

Butterman GR. Treatment of Lumbar Disc Herniation: Epidural Steroid Injection [ESI] Compared with Discectomy. JBJS Am 2004;86-A:670-679.

Design: Randomized clinical trial

Population/sample size/setting:

- 100 patients (mean age 40, gender not reported, 23 Workers Compensation) referred to the author for treatment of large lumbar disc herniation at the Midwest Spine Institute in Minnesota
- Eligibility required age between 18 and 70, with disc herniation encompassing at least 25% of the cross-sectional area of the spinal canal on axial MRI/CT, and failure of 6 weeks of conservative treatment
- 169 patients were originally enrolled, but 69 had improvement with conservative treatment and were not enrolled in the RCT (this included physical therapy, chiropractic treatment, rest, and pain medication)
- Exclusion criteria were pregnancy, cauda equina syndrome, pars defect at the level of the disc herniation, far-lateral disc herniation, multilevel symptomatic herniation, or recurrent herniation

Main outcome measures:

- Randomized by computer to either discectomy by the author (n=50) or to ESI with betamethasone by a radiologist or anesthesiologist (n=50)
 - o As many as 3 ESI could be given one week apart if decrease in pain was not reported by the patient following one or two injections
 - o All injections were done one level cephalad to the disc herniation, with the needle placed between the laminae; 76% were done with fluoroscopic guidance
 - o Betamethasone dose was 10 to 15 mg
- Most patients had neurological deficits at baseline, either motor (82% of discectomy pts, 88% of ESI pts) or sensory (70% of discectomy and 74% of ESI pts)
- More than half (n=27) of the 50 ESI patients crossed over to have discectomy because of recurrent pain; the average time from ESI to recurrence of pain was 3.3 months, and the average time from recurrence of pain to discectomy was 4.5 months
- Follow-up was scheduled at five time intervals: 1-3 months, 4-8 months, 1-12 months, 1-2 years, and 2-3 years; however, the author focused on the 1-3 month outcomes in comparing groups
 - o At this early outcome measurement, the discectomy group showed greater improvement than the ESI group on several outcomes
 - Residual motor deficits and Oswestry Disability scores
 - Lower extremity pain
 - Painful area on pain diagram
 - Use of pain medicine
 - Success of treatment as judged by the patient

- At the 2-3 year outcome assessments, the group differences were no longer significant on most of these outcomes
- Observations were made of some characteristics of the herniated discs, with some of these characteristics associated with more favorable outcomes
 - Patients with sequestered or extruded discs generally fared better
 - Hydrated discs (high signal on T2 weighted MRI) did better
 - Lateral recess stenosis at the level of the herniated disc was not observed to have an effect on outcome scores
- Of the 50 patients who had ESI, 2 had incidental dural puncture; these crossed over to discectomy
- There were 4 recurrent disc herniations requiring revision discectomy
- Two discectomy groups had fusion at 1 and 3 years after the discectomy, and 3 others were contemplating fusion because of disabling back pain

Author's conclusions:

- Most of the patients were referred for treatment of disc herniation; thus, this study does not truly define the natural history of a herniated disc
- Because 69 of the 169 patients referred for treatment improved with 6 weeks of conservative therapy, a minimum of 6 weeks of conservative treatment is reasonable prior to invasive treatment with ESI or surgery
- Because the ESI failures who crossed over to discectomy had outcomes similar to those of patients randomized to early discectomy, the study fails to show that a delay in decompression due to an early trial of ESI has any detrimental effect on function
- Because of circumstances beyond the author's control (insurance company policies), the ESI was not standardized, nor were that group's co-intervention standardized
- Because nearly half of patient randomized to ESI had favorably prompt resolution of symptoms, the study supports the use of ESI in patients who have failed to improve after 6 weeks of noninvasive treatment
- Patients with less severe disability (Oswestry), patients with sequestered or extruded discs, and patients with hydrated (high signal T2) may be more likely to succeed with ESI than patients whose discs do not have these characteristics

Comments:

- The author showed that ESI was not as effective as discectomy, but reasonably concludes that patients with large disc herniations are not harmed by waiting for discectomy after a trial of ESI
- Some of the outcome data is presented graphically; tabular reporting of numerical outcome data is clearer and should also be reported
- Up to 3 ESI were permitted in the group randomized to ESI, but the numbers of patients receiving multiple injections is not apparent
- Incidental dural puncture in 2 of the 50 ESI patients is a reminder of some of the safety issues surrounding the use of ESI; how this was ascertained when not all patients had fluoroscopic imaging is not clear

- Some potential bias related to ESI technique and co-interventions was beyond the author's control; other sources of bias were reasonably well controlled
- The disc characteristics (hydration, sequestration) associated with better outcomes should be considered observational in nature, but it may still be appropriate to consider them in deciding between a trial of ESI versus prompt discectomy in patients with large herniations

Assessment: Adequate for some evidence that a trial of ESI in selected patients is a reasonable initial treatment choice which is not necessarily likely to compromise the long term outcome of large herniated discs