

Weinstein JN, Tosteson TD, et al. Surgical versus Nonsurgical Treatment for Lumbar Spinal Stenosis. N Engl J Med 2008;358:794-810.

Design: Randomized clinical trial

Population/sample size/setting:

- 634 patients (249 women, 385 men, mean age 65) with lumbar spinal stenosis treated at 13 centers in 11 US states, divided into two cohorts, one randomized and one observational
 - o 289 patients were in the randomized cohort and 365 were in the observational cohort; 20 patients did not contribute data, leaving cohorts of 278 and 356 respectively in the randomized and observational cohorts
 - o Only patients who consented to randomization were enrolled in that cohort; any patient who had a surgical/nonsurgical treatment preference was enrolled in the observational cohort
- Eligibility criteria were neurogenic claudication or radicular leg pain with associated neurological signs, spinal stenosis on cross-sectional imaging
- All patients had been persistently symptomatic for at least 12 weeks and had been confirmed as surgical candidates by their physicians
- Spondylolisthesis was an exclusion criterion; these patients were enrolled in a separate study
- Patients in the randomized cohort received treatment assignments from a computer-generated allocation list; patients in the observational cohort chose their treatment with their physician

Main outcome measures:

- The 289 patients in the randomized cohort were allocated to surgery (n=138) or nonsurgical treatment (n=151)
- The 365 in the observational cohort chose surgery (n=219) or nonsurgical treatment (n=146)
- Stenosis was graded as severe in 53% of patients; 61% had multiple levels of stenosis
- Surgery consisted of standard posterior decompressive laminectomy; fusion could be done at the surgeon's discretion (done in only 6% of patients)
- Nonsurgical protocol included at least a form of active physical therapy, education/counseling for home exercise, and NSAIDs
- Primary outcomes were two scales of the SF-36 (body pain and physical function) and the Oswestry Disability Index (ODI), and were measured at 6 weeks, and at 3, 6, 12, and 24 months
 - o Primary analysis compared groups on changes from baseline at each follow-up time
- Secondary outcomes included patient-reported improvement and satisfaction
- The initial analysis of the randomized cohort was by intention to treat, but there was extensive crossover, and later analyses were based on treatment actually received

- 63% of those randomized to surgery had it within 12 months, and 67% had it by 2 years; the remaining 33% had not had surgery at the 2 year mark
- 42% of those randomized to nonsurgical care had surgery in the first 12 months, and 43% had had surgery by 2 years
- In the intention-to-treat analysis of the randomized cohort, there were no statistically significant effects for the primary outcomes on the basis of a global hypothesis test for differences in mean changes from baseline
 - There was a significant treatment effect in favor of surgery at 2 years on only one main outcome measure, the SF-36 body pain measure; at 2 years, the SF-36 physical function and Oswestry did not differ between groups
- As-treated analyses were done for the combined observational and randomized cohorts, and showed effects in favor of surgery for all time periods up to 2 years
 - For SF-36 body pain, the treatment effect at 3 months was 16.1 on a scale of 100; for SF-36 physical function the effect was 14.8 points, and for the ODI the effect was 13.8 points on a scale of 100
 - The as-treated effects at 2 years did not differ in the randomized and observational cohorts for SF-36 and Oswestry scores
- Subgroup analyses did not show significant treatment effect modification according to age, sex, medical comorbidity, smoking, presence or absence of straight leg raising, BMI, or other compensation
- Patients undergoing surgery in the combined cohort were younger and more likely to be working than patients receiving nonsurgical care; they also had more pain, lower function, more psychological distress, and more self-reported disability than the nonoperative patients, with radiographic evidence of more severe stenosis
- Additional surgery was done in 10 of the 155 operated patients in the randomized cohort and in 21 patients in the observational cohort at the end of 2 years; no patient had pseudarthrosis at the end of 2 years

Authors' conclusions:

- Although intention-to-treat analysis found no significant advantage of surgery over nonsurgical care, that analysis was severely limited by crossover from one group to another
- As-treated analysis showed that surgery was superior to nonoperative treatment as early as 6 weeks, reached a maximum at 6 months, and persisted after 2 years
- These results are consistent with earlier comparisons of surgical and nonoperative interventions for the same conditions
 - In the arm of the SPORT study of patients with herniated discs, the improvements in the nonoperated group were greater than for the nonoperated patients in either the spinal stenosis or degenerative spondylolisthesis study

- There was little harm from either treatment; the patients who did not have surgery had small improvements between baseline and the end of the study
- Although there was great heterogeneity in nonoperative treatment, it would have been impractical to attempt a fixed protocol for nonsurgical treatment, and the interventions received by those patients were in accord with published guidelines

Comments:

- SPORT studies were set up in a way to permit patients to choose whether to enroll in the randomized trial or in the observational cohort; large crossover was observed in the trials of herniated disc and spinal stenosis without spondylolisthesis as well
- When crossover is large and nonrandom (patients crossing to surgery doing so on the basis of worsening symptoms), the intention-to-treat analysis will underestimate the treatment effect likely to be seen outside the clinical trial
- Because of the very narrow differences between the as-treated analyses in the randomized and observational cohorts, it is reasonable to combine them as the authors did
- The majority of locations of stenosis were central or in the lateral recess; foraminal stenosis was reported in 30% of the patients who had surgery and in 37% of those who had nonoperative care; 85% of both groups had central stenosis

Assessment: High quality study supporting good evidence that surgical treatment of lumbar spinal stenosis leads to better symptomatic and functional outcomes, but patients who choose nonoperative treatment do not deteriorate but may improve slightly. These improvements with nonoperative care appear to be less for spinal stenosis (and for degenerative spondylolisthesis) than for herniated discs, for which nonoperative improvements appear to be more substantial