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Surgery for Lumbar Spinal Stenosis: Informed Patient Preferences Should Weigh Heavily

Symptomatic lumbar spinal stenosis (LSS) is a frequent source of back and lower-extremity pain in older persons. Patients with symptomatic LSS who experience activity limitation despite treatment with acetaminophen, nonsteroidal anti-inflammatory drugs, physical therapy (PT), and epidural steroid injections are often presented the option of decompressive laminectomy. Several studies have compared outcomes of surgical and nonoperative treatments for LSS, the most recent of which is a randomized trial by Delitto and colleagues (1) in this issue. Although none of these studies by itself provides definitive advice to patients, families, and physicians, when taken together, the evidence leads to sensible therapeutic recommendations and a research agenda.

The observational Maine Lumbar Spine Study compared laminectomy for symptomatic LSS with an ad hoc mélange of conservative treatments, including PT, nonsteroidal anti-inflammatory drugs, and injections. Surgically managed patients had better back and leg pain relief than those initially treated nonoperatively during 4 years of follow-up (2), but by 10 years, the groups did not differ with respect to satisfaction with their symptoms (3). Of note, 23% of surgically treated patients had 1 or more additional surgical procedures over a 10-year follow-up.

In SPORT (Spine Pain Outcomes Research Trial) (4), both randomized and observational cohorts were included. One third of patients randomly assigned to surgery did not receive the procedure, and 43% randomly assigned to nonoperative therapy had surgery in the first 2 years; this bidirectional crossover rendered the intention-to-treat (ITT) analysis uninterpretable (because each group was diluted by patients who received the treatment assigned to the other group). The as-treated analysis showed that surgically treated patients had greater pain relief and functional improvement than nonoperatively treated patients over 4 years (5). However, by 8 years, surgically and nonoperatively treated patients in the randomized cohort had similar pain and functional status and 19% of those treated surgically had a reoperation (6).

Malmivaara and colleagues (7) randomly assigned 94 patients with LSS to surgery or referral to a physiatrist for nonoperative management, including physiotherapy for select patients as needed. Crossover rates were 8% to 9% in each group in the first 2 years. Although patients randomly assigned to surgery had better pain relief and functional improvement at 2 years than those randomly assigned to nonoperative therapy, these differences dissipated by 6 years (8). Only 2% of surgically treated patients had repeated decompression by 6 years.

Each of these studies reported that initial treatment with surgery was more effective in relieving symptoms than initial treatment with nonoperative therapy, but these advantages waned after a few years. However, the studies were compromised by nonrandomized designs (Maine Lumbar Spine Study and the observational component of SPORT); extensive, bidirectional crossover (SPORT); and lack of a standardized nonoperative regimen (all 3 studies). The lack of a standardized comparison group complicates interpretation because in practice, clinicians and patients must choose between surgery and a particular nonoperative regimen, rather than an amalgam of regimens. In addition, patients randomly assigned to ad hoc nonoperative therapy may have received less attention from the study team; differential attention offers another possible explanation for differences in short-term outcomes.

Delitto and colleagues' trial overcomes several of these limitations. It was randomized and used a standardized nonoperative comparison regimen. All but 2 patients randomly assigned to surgery received the procedure. The ITT analysis showed no difference between the randomized groups in physical function, but 57% of patients randomly assigned to PT crossed over to surgery. Secondary as-treated analyses showed that 61% of patients assigned to surgery achieved an improvement of 0.5 SD in physical function compared with 52% assigned to PT who received it and 55% assigned to PT who crossed over to surgery.

These results resemble those from recent randomized, controlled trials of operative versus nonoperative therapy for other musculoskeletal conditions. For example, the ITT analysis of the MeTeOR (Meniscal Tear in Osteoarthritis Research) trial (9) found that operatively and nonoperatively treated patients with a degenerative meniscal tear achieved similar functional improvement, but 30% of nonoperatively treated patients crossed over to surgery. As seen by Delitto and colleagues, MeTeOR patients assigned to surgery who received it had similar outcomes to those assigned to nonoperative therapy who received it and those assigned to nonoperative therapy who crossed over to surgery. The KANON (Knee Anterior cruciate ligament, NON-surgical versus surgical treatment) trial of treatment for anterior cruciate ligament rupture reached similar findings, with no difference between patients randomly assigned to surgical reconstruction versus those randomly assigned to nonoperative therapy in the ITT analysis. Like MeTeOR and Delitto and colleagues' trial, KANON had substantial (39%) crossover from nonoperative therapy to surgery, and favorable results in patients who received delayed surgery after nonoperative therapy failed (10).

What is the message from these studies for clinicians, their patients, and researchers? From a research standpoint, crossover from nonoperative to surgical treatment complicates analyses and future studies should strive to minimize it. As-treated analyses may be biased because the comparison groups were not created by randomization but by patient and clinician preference. Of course, some crossover is inevitable because investigators cannot impel patients to stick with treatments that patients do not find helpful. An analytic approach to this problem that preserves the ITT principle is to establish a secondary outcome a priori that defines success as both not crossing over from the assigned treatment and achieving a clinically meaningful improvement. In this manner, the MeTeOR trial (9) showed that patients assigned to surgery had a greater proportion of successes than those randomly assigned nonoperative therapy. Finally, we must acknowledge that because these studies are not sham-controlled, we cannot determine whether the benefits associated with surgery and nonoperative therapy arise from physiologic effects of the treatments or from attention and placebo effects.

From a clinical standpoint, Delitto and colleagues' trial suggests that a strategy of starting with an active, standardized PT regimen results in similar outcomes to immediate decompressive surgery over the first several years. A substantial number of conservatively treated patients will elect surgery over this period, and they generally do well. However, the Maine Lumbar Spine Study, SPORT, and Malmivaara and colleagues' study warn that clinical benefits of laminectomy for lumbar stenosis wane over several years. Taken together, these data suggest that patients with LSS should be offered a rigorous, standardized PT regimen. Those who do not improve and ultimately consider surgery should be informed that the benefits are likely to diminish over time. Finally, because long-term outcomes are similar for both treatments yet short-term risks differ, patient preferences should weigh heavily in the decision of whether to have surgery for LSS.

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