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Cochrane in CORR®: Surgical Versus Non-surgical Treatment for Lumbar Spinal Stenosis

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Importance of the Topic

Lumbar spinal stenosis (LSS), an age-related degenerative narrowing of the spinal canal, results in considerable morbidity particularly in older patients. Patients typically present with low-back pain and activity-related leg pain that restricts their function and quality of life [3]. The socioeconomic burden of treating this pathology is

tremendous [4], highlighting the need to improve effective treatment strategies in the management of this growing demographic.

Nonsurgical interventions, including pain medications and physical therapy, are the first line of treatment in patients with LSS [8]. When indicated, surgical treatment of neurogenic claudication due to LSS may dramatically improve health-related quality of life [1]. However, complications sometimes follow surgery, particularly

spinal instability resulting in fusion. In fact, reoperation rates as high as 27% in the first postoperative year have been reported [11]. This recent Cochrane Review compared surgical and nonsurgical treatments, and included randomized and quasirandomized controlled trials [13]. Based on the five trials (643 patients) that met inclusion criteria, the authors concluded that there are no clear benefits to surgery over nonsurgical treatment for patients with LSS.

A note from the Editor-in-Chief:

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Cochrane Reviews are regularly updated as new evidence emerges and in response to feedback, and The Cochrane Library (<http://www.thecochranelibrary.com>) should be consulted for the most recent version of the review.

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Upon Closer Inspection

Substantial heterogeneity in populations and interventions was a major limitation of this Cochrane review. First, although all of the trials included patients with LSS, the standard for diagnosis and clas-

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sification of LSS [10] was not clearly defined and thus the pooled patient groups likely were not homogenous. Second, nonsurgical treatment options differed considerably across trials, including a mix of physical therapy, home exercises, epidural steroid injections, pain medications, and various other modalities without a standardized protocol. Third, there was considerable variability in the surgical treatments used, including a combination of decompression, decompression and fusion, and use of an interspinous spacer in one study [11]. Results from this meta-analysis of two studies [9, 12] showed no important differences in function at 6 months and 1 year, but found a sizeable difference favoring surgery at 2 years. Despite considerable heterogeneity at 6 months ($I^2 = 72\%$) and 1 year ($I^2 = 81\%$), no exploration of heterogeneity was performed. Although the authors performed a random-effects model, heterogeneity in systematic reviews should still be explored and explained with a priori subgroup analyses or posthoc sensitivity analyses, which may reveal poor study design and study characteristics or “real” sources of variation related to patients, interventions, or outcome measures [5].

The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) criteria for systematic reviews requires a clear specification of the population, intervention, and comparators [6]. Additionally, the

underlying biology must suggest that across the population and interventions, it is plausible that the magnitude of effect on the key outcomes is similar [6]. When multiple options are combined in the treatment arm (in this case, decompression, decompression and fusion, or interspinous spacer) or control arm (here, no treatment, pharmacologic treatment, physical therapy, or a combination) in meta-analysis, authors should specify whether all treatments are equally recommended or if some treatments are recommended over others [6]. If heterogeneous patient populations and interventions are pooled with no further explanation of heterogeneity, the review may generate misleading estimates with limited clinical applicability.

Take-Home Messages

This systematic review and meta-analysis found no clear benefit of surgery versus nonsurgical treatment, but the quality of the evidence for all outcomes was graded low due to high risk of bias, study design, and imprecision due to incomplete outcome data. According to the GRADE approach, low-quality evidence indicates little confidence in the effect estimate and that the true effect is likely to be substantially different from the estimate of effect [2].

Now with 8-year results, the Spine Patient Outcomes Research Trial

(SPORT) represents the largest and highest-quality study available to isolate spinal stenosis from stenosis secondary to degenerative spondylolisthesis [7, 12]. SPORT was included in this Cochrane review and constituted a significant proportion of patients in the meta-analysis (289 of 383 patients). In this rigorous study that compared surgical versus nonsurgical care for LSS, patients could choose between randomization or enrollment in an observational arm. Intent-to-treat analyses showed no difference between randomized cohorts; further, although the as-treated analyses showed the early benefit for surgery out to 4 years, no substantial treatment effect of surgery was seen in years 6 to 8 for any of the primary outcomes [7]. In contrast, the observational cohort showed a stable advantage for surgery in all outcomes up to 8 years. This may be due to greater baseline differences in the two groups; long-term results in the as-treated trial are less likely to be confounded by baseline differences, suggesting that the advantage of surgery may diminish over time. Although this Cochrane review and the SPORT trial are not without limitations, their analyses call into question the long-term efficacy of surgical treatment for LSS. Clinicians need to carefully inform patients with LSS the potential limitations of surgery, especially given that no side effects were reported with nonsurgical treatment.

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Appendix

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Cochrane Database of Systematic Reviews

Surgical versus non-surgical treatment for lumbar spinal stenosis (Review)

Zaina F, Tomkins-Lane C, Carragee E, Negrini S

Zaina F, Tomkins-Lane C, Carragee E, Negrini S.
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[Intervention Review]

Surgical versus non-surgical treatment for lumbar spinal stenosis

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ABSTRACT

Background

Lumbar spinal stenosis (LSS) is a debilitating condition associated with degeneration of the spine with aging.

Objectives

To evaluate the effectiveness of different types of surgery compared with different types of non-surgical interventions in adults with symptomatic LSS. Primary outcomes included quality of life, disability, function and pain. Also, to consider complication rates and side effects, and to evaluate short-, intermediate- and long-term outcomes (six months, six months to two years, five years or longer).

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, five other databases and two trials registries up to February 2015. We also screened reference lists and conference proceedings related to treatment of the spine.

Selection criteria

Randomised controlled trials (RCTs) comparing surgical versus non-operative treatments in participants with lumbar spinal stenosis confirmed by clinical and imaging findings.

Data collection and analysis

For data collection and analysis, we followed methods guidelines of the Cochrane Back and Neck Review Group (Furlan 2009) and those provided in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Main results

From the 12,966 citations screened, we assessed 26 full-text articles and included five RCTs (643 participants).

Low-quality evidence from the meta-analysis performed on two trials using the Oswestry Disability Index (pain-related disability) to compare direct decompression with or without fusion versus multi-modal non-operative care showed no significant differences at six months (mean difference (MD) -3.66, 95% confidence interval (CI) -10.12 to 2.80) and at one year (MD -6.18, 95% CI -15.03 to

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2.66). At 24 months, significant differences favoured decompression (MD -4.43, 95% CI -7.91 to -0.96). Low-quality evidence from one small study revealed no difference in pain outcomes between decompression and usual conservative care (bracing and exercise) at three months (risk ratio (RR) 1.38, 95% CI 0.22 to 8.59), four years (RR 7.50, 95% CI 1.00 to 56.48) and 10 years (RR 4.09, 95% CI 0.95 to 17.58).

Low-quality evidence from one small study suggested no differences at six weeks in the Oswestry Disability Index for patients treated with minimally invasive mild decompression versus those treated with epidural steroid injections (MD 5.70, 95% CI 0.57 to 10.83; 38 participants). Zurich Claudication Questionnaire (ZCQ) results were better for epidural injection at six weeks (MD -0.60, 95% CI -0.92 to -0.28), and visual analogue scale (VAS) improvements were better in the mild decompression group (MD 2.40, 95% CI 1.92 to 2.88). At 12 weeks, many cross-overs prevented further analysis.

Low-quality evidence from a single study including 191 participants favoured the interspinous spacer versus usual conservative treatment at six weeks, six months and one year for symptom severity and physical function.

All remaining studies reported complications associated with surgery and conservative side effects of treatment: Two studies reported no major complications in the surgical group, and the other study reported complications in 10% and 24% of participants, including spinous process fracture, coronary ischaemia, respiratory distress, haematoma, stroke, risk of reoperation and death due to pulmonary oedema.

Authors' conclusions

We have very little confidence to conclude whether surgical treatment or a conservative approach is better for lumbar spinal stenosis, and we can provide no new recommendations to guide clinical practice. However, it should be noted that the rate of side effects ranged from 10% to 24% in surgical cases, and no side effects were reported for any conservative treatment. No clear benefits were observed with surgery versus non-surgical treatment. These findings suggest that clinicians should be very careful in informing patients about possible treatment options, especially given that conservative treatment options have resulted in no reported side effects. High-quality research is needed to compare surgical versus conservative care for individuals with lumbar spinal stenosis.

PLAIN LANGUAGE SUMMARY

Surgical versus non-surgical treatment for lumbar spinal stenosis

Review question: We reviewed the evidence that compares surgery versus non-surgical treatment for a condition called lumbar spinal stenosis. This condition occurs when the area surrounding the spinal cord and nerves becomes smaller.

Background: People with lumbar spinal stenosis experience a range of symptoms including back pain, leg pain, numbness and tingling in the legs and reduced physical function. These symptoms prompt people to seek treatment. One option for treatment is surgery. Other treatment options include physical therapy, exercise, braces and injections into the spine.

Study characteristics: We included five studies that compared surgical versus non-surgical treatment in a total of 643 people with lumbar spinal stenosis. Average age of participants in all studies was over 59 years. Follow-up periods ranged from six weeks to 10 years.

Key results: We cannot conclude on the basis of this review whether surgical or non-surgical treatment is better for individuals with lumbar spinal stenosis. Nevertheless, we can report on the high rate of effects reported in three of five surgical groups, ranging from 10% to 24%. No side effects were reported for any of the conservative treatment options.

Three studies compared spine surgery versus various types of non-surgical treatment. It is difficult for review authors to draw conclusions from these studies because non-surgical treatments were inadequately described. One study that compared surgery versus bracing and exercise found no differences in pain. Another study compared surgery versus spinal injections and found better physical function with injections, and better pain relief with surgery at six weeks. Still another trial compared surgery with an implanted device versus non-surgical care. This study reported favourable outcomes of surgery for symptoms and physical function.

Quality of the evidence: Evidence obtained by comparing surgery versus non-surgical treatment is of low quality. Well-designed studies are needed to examine this problem. In particular, researchers need to do a better job of describing the details of non-surgical treatments.

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