370 LSS patients randomly assigned to standard posterior decompressive laminectomy or one of several nonsurgical treatments (at a minimum, active physical therapy, exercise, and nonsteroidal anti-inflammatory drugs plus other treatments deemed nec-

essary). Enrollment began in March 2000 and was expected to end in November 2004. Patients who declined random assignment will receive follow-up in a separate observational cohort. To be eligible for enrollment, patients must have had neurogenic claudication or radicular pain with an associated neurologic deficit of at least 12 weeks duration. They must also have a confirmatory magnetic resonance imaging or computed tomography exam that shows LSS at one or more levels. The follow-up period will be at least 24 months and possibly as long as 36 to 48 months. The primary outcomes to be measured are the Short Form 36 Health Status Questionnaire and the Oswestry Disability Index. The clinical centres (all located within the United States) participating in SPORT hope to provide high-quality medical evidence to aid decision making and improve treatment outcomes.

### Conclusion

With the completion of SPORT and continued publication of results from high quality clinical studies, a significant body of evidence may finally be available to support the treatment recommendations given to patients with mild, moderate, or severe symptoms of LSS. The available evidence suggests that conservative therapies for patients with mild to moderate symptoms may be able to prevent progression of symptoms and in a few cases actually improve symptoms, but the evidence base to support this conclusion is very small. The evidence for specific conservative therapies is lacking and efforts should be made to expand our knowledge in this area (especially through randomized controlled trials). The evidence in support of surgical intervention in patients with severe symptoms and greatly limited walking ability has expanded since our original evidence-based report. Four of the six studies which measured walking ability pre- and post-surgery were published after the AHRQ report. Evidence from these uncontrolled studies suggests that these patients can regain mobility after surgery. As additional clinical evidence accumulates, a new systematic review may be useful in estimating the magnitude

of treatment effects; judging the quality, quantity, and consistency of the available evidence; and helping to determine what works and doesn't work when caring for patients with LSS.

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The full evidence report prepared by ECRI is available from the Agency for Healthcare Research and Quality. Printed copies may be obtained free of charge from the AHRQ Publications Clearinghouse by calling 1-800-358-9295. Requesters should ask for Evidence Report/Technology Assessment No. 32, Treatment of Degenerative Lumbar Spinal Stenosis (AHRQ Publication No. 01-E048). Internet users can access the report online through AHRQ's website ([www.ahrq.gov](http://www.ahrq.gov)). ECRI is a nonprofit health services research agency and Collaborating Center for Healthcare Technology Assessment of the World Health Organization.

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