Lumbar Disc Herniation: A Controlled, Prospective Study with Ten Years of Observation

62

Alexander D.L. Baker

62.1 Author

Henrik Weber

62.2 Reference

Spine. 1983;8:131–140.

62.3 Institution

The Department of Neurology and Neurosurgery, Ullevaal Hospital, Oslo, Norway.

62.4 Abstract

Background: Prior to this study there were no randomized trials that investigated outcome following discectomy. The author highlights that as a result of the relative paucity of evidence, the indications for surgery varied according to the personal opinion of the different doctors.

Aim: The purpose of this study was to provide reliable data that might be useful in the choice of treatment for patients with lumbar disc herniation.

Method: Two hundred and eighty patients with symptoms of sciatica, who had been found to have a corresponding lumbar disc prolapse on myelography were included in this study. All received 1 week of conservative treatment with strict bed rest and analgesia. Patients were then divided into three groups. The first group (126 patients) were randomized to receive either further conservative therapy or surgery (discectomy). The second group (67 patients) were thought to have definite indications for surgery. These indications included: severe immobile scoliosis, intolerable pain, suddenly occurring or progressive muscle weakness or loss of bladder or bowel function. These patients underwent surgery. The third group (87 patients) were treated conservatively because they demonstrated progressive improvement with initial conservative treatment. For those patients randomized between treatments, follow-up examinations were performed after 1, 4 and 10 years. Outcome was assessed with a questionnaire, repeat myelography and re-examination by the author.

Conclusion: At 1-year follow-up there was a statistically significant better outcome in the surgically treated group compared to those treated conservatively.

62.5 Citation Count

559

62.6 Summary

This was a randomised controlled trial examining the outcome of conservative treatment vs. surgical treatment in 126 patients with lumbar disc prolapse diagnosed using radiculography. Two hundred and eighty patients were initially observed for a period of 14 days in hospital. Those with severe pain, immobile scoliosis and muscle weakness of bladder or rectum were excluded. They underwent operation and were excluded from the analysis. Those who improved within the 2 weeks of observation were also excluded and received further conservative treatment. Conservative treatment was 1 week of bed rest followed by progressive mobilization in a 'back school'. Those who had persistent pain compatible with findings on radiculography underwent randomisation between discectomy and ongoing conservative care.

A.D.L. Baker, BSc, MBChB, MRCS, MSc, FRCS (Tr & Orth)
Department of Orthopaedic Surgery, Royal Preston Hospital, Lancashire Teaching Hospitals NHS Trust, Preston, UK
e-mail: alexbaker@nhs.net

P.A. Banaszkiewicz, D.F. Kader (eds.), *Classic Papers in Orthopaedics*,
DOI 10.1007/978-1-4471-5451-8_62,

Patients were followed-up with a questionnaire that was administered at 3, 6, 9 months and at 1 year. Similar questionnaires were administered at 2, 3 and 4 years. Examinations were performed at 1 year, and 10 years by the author.

Patients were allocated to one of four categories, Good, Fair, Poor or Bad, these correspond to the 'subjective statements' completely satisfied, satisfied, not satisfied and completely incapacitated for work.

Analysis of the study was complicated by a crossover group of 17 patients. All of these crossed over from the nonsurgical group to the surgical group. The results were analysed on both an intention-to-treat basis and on an as-treated basis and this demonstrated that the crossover group did not affect statistical significance.

The paper showed a statistically better outcome at 1 year for surgically treated patients but by 4 years the difference was no longer significant and by 10 years the trend was no longer observable.

62.7 Citation Count

452

62.8 Related References

1. Hoffman RM, Wheeler KJ, Deyo RA. Surgery for herniated lumbar discs: a literature synthesis. J Gen Intern Med. 1993;8(9):487–96.
2. Gibson JN, Waddell G. Surgical interventions for lumbar disc prolapse. Cochrane Database Syst Rev. 2007;(1): CD001350.
3. Komori H, Shinomiya K, Nakai O, Yamaura I, Takeda S, Furuya K. The natural history of herniated nucleus pulposus with radiculopathy. Spine. 1996;21(2):225–9.

62.9 Key Message

Both patient and observer ratings showed that discectomy was significantly better than conservative therapy at 1 year, but there were no significant differences in outcomes at 4 and 10 years. Regardless of treatment, impaired motor function had a good prognosis, whereas sensory deficits remained in almost half of the patients.

The long-term outcome of conservative treatment was better than expected. The short-term outcome was better with surgery than with conservative treatment.

62.10 Why It's Important

Although the Weber study has been criticized for not meeting current standards for randomized trials, it was, for many years, the only randomised comparative trial of surgical versus nonsurgical treatment for patients with sciatica due to a lumbar intervertebral disc herniation.

At 10 years, Weber reported good results in 63.6 % of patients initially randomized to surgery and 56 % of those initially receiving conservative treatment, but the difference was not statistically significant. The narrowing of outcomes between 4 and 10 years represented a small improvement for conservatively treated patients and worse outcomes in surgically treated patients.

62.11 Strengths

This was a randomised trial examining surgical outcome. It was well designed and the first of its type investigating outcome following lumbar disc prolapse.

62.12 Weaknesses

There were relatively small numbers of patients treated, the trial was not blinded and there was considerable crossover to surgery. The outcome measures used were specific to the trial and have not been validated.

The diagnostic test of radiculography is now rarely used for the diagnosis of lumbar disc prolapse. How the sensitivity and specificity of radiculography compares to MRI is unknown.

62.13 Relevance

Sciatica or lumbosacral radiculopathy as a consequence of lumbar nerve root compression from a prolapsed intervertebral disc is a frequent cause of pain and disability [1]. Lumbar discectomy (or microdiscectomy) is the most frequently performed lumbar spine operation in the United States. It is a procedure that aims to improve pain by removal of the prolapsed disc fragment. However, the natural history of most lumbar disc prolapses is that they resolve in time. Other conservative treatments such as physiotherapy or steroid injection have been used with good effect and surgery carries with it the risk of neurological complications. This was a well-designed prospective study that showed improved outcomes with surgical rather than conservative treatment.

It provides good quality evidence for surgical intervention in these patients.

The large regional difference in the rates of lumbar discectomy seen in the United States with up to a 15-fold variation raised questions on the appropriateness of some of these surgeries.

A number of studies have compared surgical and conservative treatment of patients with herniated disc. Baseline differences between treatment groups, small sample sizes, or use of unvalidated outcome measures limits evidence-based conclusions regarding optimal treatment [2–4].

Weinstein et al. [5] in a large prospective study (The Spine Patient Outcomes Trial – SPORT) demonstrated that patients in both surgery and non-operative treatment groups improved substantially over the first 2 years. Results were initially analysed on an intention to treat basis. Between-group differences in improvements were consistently in favour of surgery for all outcomes and at all time periods, but were small and not statistically significant except for the secondary measures of sciatica severity and self-rated improvement. Because of the high numbers of patients who crossed over in both directions the authors report that conclusions about the superiority or equivalence of the treatments were not warranted based on the intention-to-treat analysis alone. An as-treated analysis was performed which showed a clear statistically significant advantage for surgery at all follow-up times throughout the 2 years of follow-up. In the same journal Weinstein et al. [6] published an observational cohort study. These patients had declined randomisation for inclusion into the initial study. This observational study did show a statistically significant difference between the two groups with those treated surgically showing a greater improvement in self-reported outcome.

Atlas et al. [7] reported on the 10-year outcome of a prospective series of 400 patients with sciatica treated surgically and non-surgically. Surgically treated patients had more complete relief of leg pain and improved function and satisfaction compared with non- surgically treated patients over 10 years. Nevertheless, improvement in the patient's predominant symptom and work and disability outcomes were similar regardless of treatment received.

Peul et al. [8] reported a multicentre trial of 283 patients who had severe sciatica for 6–12 weeks. Patients were assigned to either early surgery or prolonged conservative treatment with surgery if needed. They found similar outcomes at 1 year but the rates of pain relief and of perceived recovery were faster for those assigned to early surgery.

The Spine Patient Outcomes Trial (SPORT) discussed above demonstrated further evidence for the benefit of surgery in a follow-up study over 4 years [9]. Pearson et al. [10] analysed the SPORT data for 37 baseline variables to define subgroups with greater treatment effect. Being married, absence of joint problems, a worsening symptom trend at baseline, high school education or less, older age, no worker's compensation, longer duration of symptoms and an SF-36 mental health dimension score <35 were associated with greater treatment effects.

The cost effectiveness and benefits of surgery versus non-operative treatment has been extensively investigated in recent years.

Malter et al. [11] reanalysed Weber's data and suggested that discectomy was cost effective, at approximately $29,000 per quality-adjusted life year gained. This study had important limitations; the effect of surgery on worker productivity (indirect costs) was not addressed and costs and health outcomes were derived from two different populations.

A more recent cost effectiveness analysis, investigating surgery relative to non-operative care [12], reported that although the cost per QALY gained for surgery relative to non-operative care varied with the cost of surgery it remained relatively favourable when compared to well established costs such as antihypertensive treatment. This was more marked in a later study, which accessed outcome over a 4 years period [13].

Overall the results of Weber's study investigating the outcome of discectomy have been upheld over time with surgery producing relatively greater improvements in patient reported outcomes than conservative treatment.

References

1. Konstantinou K, Dunn KM. Sciatica: review of epidemiological studies and prevalence estimates. Spine. 2008;33(22):2464–72.
2. Buttermann GR. Treatment of lumbar disc herniation: epidural steroid injection compared with discectomy. A prospective, randomized study. J Bone Joint Surg Am. 2004;86(4):670–9.
3. Hakelius A. Prognosis in sciatica. A clinical follow-up of surgical and non-surgical treatment. Acta Orthop Scand Suppl. 1970;129:1.
4. Nykvist F, Knuts LR, Alaranta H, et al. Clinical, social, and psychological factors and outcome in a 5-year follow-up study of 276 patients hospitalized because of suspected lumbar disc herniation. Int Disabil Stud. 1990;12(3):107–12.
5. Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical vs non-operative treatment for lumbar disk herniation. JAMA. 2006; 296(20):2441–50.
6. Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical vs non-operative treatment for lumbar disk herniation: observational cohort. JAMA. 2006;296(20):2451–9.
7. Atlas SJ, Keller RB, Wu YA, et al. Long-term outcomes of surgical and nonsurgical management of sciatica secondary to a lumbar disc herniation: 10 year results from the Maine Lumbar Spine Study. Spine. 2005;30(8):936–43.

8. Peul WC, van Houwelingen HC, van den Hout WB, et al. Surgery versus prolonged conservative treatment for sciatica. N Engl J Med. 2007;356(22):2245–56.
9. Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical versus nonoperative treatment for lumbar disc herniation: four-year results for the Spine Patient Outcomes Research Trial (SPORT). Spine. 2008;33(25):2789–800.
10. Pearson A, Lurie J, Tosteson T, et al. Who should have surgery for an intervertebral disc herniation? Spine. 2012;37(2): 140–9.
11. Malter AD, Larson EB, Urban N, Deyo RA. Cost-effectiveness of lumbar discectomy for the treatment of herniated intervertebral disc. Spine. 1996;21(9):1048–54.
12. Tosteson AN, Skinner JS, Tosteson TD, et al. The cost effectiveness of surgical versus non-operative treatment for lumbar disc herniation over two years: evidence from the Spine Patient Outcomes Research Trial (SPORT). Spine. 2008;33(19):2108–15.
13. Tosteson ANA, Tosteson TD, Lurie JD, et al. Comparative effectiveness evidence from the spine patient outcomes research trial. Spine. 2011;36(24):2061–8.