The Spine Journal 19 (2019) 1463−1469

Clinical Study

Increasing reoperation rates and inferior outcome with prolonged symptom duration in lumbar disc herniation surgery — a prospective cohort study

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Received 16 January 2019; revised 4 April 2019; accepted 4 April 2019

Abstract

BACKGROUND CONTEXT: Lumbar disc herniation (LDH) is associated with great morbidity and significant socioeconomic impact in many parts of the world. Studies have shown that most LDH can be treated effectively with nonoperative management. However, for some patients in whom pain and disability are unacceptable, surgical intervention provides effective clinical relief. Currently, there is little consensus in the medical community on the timing of surgery for patients suffering from radicular pain due to LDH. Multiple studies suggest that prolonged symptom duration adversely affects clinical outcome.
PURPOSE: The aim of this study is to evaluate if prolonged symptom duration is correlated with less favorable outcome following surgery for LDH.
STUDY DESIGN/SETTING: Consecutive series of patients from a single-center, multisurgeon, tertiary spine practice.
PATIENT SAMPLE: Consecutive series of patients who underwent surgery for LDH.
OUTCOME MEASURES: Oswestry Disability Index (ODI), EuroQol-5D (EQ-5D), and Visual Analog Scale (VAS) for back and leg pain (0−100).
METHODS: Patients with a first-episode LDH were included. Data were prospectively collected in DaneSpine, the Danish National Spine Registry. Subjects were divided into three groups based on their preoperative self-reported duration of leg pain: <3 months, 3 to 12 months, and >12 months. Associations between patient-reported outcomes (PROs), perioperative complications and duration of symptoms were evaluated. Statistical significance level was set at p value <.01.
RESULTS: There were 2,144 patients included in the study, with complete 1-year follow-up on 1,694 patients (79%) and a reoperation rate of 8.4%. Incidence of surgical complications, specifically dural tears, was higher with increasing duration of leg pain; however, this did not reach statistical significance (p=.039). Prolonged preoperative symptoms adversely influenced all PROs (EQ-5D, ODI, VAS) 1 year after surgery (p=.001). Furthermore, reoperation rates increased with longer duration of preoperative symptoms. A statistically significant trend (p=.008) of increasing incidence of reoperation was found with increasing length of symptom duration.
CONCLUSIONS: Delayed surgical intervention results in inferior outcomes and increased reoperation rates. Patients who had surgery within the first 3 months of leg pain achieved significantly better outcome 1 year after surgery when compared to the other groups.

FDA device/drug status: Not applicable.

Author disclosures: ***CCS:*** Grants: A.P. Møller og Hustru Chastine Mc-Kinney Møllers Fond til lægevidenskabens fremme (B); Overlæge Jørgen Werner Schous og hustru, Else-Marie Schou, født Wonge's fond (B). ***AKA:*** Nothing to disclose. ***LC:*** Consulting: AO Spine (B); Trips/Travel: University of Southern Denmark (C). ***MØA:*** Research Support (Investigator Salary, Staff/Materials); Grants.

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https://doi.org/10.1016/j.spinee.2019.04.001
1529-9430/

Keywords: Complications; Discectomy; Duration of symptoms; Herniated disc; PROs, Patient-reported outcomes

Introduction

Lumbar disc herniation (LDH) is associated with great morbidity and significant socioeconomic impact in many parts of the world [1−3]. Based on data from The Danish National Health Authority, 1% to 3% of the Danish population reported radicular pain due to LDH [4]. Approximately 2,000 Danes undergo operative treatment for this indication annually [5].

The majority of patients suffering from symptoms due to LDH can be treated effectively with nonsurgical management. However, in some patients with severe pain and disability or whose recovery is unacceptably slow, surgical intervention can provide effective clinical relief [6−8].

Danish national clinical guidelines recommend that patients with LDH without neurologic deficits or intractable pain are managed with nonoperative treatment for up to 12 weeks before they are considered surgical candidates [9]. Currently, there is little consensus in the medical community on the timing of surgery for patients suffering from radicular pain due to LDH.

Depending on the outcome measure used, 10% to 40% of patients report unsatisfactory results after lumbar disc surgery [10−12]. Many previous cohort studies have reported inferior results and adverse effects of prolonged preoperative symptoms [13−16]. Contrary to these, some randomized controlled trials report no inferiority in outcome of patients with prolonged symptoms [10,17,18]. Systematic reviews on the subject find the same adverse effects as reported by most cohort studies [19]. Despite the relatively vast amount of literature available, no studies seem to have found the optimal time window to intervene and perform surgical treatment. Also, many of previously mentioned cohort studies suffer from relatively small patient populations, leading to uncertain results and conclusions. The largest previous study covering the subject is the SPORT study, which found inferior outcomes with prolonged symptom duration [16,20]. The aim of the current study is to investigate if prolonged symptom duration is correlated with less favorable outcome following surgery for LDH.

Materials and methods

The current study is a retrospective cohort study using prospectively collected data from the Danish national surgical spine database (DaneSpine) [21]. DaneSpine collects patient-reported outcomes using pre- and postoperative questionnaires, completed before surgery and at 1, 2, 5, and 10 years postoperatively. The preoperative data are entirely patient reported, including age, sex, height, weight, duration of back, and leg pain prior to surgery, back and leg pain on a 0-100 VAS scale [22], health-related quality of life as measured by the EuroQol-5D (EQ-5D) [23,24], and spine-related disability as measured by the Oswestry Disability Index (ODI) [25,26]. Durations of symptoms are collected as categorical values of <3 months, 3 to 12 months, and >12 months. Surgical data are entered by the surgeon at the time of discharge from hospital and include diagnosis, procedure, antibiotic prophylaxis, and occurrence of complications.

At follow-up, the same data registered at baseline are collected. At 1-year follow-up, patients are asked about their attitude toward the surgical outcome, with the options being: satisfied, neither satisfied, nor dissatisfied, and dissatisfied.

All patients who had surgery at the Center for Spine Surgery and Research, Middelfart Hospital, for a LDH with radicular pain from June 1, 2010 to May 1, 2017 were included. They had all followed the Danish national guidelines for treatment of patients with LDH [27], having received physiotherapy or other relevant exercise therapy before being referred from primary care to a spine specialist. None of the patients had cauda equina syndrome or severe neurologic deficits at the time of surgery. All had a magnetic resonance imaging that demonstrated LDH, with the level and side corresponding with clinical symptoms. Baseline questionnaires were filled out no more than 1 week prior to surgery. Patients underwent discectomy by a senior consultant employed at the facility. Patients who had previous spine surgery were excluded from further analysis. Subjects were divided into three groups based on their self-reported duration of leg pain prior to enrollment into the registry: <3 months, 3 to 12 months, and >12 months.

Patient and public involvement

The current study was done without patient involvement. As data originate from a database, it was not found feasible to involve patients in the study design nor the outcome measures, as these could not be changed. Patients were not invited to contribute to the writing or editing of this study for readability or accuracy.

Statistics

All statistical analysis was done using STATA 15 (StataCorp., College Station, TX). Categorical data are presented by frequencies and related percentages; continuous data are displayed by means of descriptive statistics (mean, confidence interval, number of observations). Continuous variables were analyzed for significant difference between the three groups using analysis of variance (ANOVA), categorical variables using Fisher's exact test. Continuous variables found to change orderly across groups were analyzed using a Wilcoxon-type test for trend as developed by Cuzick (1985). Significance level was set at p value <.01. Adjustment for potential confounders was done using a forward stepwise regression analysis with an inclusion p value of .10 and a confounding level of 15%.

Results

During the nearly 7 years of inclusion, a total of 2,586 patients had surgery for a LDH causing radiculopathy. Of these, 442 (17.1%) had a history of previous spine surgery and were excluded from further analysis. Of the remaining 2,144 patients, 1-year follow-up data were available on 1,694 (79.0%). Most patients had surgery within 1 year of radicular leg pain onset, 613 (28.6%) with less than 3 months' history of leg pain, 1,095 (51.1%) with 3 to 12 months, and 436 (20.3%) with more than 12 months.

Mean age for the entire cohort was 46.8 years and statistics indicating significant differences among groups; however, only of 1 to 3 years. There were more males in the <3-month duration group (59.7% vs. 52.2% vs. 52.5%), with statistics indicating a significant difference in gender distribution. About one-third of the entire cohort (699, 32.7%) were active smokers at the time of surgery, and there was no statistically significant difference in the groups with longer history of leg pain (p=.015). There was no difference in pain medication use or comorbidities among the three groups (Table 1). When asked about welfare payments, 22.9% (393) reported to receive welfare support, with no difference among the three groups.

Incidence of surgical complications, specifically dural tears, was higher with increasing duration of leg pain; however, this did not reach statistical significance (Table 2). Postoperative complications were diverse (Table 2) with hematoma being the most common but no significant differences found among groups.

As of December 1, 2018, 179 patients (8.4%) had undergone reoperation within 1 year of primary surgery, 132 cases underwent repeat discectomy, 16 received additional decompression, 16 had a hematoma removed, three underwent drainage of infection, and 12 received other nonspecified surgery. A statistically significant trend of increasing incidence of reoperation was found with increasing length of symptom duration. Approximately 17% of all patients who underwent reoperation did so during their primary admission.

All groups had a significant improvement in EQ-5D, ODI, VAS leg pain and VAS back pain 1 year after surgery compared to baseline (Table 3). However, statistically significantly greater improvement in EQ-5D and ODI was seen in the <3-month pain duration group compared to the two other groups. In contrast, statistically significantly less improvement in VAS leg and VAS back was seen in the >12-month pain duration group compared to the two other groups (Figure).

All of the above outcome variables have been tested for potential confounding with regards to age, gender, BMI, smoking status, duration of back pain, and whether the patient received social welfare or not (data not shown). Longer duration of back pain had a borderline significant negative effect on the outcome (p=.022) and patients receiving welfare at the time of surgery also showed better outcome at 1 year compared to those not receiving welfare (p<.001). Smoking shows no significant effect on surgical outcome (p=.038). Age and BMI were not included in the model as neither significance level nor confounding level was above the set limits.

Discussion

This retrospective cohort study divides patients surgically treated for LDH into groups dependent on the duration of their preoperative symptoms. The present study found worse self-reported outcomes in patients with duration of preoperative leg pain of >3 months. Furthermore, a strong trend of increasing risk of reoperation was found with increasing duration of preoperative leg pain.

Previous literature as well as the present study shows that surgery for LDH is an effective treatment regardless of symptom duration [15]. Like previous studies, the current study population are patients in their 40s with a slight majority of men [10,17,20]. The current study comprises more smokers than found in the general Danish population (ie, 32.7% vs. 23%) [28]. Overall, this study's population seems comparable to that of earlier studies on symptom duration and outcome after surgery for LDH.

Table 1
Characteristics of the subgroup populations

	All (n=2.144)	<3 months (n=613)	3−12 months (n=1.095)	>12 months (n=436)	p Value of difference
Age, mean (95% CI)	46.8 (46.2; 47.4)	48.1 (47.1; 49.2)	46.7 (45.8; 47.5)	45.2 (43.8; 46.6)	.003
Males, n (%)	1.167 (54.4)	366 (59.7)	572 (52.2)	229 (52.5)	.008
Smokers, n (%)	699 (32.7)	173 (28.3)	369 (33.8)	157 (36.2)	.015
Pain medication, n (%)	1,939 (90.6)	556 (90.7)	1.001 (91.6)	382 (88.0)	.101
Comorbidities, n (%)					
Heart disease	16 (0.8)	2 (0.3)	12 (1.1)	2 (0.5)	.181
Neurologic disease	31 (1.5)	9 (1.5)	12 (1.1)	10 (2.3)	.193
Cancer	13 (0.6)	2 (0.3)	9 (0.8)	2 (0.5)	.468
Other, affecting walking capabilities	74 (3.5)	17 (2.8)	35 (3.2)	22 (5.1)	.122
Other, pain related	148 (6.9)	40 (6.5)	68 (6.2)	40 (9.2)	.114
Receiving welfare, n (%)	491 (22.9)	132 (21.6)	249 (22.8)	110 (25.3)	.368

Table 2
Per- and postoperative complications

	All (n=2.144)	<3 months (n=613)	3−12 months (n=1.095)	>12 months (n=436)	p Value of trend
Surgical complication, n (%)					
Dural tear	60 (2.8)	11 (1.8)	32 (2.9)	17 (3.9)	.039
Vascular damage	2 (0.1)	−	1 (0.1)	1 (0.2)	.235
Postoperative complications, n (%)					
Death	−	−	−	−	−
Thrombosis	−	−	−	−	−
Emboli	−	−	−	−	−
Urinary tract infection	7 (0.3)	1 (0.2)	4 (0.4)	2 (0.5)	.393
Urine retention	5 (0.2)	−	3 (0.3)	2 (0.5)	.121
Hematoma	16 (0.8)	4 (0.7)	6 (0.6)	6 (1.5)	.233
Wound infection	−	−	−	−	−
Nerve root lesion	6 (0.3)	1 (0.2)	4 (0.4)	1 (0.2)	.775
Cauda Equina	5 (0.2)	1 (0.2)	1 (0.1)	3 (0.7)	.121
Other	8 (0.4)	3 (0.5)	5 (0.5)	−	.229
Reoperation, n (%)					
Within 12 months	179 (8.4)	38 (6.2)	94 (8.6)	47 (10.8)	.008
During primary admission (% of reoperated)	30 (16.9)	6 (15.8)	13 (14.0)	11 (23.4)	.313

As shown in both Table 3 and Figure, longer preoperative duration of symptoms adversely affects clinical outcome in both EQ-5D, ODI, and VAS leg pain. All groups reached clinically relevant improvements in the before-mentioned parameters. The present study found a total postoperative complications risk of approximately 2%. The risk of reoperation increased with longer symptom duration, and a trend analysis indicates that the timing of surgery is important, not only because of the poorer outcome, but also due to the risk of reoperation. The higher reoperation rates might also be affected by a lower surgeon and patient threshold in patients with longer preoperative leg pain if outcome is worse than expected. A subgroup analysis showed no difference in reoperation rates during primary admission.

Previous literature has found similar results, however with inconsistency regarding the timing of surgery. Nygaard et al. has previously found that surgical outcome is more favorable in patients with less than 6 months' preoperative symptoms, when compared to both 6 to 12 months and >12 months of preoperative symptoms [13]. In a subsequent cohort study by the same lead author, patients with more than 8 months of preoperative leg pain were found to have less favorable outcome [14]. Both studies featured a relatively low number of patients, 93 and 132, respectively.

In 2015, Pitsika et al. [15] found statistically significant improvement in ODI regardless of preoperative duration, and advocated that surgery is indicated even after 1 to 2 years of symptoms. However, they also found a downward trend of improvement in ODI with increasing duration of symptoms. The study was a single surgeon sample, with follow-up on 97 patients (90.7 %). Thus, the sample size is relatively small, leading to small subgroups for further analysis. In a larger study, based on the SPORT cohort, prolonged duration of symptoms was also found to have

Table 3
One-year PROM follow-up

	All (n=2.144)	<3 months (n=613)	3−12 months (n=1.095)	>12 months (n=436)	p Value of trend
EQ-5D; mean (95% CI)					
Preoperative	0.45 [0.44;0.46]	0.39 [0.37;0.42]	0.47 [0.45;0.48]	0.48 [0.45;0.50]	<.001
Postoperative	0.77 [0.76;0.78]	0.78 [0.76;0.80]	0.77 [0.76;0.79]	0.72 [0.70;0.75]	.001
Difference	0.31 [0.30;0.33]	0.39 [0.35;0.42]	0.30 [0.28;0.32]	0.24 [0.20;0.27]	<.001
ODI; mean (95% CI)					
Pre-operative	47.76 [46.97;48.55]	52.14 [50.47;53.80]	46.55 [45.54;47.56]	44.69 [43.05;46.32]	<.001
Post-operative	20.91 [20.05;21.77]	19.36 [17.86;20.86]	20.50 [19.31;21.69]	24.25 [22.20;26.31]	.001
Difference	26.72 [25.62;27.83]	32.87 [30.71;35.03]	25.96 [24.49;27.43]	19.68 [17.41;21.94]	<.001
VAS leg; mean (95% CI)					
Preoperative	67.76 [66.74;68.78]	67.92 [65.85;69.99]	67.94 [66.58;69.29]	67.10 [64.87;69.33]	.138
Postoperative	24.39 [23.07;25.72]	23.05 [20.72;25.37]	22.51 [20.72;24.30]	31.51 [28.17;34.85]	.001
Difference	43.16 [41.53;44.80]	44.92 [41.86;47.99]	45.10 [42.87;47.34]	35.21 [31.51;38.91]	<.001
VAS back; mean (95% CI)					
Preoperative	48.10 [46.86;49.34]	43.75 [41.39;46.12]	48.82 [47.11;50.52]	52.41 [49.69;55.12]	<.001
Postoperative	26.89 [25.59;28.19]	23.88 [21.67;26.10]	25.99 [24.21;27.78]	34.03 [30.73;37.32]	<.001
Difference	20.12 [18.57;21.68]	19.88 [17.00;22.77]	21.32 [19.13;23.52]	17.23 [13.83;20.62]	.436

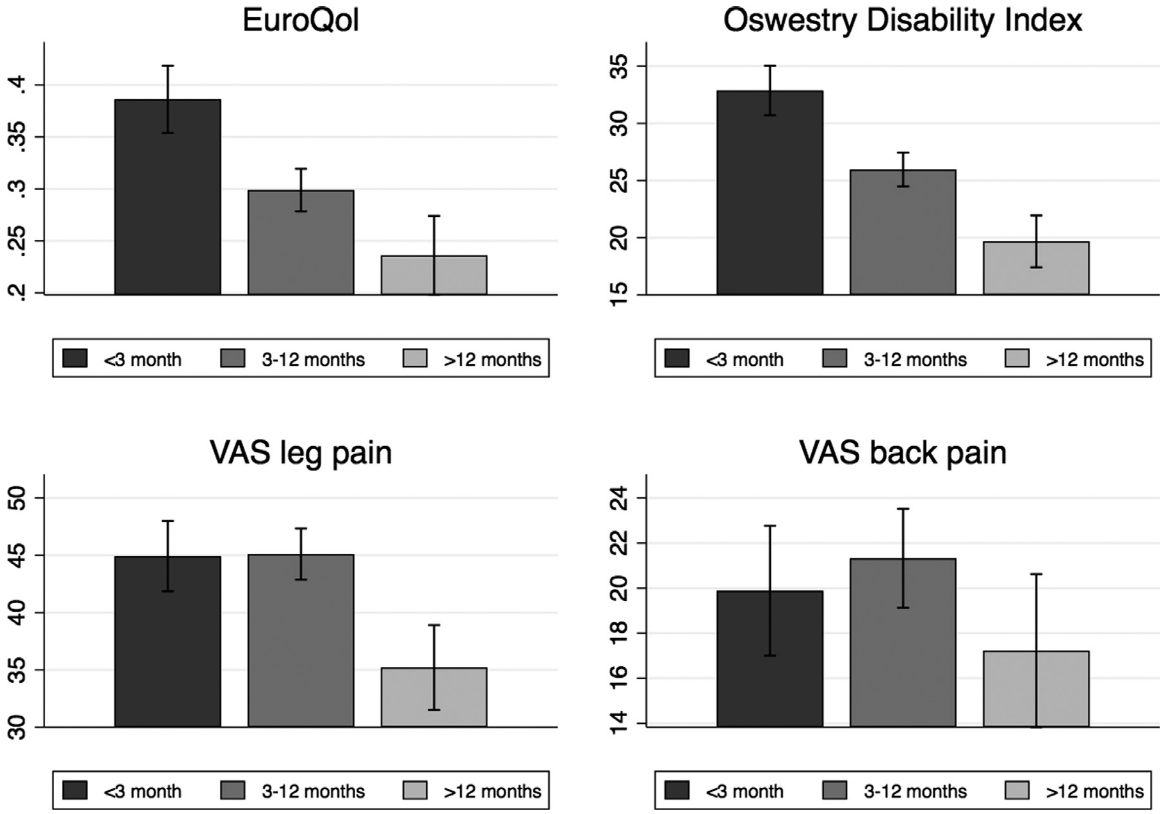

Figure. Change in patient-reported outcomes (PROs) at 1-year follow-up (mean; CI).

adverse effects on outcome, following both surgical and nonsurgical treatment [16].

The major limitation of the present study is the retrospective analysis of data from a database and subsequent lack of full 1-year follow-up on all patients. A previous drop-out analysis on a similar population found that nonresponders often were younger males, who were back at work and with better self-reported outcomes [29]. Thus, lack of complete follow-up is not likely to negatively affect results. Another major limitation is the fixed categorical intervals of duration of leg pain prior to surgery. Previous literature has suggested the "golden cut-off" timepoint to be somewhere around 6 months. The current intervals were chosen as a result of the data available in DaneSpine; however, future studies should aim to measure duration of preoperative symptoms as continuous variables, thereby allowing for more detailed analysis to be performed.

Being a publicly funded institution, there are no economic barriers to undergo surgery at any time, and no bias in timing of surgery is instituted by insurance companies in the present study population. The study includes a large population of 2,144 consecutive patients, well dispersed in subgroups, and no significant preoperative demographic differences. Patients are included consecutively, and all data collected prospectively at a single center for spine surgery.

All outcome variables were tested for potential confounders, and analysis showed borderline significant correlation with duration of back pain. This is, however, most likely due to collinearity with duration of leg pain as one is rarely present in complete absence of the other. If patients received social welfare at the time of surgery, they also had greater improvement in the before-mentioned outcome variables at 1-year follow-up. This might not be due to confounding, as an unsettled social welfare case would most likely lead to a surgical delay. However, as delayed surgery has negative correlation with outcome, it would be more plausible that social welfare status is simply an isolated predictor. As published by Andersen et al., patients with prolonged sick leave have significantly lower return to work rate, compared to those with shorter duration sick leave prior to surgery [30]. This might also explain the poorer outcome in especially life quality at 1-year follow-up, as patients are highly affected by their ability to take part in society, that is, work. Smoking, BMI, and age could all have been relevant confounders, or even mediators, but no such relation was found.

The causal relation for prolonged duration of leg pain to cause inferior outcome is not immediately apparent. One might speculate in both psychological and somatic explanations. Previous literature suggests that prolonged sick leave, which would be more likely with prolonged symptom duration, leads to a lower chance of speedy return-to-work and therefore also a state of well-being with regards to serving society and a more purposeful living. There might also be a more biological relation both in respect of inflammatory processes and the tissues ability to repair/regenerate, or the brains more complex perception of pain and modulation of such. We know that surgery leaves a large immunologic inflammatory response in the tissue, leading to great remodulation. If a disc herniation creates a similar response, and it persists for a prolonged duration of time, it might cause the surrounding tissue and structures to be less susceptible to recovery after the removal of the herniation. As a result, the pain may persist, thereby giving the patient an inferior surgical outcome. We have little certainty and knowledge about how the brain and spinal cord receives, modulates, and translates pain; however, science suggests that pain is very subjective and that the human brain has great power with regards to its modulation. One might speculate that with prolonged pain stimuli, that is, that of a persistent disc herniation, the brains modulation of pain might change, and of such the conscious perception of pain would also change. This might in turn lead to a more permanent state, in which, the conscious part of the brain would perceive pain, despite the fact, that the painful stimulus has been removed. Such hypothesis has previously been suggested and tested, but no clear evidence or consensus has been reached [31].

Conclusion

In line with previous literature, the present study shows that prolonged preoperative symptom duration adversely affects clinical outcomes in patients with LDH. Despite present data suggesting that the greatest treatment effect is achieved with the shortest duration of preoperative symptoms, the optimal timing of surgical treatment in LDH may be found in the interval of 3 to 12 months. Furthermore, the present study finds a greater risk of reoperation with longer duration of preoperative symptoms.

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