Is surgery for recurrent lumbar disc herniation worthwhile or futile? A single center observational study with patient reported outcomes

Fifth year thesis

MD4051

Faculty of Medicine and Health Sciences

NTNU

Trondheim, 2020

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Abstract

Objective To examine outcomes and complications following microdiscectomy for recurrent lumbar disc herniation

Methods Prospective data for patients operated at the Department of Neurosurgery, St. Olavs University Hospital, Norway, were obtained from the Norwegian Registry for Spine Surgery from May 2007 through July 2016. All patients underwent lumbar microdiscectomy. The primary outcome was change in the Oswestry Disability Index (ODI) at one year. Secondary endpoints were change in quality of life measured with EuroQol 5 Dimensions (EQ-5D), back and leg pain measured with numerical rating scales (NRS), complications, and duration of surgery and hospital stays.

Results 276 patients were enrolled in the study. A total of 161 patients (58.3%) completed one-year follow-up. The mean improvement in ODI at one year was 27.1 points (95% CI 23.1 to 31.0, P <0.001). The mean improvement in EQ-5D at one year of 0.47 points (95% CI 0.40 – 0.54, P <0.001), representing a large effect size (Cohens D = 1.3). The mean improvement in back pain and leg pain NRS were 4.3 points (95% CI 2.2 – 3.2, P <0.001) and 3.8 points (95% CI 2.8 – 3.9, P <0.001), respectively. Nine patients (3.3%) experienced intraoperative complications, and 15 (5.5%) out of 160 patients reported complications within three months following hospital discharge.

Conclusions
This study shows that patients operated for recurrent lumbar disc herniation in general report significant clinical improvement.

Keywords
Lumbar disc herniation; Neurosurgical procedures; Quality of life; Sciatica

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Introduction

Sciatica due to lumbar disc herniation (LDH) is the most common indication for spine surgery. (1) Recurrent LDH with sciatica is a frequent condition with a reported incidence rate of 0.5-25% after the initial operation (2-5). Management of recurrent LDH varies, and there are no concise guidelines, only general opinions. Currently, discectomy and discectomy with fusion are the two most popular surgical options. However, there is still not enough adequate evidence in favor of either one. Even though evidence is limited, surgery is still considered to be a safe and effective alternative for patients with recurrent LDH (6). There are several studies reporting incidence rate of recurrent LDH and the rate of repeat discectomy, fusion or other treatment methods. However, few studies report patient reported clinical outcomes following repeat surgery. Those available report inconclusive result varying between comparable results to primary discectomies, no difference, and even worse outcomes (7-10). As a result, there are currently limited data on what patients can expect when undergoing multiple surgeries for LDH.

The aim of this observational study was to investigate patient reported outcomes and complications following microdiscectomy for recurrent lumbar disc herniation.

Methods and material

Study population

Data were collected through NORspine, a comprehensive registry for quality control and research (11) Participation in the NORspine registry is not mandatory for providers or patients, and it is not required for a patient to gain access to health care or for a provider to be eligible for payment. Follow-up time from the date of the last operation was one year, regardless of previous number of surgeries.

We included all patients with a definitive diagnosis of symptomatic recurrent LDH who were scheduled for a single-level lumbar microdiscectomy at St. Olavs University Hospital in Trondheim, Norway between January 2007 and July 2016. All patients had undergone

previous lumbar spine surgery in the same level and on the same side at least three months earlier and were all included in the NORspine registry. Patients who had coexisting degenerative spondylolisthesis and/or scoliosis were excluded, as well as patients who had previously undergone fusion surgery.

Data collection and registration by the NORspine registry protocol

On admission for surgery, the patients completed the self-administered baseline questionnaire, which included questions about demographics and lifestyle issues in addition to the outcome measures. During the hospital stay, using a standard registration form, the surgeon recorded data concerning diagnosis, previous lumbar spine surgery, comorbidity, *American Society of Anesthesiologists* (ASA) grade, image findings, and surgical approach and procedure. The surgeons provided data on the following possible complications and adverse events to the NORspine registry: intraoperative hemorrhage requiring blood transfusion, postoperative hematoma requiring repeated surgery, unintentional durotomy, nerve injury, cardiovascular complications, respiratory complications, anaphylactic reactions, and wrong level surgery. Patients reported the following complications if they occurred within three months after surgery: wound infection, urinary tract infection, pneumonia, pulmonary embolism, and deep venous thrombosis. A questionnaire was distributed to patients by regular mail at three months and one year after surgery, completed at home by the patients, and returned. The patients who did not respond received one reminder with a new copy of the questionnaire. The patients completed preoperative questionnaire data and postal follow-up questionnaires without any assistance from the surgeon or other staff from the treating hospital. Information about previous or future surgery not originally registered in NORspine were collected from electronical patient journals.

Ethical approval

The study was evaluated and approved by the regional committee for medical research in Central-Norway (2016/840), and all participants provided written informed consent. The Data Inspectorate of Norway approved the registry protocol

Primary outcome measure

The primary outcome measure was change of Oswestry Disability Index from baseline to one year after surgery. NORspine uses version 2.0 of the Oswestry disability index (ODI) (12). This version has been translated into Norwegian and tested for psychometric properties (13,

14). ODI contains 10 questions on limitations of activities of daily living. Each variable is rated on a 0- to 5-point scale, summarized, and converted into a percentage score. Scores range from 0 (no disability) to 100 (bedridden). A frequently applied criteria for success is minimal disability (i.e. ODI ≤ 20 points) at one year. Others have suggested that an improvement of at least 13 points at one year could serve as a success criterion (15). A change in ODI score of less than 33% or a raw ODI score of 48 or more after surgery have been suggested as the criteria with the highest accuracy for defining failure and worsening after surgery for lumbar disc herniation (16)

Secondary outcome measure

Changes in generic health-related quality of life was measured with the generic Euro-Qol-5D (EQ-5D) instrument. The EQ-5D questionnaire evaluates the generic quality of life with one question for each of the five dimensions that include mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Intensity of pain will be graded in two separate 0–10 numerical rating scales (NRS) for back pain and leg pain where 0 equals no pain and 10 represents the worst conceivable pain (17). The NRS pain scales and ODI have shown good validity and are frequently used in research on back pain (13). We also evaluated duration of procedures, length of hospital stays, repeated surgery at the index level within three months of surgery, and surgical complication rates. A clinically significant improvement in leg and back pain NRS is defined as improvement of 2 points or more (18).

Surgical procedures

Lumbar microdiscectomy was performed on all patients. The procedure involves preoperative fluoroscopy for detection of the target level, paramedian or median skin incision of about 3 cm, straight or curved opening of the paravertebral muscular fascia, and subperiosteal release of the paravertebral muscles from the spinous process and basal lamina above and occasionally below the target disc-level. Self-retaining retractors (typically Caspar retractors) are introduced and an operating microscope is used for magnification. Following removal of scar tissue, flavectomy, and required bony decompression (i.e., arcotomy and/or partial medial facetectomy), the dural sac and nerve-root are carefully mobilized medially and the herniated disc evacuated. Removal of the disc herniation might involve entering the disc space or just removing a free sequestrated disc fragment (sequestrectomy).

Statistical analysis

Statistical analyses were performed with SPSS version 25.0 (IBM Corporation, Chicago, IL, USA). Statistical significance level was defined as $p \leq 0.05$ on the basis of a two-sided hypothesis test with no adjustments made for multiple comparisons. Central tendencies are presented as means when normally distributed and as medians when skewed. We used the Chi square test for categorical variables. Baseline and one-year scores are compared with one-samples t-test for normally distributed data.

Missing data

Missing data for ODI, EQ-5D, NRS back and leg pain was handled with mixed linear models. This strategy is in line with studies showing that it is not necessary to handle missing data using multiple imputations before performing a mixed model analyses on longitudinal data (19).

Results

Study population

In total, 276 patients were enrolled in the study. A total of 161 patients (58.3%) completed the one-year follow-up period. Baseline characteristics, surgical treatments, and comorbidities are summarized in table 1. The mean patient age at baseline was 48.5 ± 13.3 years, and 38.4% were female. Non-responders were younger (44.2 vs 51.1) and had lower baseline ODI than responders (48.8 vs 53.2). The majority of patients (75%) had only one previous operation for lumbar disc herniation

Primary outcome

Changes in ODI between baseline and one year after surgery are presented in table 2. There was a significant improvement in the cohort between mean preoperative ODI and mean ODI at the one-year follow-up (27.1 points, 95% CI, 23.1 to 31.0; P <0.001). We performed a complete case analysis on the group that completed the one-year follow-up, presented in diagram 1 (stacked bar plot). Among 161 patients with completed one-year follow-up, 68 (42%) had an ODI score of 20 or less at 12 months compared to 12 out of 275 patients (4.4%) at baseline. 105 patients (65.2%) experienced a clinically significant improvement (defined as an improvement of at least 13 ODI points).

In total, 54 patients (33.5%) of the patients who completed the one-year follow-up experienced a change in ODI score of less than 33%. In addition, 25 patients (15.5%) had a raw ODI score of 48 or more or more after surgery.

Secondary outcomes

Changes in EQ-5D, back pain NRS, and leg pain NRS at one year are presented in table 2. There was a significant difference between mean preoperative EQ-5D score and mean EQ-5D score at 1 year (0.47 points, 95% CI 0.40 – 0.54; P <0.001). An effect size of 1.3 was found for change in EQ-5D at one year, indicating a large clinical difference between the two time points.

The mean difference between the mean baseline value and one-year value in back pain NRS was 4.3 points (95% CI 2.2 – 3.2 P <0.001). Among patients who completed the follow-up 94.3% experienced a clinically significant improvement (2 points or more).

The mean difference between the mean baseline value and one-year value in leg pain NRS was 3.8 points (95% CI 2.8 – 3.9, P <0.001). 95.6% of the patients experienced a clinically significant improvement (2 points or more).

Mixed linear model analyses showed similar results for all patient-reported outcomes.

Complications are presented in table 3. Out of the 276 patients included, nine (3.3%) experienced intraoperative complications, with unintentional durotomy as the most common complication (7 cases, 2.5% in total). Out of the 160 patients who completed the three-month follow up period, 15 (5.5%) experienced complications post-surgery following hospital discharge, with urinary tract infection as the most common complication (2.5%).

A total of 37 reoperations were performed within 90 days of the initial surgery. 23 of these (62.2%) were due to residual LDH. One reoperation was due to hematoma.

Discussion

This study clearly demonstrates that patients undergoing lumbar microdiscectomy for recurrent LDH can expect considerable improvement, and in total 65.2% experienced a

clinically significant improvement, defined as an improvement of at least 13 ODI points. Among the patients with complete one-year follow-up, 54 (33.5%) experienced a change in ODI score of less than 33%. In addition, 25 patients (15.5%) had a raw ODI score of 48 or more or more after surgery. These have been suggested as criteria with high accuracy for defining failure of surgery for lumbar disc herniation (16). Serious complications following microdiscectomy for recurrent LDH were rare, and in our study population the frequency of unintentional durotomies was only 2.5%.

Among the patients with complete follow-up, 42% experienced no or minimal disability at one year (i.e., an ODI score between zero and twenty). This is a lower proportion than previously reported in a study that excluded patients who had undergone previous spine surgery and found that 69,4% experienced no or minimal disability (20).

The mean improvement in ODI score of 27.1 points is less than what has been reported in both the SPORT trial (21) and previous registry based observational studies (22, 23). These studies all excluded patients who had undergone previous lumbar spine surgery in the same level. This seems to suggest that previous surgical procedures have a negative impact on improvement. A study conducted in Sweden examining operations for recurrent LDH using data from the SWEspine register showed similar mean ODI score at baseline (51 points), and similar mean change in ODI (24 points) after a two-year follow-up period, but with a smaller sample size (5).

Studies conducted in Asia found an improvement in percent after surgery for recurrent LDH ranging from 52.17% to 64.8%, using the JOA-scale (ODI translated to Japanese) (24-26). These studies all showed positive results in pain relief after surgery for recurrent LDH. However, these studies used different PROM (JOA, VAS), had significantly smaller sample sizes and included multiple surgical techniques, which makes direct comparison to our study challenging (25-27).

Previous studies have explored whether factors such as older age, obesity, and smoking influence outcomes following lumbar microdiscectomy (2, 20, 28, 29). In patients undergoing microdiscectomy for LDH, promising results with decreased risk of reherniation and reoperation have been reported for the addition of a bone-anchored annular closure device in patients with large annular defects (30, 31).

Strengths and limitations

Our study is strengthened by prospective data collection, high external validity, and widely applied and validated outcome measures (12-14, 18, 19) Although this is a single center study, it is the largest to date with prospectively collected patient reported outcomes following surgery for recurrent LDH (25).

Our study is limited by a relatively high loss to follow-up (41.1%) at one year for the primary outcome measure, despite non-responders receiving reminders. Missing data in spine registries remain a concern and may introduce bias (32). However, a previous study examining a similar population with 22% loss to follow-up found no difference between responders and non-responders on long-term follow-up (33). The use of mixed linear models in the management of missing data did not alter the results.

Another limitation is the lack of randomization as we did not have control groups that underwent non-surgical management or other surgical interventions than lumbar microdiscectomy.

Conclusion

This study demonstrates that patients operated with microdiscectomy for recurrent lumbar disc herniation in general report significant clinical improvement. The safety profile of lumbar microdiscectomy for recurrent LDH also seems to be acceptable.

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Table 1. Baseline characteristics

Variable	**Value**
Age at surgery (years), mean +/- SD	48.5 +/- 13.3
Female sex	106 (38.4%)
ASA > 2	34 (12.4%)
BMI, mean +/- SD	27 +/- 4.4
Obesity, BMI ≥ 30	48 (23.2%)
College education	95 (34.9%)
Daily tobacco smoking	100 (36.5%)
Mean preoperative ODI +/- SD	51.6 +/- 19.3
Mean preoperative EQ-5D	0.16 +/- 0.36
Preop. Leg pain NRS, mean +/- SD	7.2 +/-2.1
Preop. Back pain NRS, mean +/- SD	6.9 +/- 2.2
Spine level of surgery:	
L2-L3	5 (1.8%)
L3-L4	19 (6.9%)
L4-L5	130 (47.1%)
L5-S1	120 (43.5%)
Number of previous surgical procedures in the operated level (N=273)	
1	206 (74.6%)
2	49 (17.8%)
3	16 (5.8%)
4	2 (0.7)

Table 2. Patient reported outcome measures following lumbar microdiscectomy (complete case analyses)

Variable	Baseline	One year	Mean change	95% CI	P - Value
Oswestry disability index	53.6	26.5	27.1	23.1 to 31.0	<0.001
Euro-Qol 5D	0.13	0.60	-0.47	-0.54 to -0.40	<0.001
Leg pain NRS	7.2	3.8	3.4	2.8 to 3.9	<0.001
Back pain NRS	7.0	4.2	2.7	2.2 to 3.2	<0.001
Mixed linear models:					
Oswestry disability index	51.4	25.2	26.2	23.0 to 29.4	<0.001
Euro-Qol 5D	0.17	0.62	-0.44	-0.5 to -0.38	<0.001
Leg pain NRS	7.2	3.6	3.6	3.2 to 4.0	<0.001
Back pain NRS	6.9	4.1	2.8	2.4 to 3.2	<0.001

Table 3. Complications

Perioperative complications no. (%)	**9 (3.3%)**
Unintentional durotomy	7 (2.5%)
Nerve injury	1 (0.4%)
Blood replacement	0
Cardiovascular complications	0
Anaphylactic reaction	0
Wrong level surgery	0
Respiratory complications	0
Complications within 3 months no. (%) (N=160)	**15 (5.5%)**
Wound infection	3 (1.1%)
Urinary tract infections	7 (2.5%)
Pneumonia	0
Pulmonary embolism	1 (0.4%)
Deep vein thrombosis	1 (0.4%)
Micturition problems	3 (1.1%)
Reoperations (%)	
Within 90 days:	37 (13.4%)

Figure 1. Case analysis of the group comparing ODI scores presurgery and twelve months after surgery. Data are presented in a stacked bar plot and table.

	ODI 0-20	ODI 21-40	ODI 41-60	ODI 61-80	ODI > 81
ODI Pre-surgery (n=275)	12	79	95	71	18
ODI Post-surgery (n=161)	68	54	34	5	0

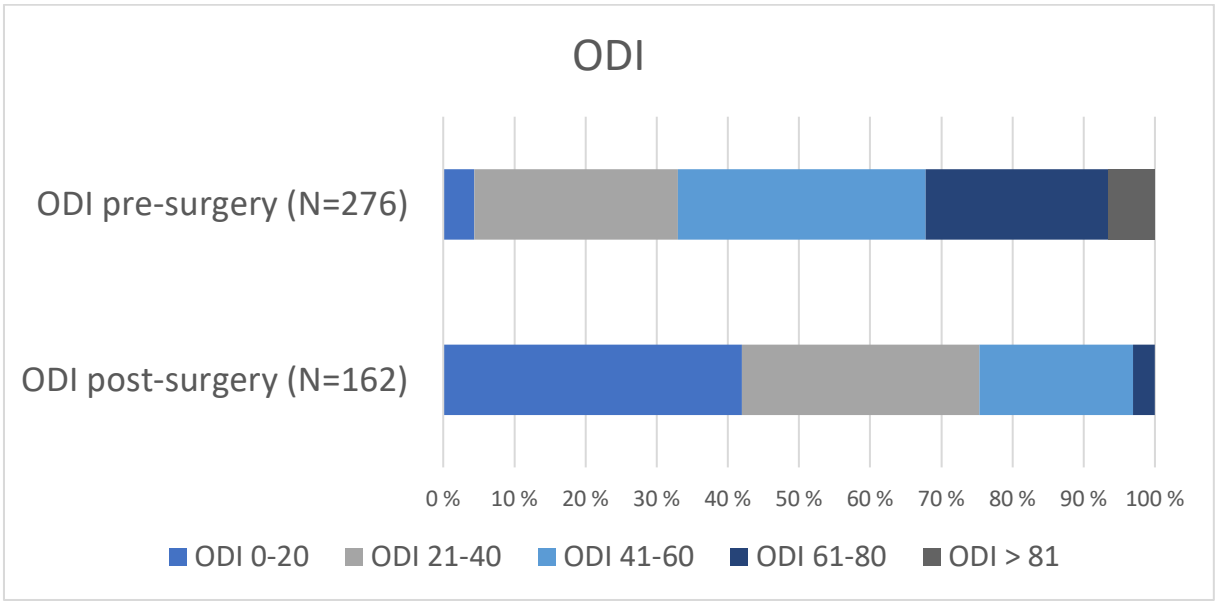

Figure 2. Oswestry disability index score at baseline, three months, and one year according to previous number of surgeries in the operated level. Error bars represent 95% confidence intervals.