

Weinstein JN, Tosteson TD, et al. Surgical vs Nonoperative Treatment for Lumbar Disc Herniation. JAMA 2006;2441-2450.

Design: Randomized clinical trial

Population/sample size/setting:

- 472 patients (194 women, 278 men, mean age 42), treated for lumbar herniated discs at 13 centers in 11 states
- Eligibility criteria were symptoms diagnosed as due to an intervertebral disc herniation and treated nonoperatively for 6 weeks, with radicular pain and evidence of nerve-root irritation (straight leg raising between 30° and 70° or a positive femoral tension sign), or a corresponding neurologic deficit (weakness or decreased sensation); all participants had imaging showing disc herniation (protrusion, extrusion, or sequestered fragment) at the level and side corresponding to symptoms
- Exclusion criteria were prior lumbar surgery, cauda equina syndrome, scoliosis greater than 15°, segmental instability >4 mm translation, vertebral fracture, infection/tumor, inflammatory spondyloarthropathy, pregnancy, or unwillingness to have surgery within 6 months
- Only patients willing to be assigned to treatment randomly entered the trial; a separate observational study was done for patients who were otherwise eligible but had definite treatment preferences, and this was published separately

Main outcome measures:

- Treatment allocation was done with permuted block randomization to either surgery (n=232) or nonoperative treatment (n=240)
- Surgery was a standard open discectomy with examination and decompression of the involved nerve root, leaving it freely mobile
 - o 95% of operations had no complications; 4% had intraoperative dural tears
- Nonoperative treatment varied among patients but the protocol recommended that patients receive active physical therapy, education, home exercise instruction, and NSAIDs
 - o Additional interventions were individualized but were documented and tracked prospectively
 - o 93% of nonoperative group received education/counseling, 63% received NSAID/oral steroid/COX 2 drugs, 46% receive opiates, 50% had injections (epidural steroids), and 29% had activity restriction
- Main outcome measures were changes in the physical function and bodily pain subscales of the SF-36 and the Oswestry Disability Index (ODI)
 - o Secondary measures were self-reported improvement, work status, satisfaction with care, and the Sciatica Bothersomeness Index
- Main analysis was by intention to treat, but a preplanned “as-treated” analysis was part of the study protocol, due to the anticipated crossover rates

- During the 2 years of the trial, crossover rates were high; only 60% of the group assigned to surgery actually had surgery; of the patients assigned to nonoperative treatment, 45% underwent surgery
- For both groups, there were substantial improvements in SF-36 and ODI scores during the 2 years of observation (e.g., the ODI improved by 31.4 points in the surgery group and by 28.7 points in the nonoperative group)
- The SF-36 and ODI changes favored surgery at every follow-up point, but for these primary outcomes, the group differences fell short of statistical significance in the intention-to-treat analysis which ignored crossovers
 - However, the crossovers did not occur randomly
 - The surgery patients who did not undergo surgery had less pain and disability at baseline, were improving at the time of enrollment, were older, and had higher incomes
 - The nonoperative group which crossed over to surgery had worse baseline symptoms and disability, were getting worse at the time of enrollment, and were younger, and had lower incomes
 - When these crossover differences were taken into account in the as-treated analysis, there were statistically significant advantages for surgery at all follow-up times for the two years of the study
- For the Sciatica Bothersomeness Index, the improvements were greater for the surgery group at all follow-up times

Authors' conclusions:

- Both operated and nonoperated patients with lumbar intervertebral disc herniations improved over the two years of the study
- The results may not generalize to patients unable to tolerate 6 weeks of nonoperative treatment, and may not generalize to patients without clear signs and symptoms of radiculopathy with confirmatory diagnostic imaging
- The improvements in the nonoperative group were greater than observed in previous studies of nonoperative treatment of herniated disc disease; this large improvement contributed to the small treatment differences observed between that group and the surgery group
- Because of the degree of crossover from the randomized treatment, it is doubtful that the intention to treat analysis will form by itself a true estimate of the treatment effect of surgery
- The nonoperative group received its interventions at the discretion of the treating physician, which is a limitation of the study; however, the nonoperative treatments were consistent with published guidelines
 - The use of epidural steroid injections and opiates was fairly high
- Between-group differences did favor surgery, but intention to treat analysis does not support conclusions about the superiority or equivalence of treatments

Comments:

- All reasonable measures to control bias were undertaken, including randomization done in a way which protects the concealment of allocation, and a priori planning of the additional analyses
- Because the very frequent crossovers were not random, it is likely that the intention to treat analysis underestimates the benefit of surgery in patients with high levels of pain and disability who are getting worse with nonoperative treatment
- The frequency of injections and opiates in the nonoperative group may account for much of the treatment effect seen in that group; this should be interpreted as high-intensity nonoperative treatment, and physical therapy alone would probably have a more modest treatment effect
- The planning and execution of the protocol add to the credibility of the as-treated analysis, which cannot be dismissed as data-driven

Assessment: High quality for evidence that open discectomy is likely to benefit patients with imaging-confirmed lumbar disc herniations who are failing to improve with several weeks of conservative treatment