

## Surgery versus Conservative Care for Persistent Sciatica Lasting 3 to 6 Months

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### ABSTRACT

**Background:** Low back pain due to lumbar disc prolapse is a common disorder. The treatment of chronic sciatica caused by herniation of a lumbar disk has not been well studied in comparison with acute disk herniation.

**Patients and Method:** In a single-center trial, we randomly assigned 150 patients ?? how many with sciatica that had lasted for 3 to 6 months and lumbar disk herniation at the L4–L5 or L5–S1 level in a 1:1 ratio (75 patients in each group) to undergo discectomy or to receive 6 months of standardized non-operative care followed by surgery if needed. The study was conducted for 1 year from 2020 to 2021.

**Results:** The mean score for leg-pain intensity was 7.7 in the surgical group and 8.0 in the nonsurgical group. The primary outcome of the leg-pain intensity score at 6 months was 2.8 in the surgical group and 5.2 in the nonsurgical group

**Conclusion:** Discectomy was superior to nonsurgical care concerning pain intensity at 6 months of follow-up.

**Keywords:** Low back pain, Sciatica, Chronic disc disease.

### INTRODUCTION

The treatment of chronic sciatica caused by herniation of a lumbar disk has not been well studied in comparison with acute disk herniation. Data are needed on whether discectomy or a conservative approach is better for sciatica that has persisted for several months<sup>(1)</sup>.

### PATIENTS AND METHODS

In a single-center trial, randomly assigned 150 patients with sciatica that had lasted for 3 to 6 months and lumbar disk herniation at the L4–L5 or L5–S1 level in a 1:1 ratio (75 patients in each group) to undergo discectomy or to receive 6 months of standardized non-operative care followed by surgery if needed. Surgery was performed by spine surgeons who used conventional discectomy techniques. The primary outcome was the intensity of leg pain on a visual analog scale, the secondary outcome was the incidence of complications. The study was conducted for 1 year from 2020 to 2021.

**Inclusion criteria:** (1) Provide levels I to IV evidence (2) RCT & comparative studies (3) They included measures of functional and clinical outcomes.

**Exclusion criteria:** (1) Non-English papers. (2) Non-human trials. (3) Articles with no clinical data.

**Outcomes:** All outcomes were assessed at baseline, 6 weeks, 3, and 6 months after enrollment. The primary outcome was the leg-pain intensity score on the visual analog scale (ranging from 0 to 10, with higher scores indicating a greater intensity of pain) 6 months after randomization. Secondary outcomes, which were analyzed at 6 months, were a combination; (standardized mean [ $\pm$ SD]) of  $50\pm 10$  determined with the use of norm-based scoring with higher scores

indicating a better quality of life). For patients in the nonsurgical group who crossed over to undergo surgery, outcome measures were obtained at the same predefined time points postoperatively.

### Ethical consent:

An approval of the study was obtained from Helmeya Hospital Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of participation in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

### Statistical Analysis

The null hypothesis was that there would be no significant between-group difference in the mean score for leg-pain intensity at 6 months. All the analyses were performed according to the intention-to-treat principle with SPSS software, version 25. A P-value of less than 0.05 was considered statistically significant. The primary outcome analysis used a mixed model of longitudinal regression for repeated measures that accounted for the correlation (on the assumption of compound symmetry) among the outcome scores for the same patient. The adjusted mean difference in the primary outcome was tested at the 6-month follow-up.

### RESULTS

From 2020 through 2021, a total of 600 patients were screened; of those patients, 150 were enrolled, with 75 in each group. Among the patients assigned to undergo surgery, the median time from randomization to surgery was 3.1 weeks; of the 75 patients in the surgical group after enrollment. At baseline, the mean score for leg-pain intensity was 7.7 in the surgical group and 8.0 in the nonsurgical group. The primary outcome

of the leg-pain intensity score at 6 months was 2.8 in the surgical group and 5.2 in the nonsurgical group (adjusted mean difference, 2.4; 95% confidence interval, 1.4 to 3.4;  $P < 0.001$ ). Secondary outcomes including complications of surgery or delayed treatment in the non-operative group at 6 months were in the same direction as the primary outcome. Nine patients had adverse events associated with surgery, and one patient repeated surgery for recurrent disk herniation. Outcomes at 6 months, the score for leg-pain intensity was  $2.8 \pm 0.4$  in the surgical group and  $5.2 \pm 0.4$  in the nonsurgical group (difference, 2.4; 95% confidence interval [CI], 1.4 to 3.4;  $P < 0.001$ ). Secondary outcomes were generally in the same direction as the primary outcome. Patients in the two groups had a reduction in symptoms at the 6-month follow-up visit. Sensitivity analyses for missing data were similar in direction to the results of the primary analysis.

symptoms for a shorter duration than the minimum of 4 months required for entry in our trial.

(2,5,13,14) One trial, which included only patients with a history of 6 to 12 weeks of severe sciatica, showed that the benefit of early surgery was no longer different between the surgical group and the nonsurgical group by 6 months. (2,3) Another trial involving patients with radicular pain lasting 3 to 6 weeks showed no difference in outcomes between the surgical group and the non-surgical group at 6 weeks. (4) In SPORT (Spine Patient Outcomes Research Trial) (5), which recruited a majority of patients who had symptoms lasting less than 6 months, investigators found a significant advantage of surgery over non-surgical care in the as-treated analysis. In our trial, we found that the treatment effect for secondary outcome measures (e.g., back pain and physical functioning) at both 3 months and 6 months were in the same direction as the primary outcome, but a formal analysis was not possible because the original statistical plan made no accommodation for multiple comparisons. The decision about whether to recommend discectomy or nonsurgical treatment in this population is controversial because a longer duration of symptoms has been correlated with a poorer outcome associated with a lumbar discectomy in some studies (15,19). However, patients may prefer to avoid surgery if they think that non-surgical treatment could be successful or if they anticipate a risk from surgery (20). In a post hoc analysis of SPORT data, symptom duration of 3 months or more was associated with a worse outcome than a shorter duration after either surgical or nonsurgical treatment (19). Other studies have shown that patients who were waiting to undergo surgery for 6 weeks or more had worse pain 3 months after surgery than those who had a shorter waiting period (16). The prolonged waiting time to see a surgeon was an opportunity to minimize the crossover effect since only 2 patients underwent surgery within 3 months after enrollment in our trial. By design, the patients in the nonsurgical group received standardized treatment by a designated separate trial physician who would not provide surgical care. Such patients remained on the surgeon's waiting list for surgical consultation, which occurred approximately 3 months after enrollment. A strength of this trial is that the nonsurgical cohort received standardized treatment.

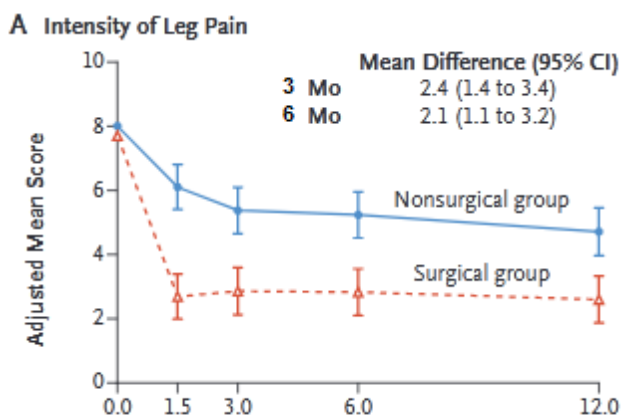
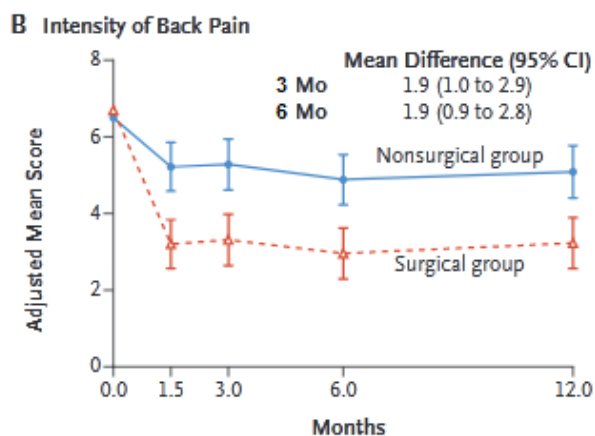


Figure 1: A shows difference in leg pain intensity B shows difference in back pain intensity



## DISCUSSION

In our single-center trial involving patients with sciatica lasting 3 to 6 months caused by lumbar disk herniation at the L4–L5 or L5–S1 level, surgery resulted in less leg pain at 3 months than nonsurgical treatment. Randomized trials have shown a beneficial treatment effect for surgery over conservative care in the first 3 months among patients with lumbar disk herniation. However, in some randomized trials, the patients had

## CONCLUSIONS

In this single-center trial involving patients with sciatica lasting more than 3 months and caused by lumbar disk herniation, a discectomy was superior to nonsurgical care concerning pain intensity at 6 months of follow-up.

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