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Clinical Study

# Effect of preoperative symptom duration on outcome in lumbar spinal stenosis: a Canadian Spine Outcomes and Research Network registry study

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**Abstract**

**BACKGROUND CONTEXT:** Lumbar degenerative stenosis is one of the most common spine pathologies for which surgical intervention is indicated. There is some evidence that a prolonged duration of neurological compression could lead to a failure of surgery to alleviate symptoms.
**PURPOSE:** Determination of whether longer symptom duration was associated with worse post-operative disability outcomes after decompressive surgery for lumbar degenerative stenosis.

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**STUDY DESIGN/SETTING:** The Canadian Spine Outcomes and Research Network (CSORN) prospective database includes pre- and postoperative data from 18 tertiary care hospitals.
**PATIENT SAMPLE:** The CSORN database was queried for all cases of degenerative lumbar stenosis receiving surgical decompression for neurogenic claudication or radiculopathy. Patients with tumor, infection, fracture, or previous surgery were excluded. Patients were divided into groups based on symptom duration (<6 weeks, 6−12 weeks, 3−6 months, 6−12 months, 1−2 years, and >2 years).
**OUTCOME MEASURES:** Change between preoperative and 12-month postoperative Oswestry Disability Index (ODI) was compared between symptom duration groups. Secondary outcomes included SF12 physical component score (PCS), and numeric rating scales for leg and back pain. Outcomes were also assessed at 3 months and 24 months postoperatively.
**METHODS:** Change in ODI, and secondary outcome measures, were compared between different symptom duration groups. Multiple regression analysis was used to identify factors interacting with symptom duration to predict change in ODI.
**RESULTS:** Four hundred and seventy-eight cases of lumbar stenosis with 12-month postoperative data were identified. Longer symptom duration correlated with less improvement in ODI ($p<.001$). Patients with >1 year of symptoms were less likely to achieve a Minimal Clinically Significant Difference in ODI (54.4% vs. 66.1%; $p=.03$) and were more likely to experience no improvement or worse disability, postoperatively (22.1% vs. 11.3%; $p=.008$). Similar results were found at 3- and 24-month timepoints. Smaller postoperative improvements in SF12 PCS and leg pain scales were also correlated with longer symptom duration ($p<.05$).
**CONCLUSIONS:** Multicenter registry data provides important real-world evidence to guide consent, surgical planning, and health resource management. Longer symptom duration was found to correlate with less improvement in pain and disability after lumbar stenosis surgery suggesting that these patients may benefit from earlier treatment. 

*Keywords:* Symptom duration; Outcome; Degenerative stenosis; Disability; Registry; Lumbar

## Introduction

Lumbar stenosis is one of the most common indications for lumbar spine surgery. Although some patients with lumbar stenosis improve with conservative management, controlled studies demonstrate superior improvement with surgery [1,2]. In addition, a number of studies of degenerative lumbar spine conditions suggest an association between longer wait times to surgery and worse outcomes; however, most of these are single institution analyses employing inconsistent outcome measures and definitions of symptom duration, making generalizability, and interpretation difficult [3−10]. Larger studies on the effect of a delay in surgical treatment include post hoc analyses of data collected for other purposes, such as the Spine Outcomes Research Trial (SPORT) [7,8]. Still others have not found an association between symptom duration and outcome [6]. To guide informed consent, sound medical resource management, and evidence-based surgical decisions, it is vital to identify factors that are associated with outcome.

In addition to longer symptom duration, a variety of factors predictive of worse outcomes following surgery for lumbar spine degenerative disease have been proposed including smoking, depression, other psychiatric diagnoses, severity of neurological deficits, worker's compensation status [11], and obesity [6,12,13]. Multicenter outcome registries such as the Canadian Spine Outcomes and Research Network (CSORN) database provide an opportunity to examine real world surgical outcomes on a large scale. We therefore set out to identify whether longer preoperative symptom duration was associated with worse disability at 1-year after surgery among lumbar stenosis patients.

## Material and methods

### Study design

The CSORN is a group of over 50 neurosurgical and orthopedic spine surgeons from 18 tertiary care academic and nonacademic hospitals across Canada that prospectively collects data on consecutive patients with spinal conditions. This database serves as a national registry created to answer research questions and to facilitate the implementation of best practices.

A national database research coordinator audits data quality and performance and sends reports to each contributing hospital site coordinator on a quarterly basis. Reports track data completion and follow-up rates to facilitate internal data validation at each site. A national privacy and security framework was created for CSORN that includes a governance structure, standard operating procedures, training processes, physical and technical security, and privacy impact assessments. This model ensures privacy and security of personal health information. Written informed consent is obtained from all participating patients. All data is anonymized. Individual Research Ethics Board approval is maintained at each site. Decisions regarding data collection,

storage, and analysis are independent of any company or commercial interest.

### *Patient sample*

The CSORN outcome database was queried on October 25, 2017 for all patients who had presented with the chief complaint of neurogenic claudication or radiculopathy and who had undergone lumbar spine surgery for degenerative lumbar stenosis without deformity. Patients with prior lumbar surgery were excluded, as were those who had lumbar scoliosis, spondylolisthesis, fracture, inflammation, tumor, or infection. There were no pediatric cases. There was no restriction on the included surgical procedures which were chosen at the discretion of the operating surgeon and included single and multilevel decompressions as well as fusions.

### *Study measures*

The primary endpoint was change in Oswestry Disability Index (ODI) [14] between the preoperative and 1-year postoperative evaluation. Therefore, only patients with surgical dates before August 1, 2016 (to allow for patients whose 1-year assessments were not returned exactly 1-year postoperation) were eligible for 1-year follow-up and were included. The ODI is a patient reported outcome measure with scores ranging from 0 to 100. A higher score indicates a higher level of disability. A diagnosis-specific minimal clinically significant difference of 12.4 on the ODI has been established for lumbar spine stenosis [15]. Secondary outcomes included change in Short Form 12 Physical Component Score (SF12 PCS; ranging from 0 −100, with higher equating to better health) [16], leg pain Numeric Rating Scale (NRS; 0−10 with higher scores indicating worse pain) and back pain NRS (similar to the leg pain NRS). Outcomes were also assessed at 3 and 24 months postoperative follow-up (eligible if surgical dates were before May 1, 2018 and August 1, 2017, respectively) to assess durability of any effect over time. Although obtained through patient interview by the treating surgeon, many patients cannot recall a specific date in which symptoms of stenosis begin, and therefore the CSORN registry records symptom duration in intervals as follows: <6 weeks, 6 to 12 weeks, 3 to 6 months, 6 to 12 months, 1 to 2 years, and >2 years. Symptom duration, along with other patient reported measures such as ODI, etc., was obtained from at the same preoperative visit where the decision to operate was made and medical intervention management was considered to have been unsuccessful. Duration related to the main neurological leg complaint (neurogenic claudication or radiculopathy) rather than other common symptoms such as back pain which might be of longer duration in some patients. The time (days) between the decision to operate and the operative date was examined as a potentially confounding variable but as it was interval data could not be combined directly with main symptom duration ordinal data in a consistent manner and was therefore controlled for as a separate factor in the multivariate analysis.

### *Statistical analysis*

Symptom duration groups were dichotomized for univariate and multivariate tests into greater or less than 1-year groups caused by the relatively small numbers in the shortest duration groups. However, correlations were also assessed across all symptom duration groups (rank data) using Spearman rho statistics. Pairwise comparisons were made using Student *t* tests, Mann-Whitney *U* (unpaired), or Wilcoxon (paired) tests as appropriate. Proportions were compared using chi-squared or Fisher exact tests. Two-way tests were used despite the unidirectional hypotheses as a conservative approach. Results are presented as means and 95% confidence intervals (95%CI) or percentages for proportional data. Multivariate regression analysis was used to identify predictive factors for ODI change at 12 months postoperation based on candidate variables identified from the CSORN database, including preoperative demographic factors (age, gender, BMI, current smoking status, worker's compensation, enrolling site, and province), medical services usage (emergency department, chiropractor, homeopaths, specialist pain clinics, and narcotic usage), baseline health related quality of life measures (ODI, mental component score [MCS], PCS, leg, and back pain), and intraoperative factors (intraoperative blood loss, operative time, American Society of Anesthesiologists score [ASA], >1 surgical level, minimally invasive surgery, use of instrumentation). Statistical analysis was performed using R (R v3.4.1, The R Foundation for Statistical Computing, Vienna, Austria).

## Results

### *Patient demographics*

Out of 692 patients who met the inclusion criteria and were eligible for 12-month postoperative assessment, 478 (69.1%) had 12-month follow-up data in the registry (see Table 1 for preoperative characteristics). With all duration groups combined, mean preoperative ODI was 45.5 (95%CI 44.1−47.0) decreasing to 27.7 (95%CI 25.9−29.6;

Table 1
Preoperative characteristics of patients with lumbar degenerative stenosis who received surgery for their neurological symptoms and had 12-month postoperative clinical assessments available in the CSORN registry

| Demographic | Preoperative Value |
|---|---|
| Male (n [%]) | 298 (62%) |
| Female (n [%]) | 180 (38%) |
| Age (mean±SD) | 65.4±11.2 |
| BMI (mean±SD) | 29.2±5.8 |
| Smokers (n [%]) | 67 (14%) |
| Worker's Compensation (n [%]) | 23 (4.8%) |
| Narcotic Use (n [%]) | 213 (44.6%) |

SD, standard deviation.

p < .0001) at 12 months postoperative. There was no difference in preoperative ODI, BMI, Age, narcotic use, rate of fusion or >1 level surgery, education level, or worker's compensation claims between those with follow-up at 12 months and those without (all p>.10). Current smoking rates were higher in those who did not follow-up compared with those who did (27.1% vs. 16.3%; p=.024). The very short symptom duration groups had only a small number of cases (<6 weeks, n=5; 6–12 weeks, n=7; 3–6 months, n=26), whereas the 6 to 12 months group had 85 cases, the 1 to2 years group 125 cases, and the >2 years group, 230 cases. Overall, 123 patients had <1 year of symptoms and 355 had >1 year of symptoms. The symptom duration groups did not vary significantly by preoperative age, gender, BMI, marital status, education level, SF-12 MCS, PCS, smoking status, employment status, workers compensation claims, rate of fusion>1 level or rate of narcotic, or antidepressant use (p>.10).

*Primary outcome*

There was a direct correlation between symptom duration and ODI change at the 12-month postoperative assessment; in other words, longer preoperative symptom duration was associated with a smaller improvement in ODI (rho=0.16, p=.0004; see Fig. 1). A minority (123/478; 25.7%) had <12 months symptom duration but these patients had a better outcome; fewer patients with >12 months of symptoms achieved the Minimally Clinically Important Difference (MCID) in ODI at 1-year postoperatively compared with those with <1 year of symptoms (54.4% vs. 66.1%; p=.02; see Fig. 2). Furthermore, patients with >1 year of symptoms had twice the likelihood of having no improvement, or worsening, of their ODI at 1 year postoperative compared with those with <1 year of symptoms (22.1% vs. 11.4%; p=.008). All stenosis patients with <6 months of preoperative symptoms achieved at least the MCID improvement in ODI.

*Secondary endpoints*

The ODI data was available for 87.8% of patients eligible for 3-month follow-up and 53.2% of patients eligible for 24-month follow-up postoperation. The correlation found at 12-months postoperative between ODI change and preoperative symptom duration was also present at 3 months (p=.0001) and 24 months postoperatively (p=.03) indicating that the effect seen at 12 months postoperation was durable over time. Mean leg pain improved from 7.6 (95%CI 7.4–7.7) at baseline to 3.2 (95%CI 3.0–3.8) at 3 months (p<.0001) and did not change further between 3 to 12 months or 12 to 24 months (p>.05). There was a correlation between symptom duration and change in leg pain at the primary endpoint of 12 months postoperatively compared with preoperatively, with less improvement with longer symptom duration (Fig. 3; rho=0.1; p=.03). There was also a negative correlation between change in SF12 PCS and symptom duration, with longer symptom duration associated with less improvement in the PCS (rho=−0.14, p=.002). There was an overall improvement in back pain between the preoperative assessment and 12 months after surgery from 6.7 (95%CI 6.4–6.9) to 3.4 (95%CI 3.2–3.7; p<.0001) with no correlation to symptom duration (p=.33).

Caused by the subjective nature of patient reported measures such as ODI, change in ODI had been selected a

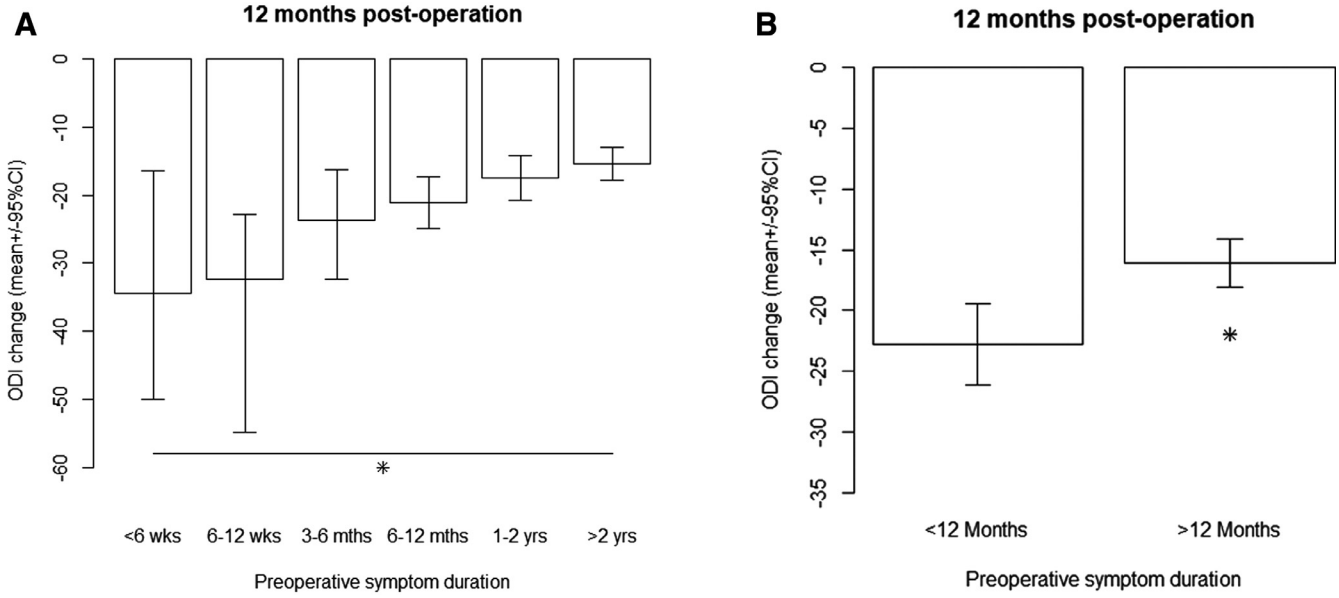


Fig. 1. Change in ODI between preoperative and 1-year postoperative assessment in lumbar degenerative stenosis in patients with different preoperative symptom durations. There was a significant correlation between ODI change and preoperative symptom duration (A). The difference remains significant when grouped by greater than or less than 12 months of symptoms (B). *p<.05.

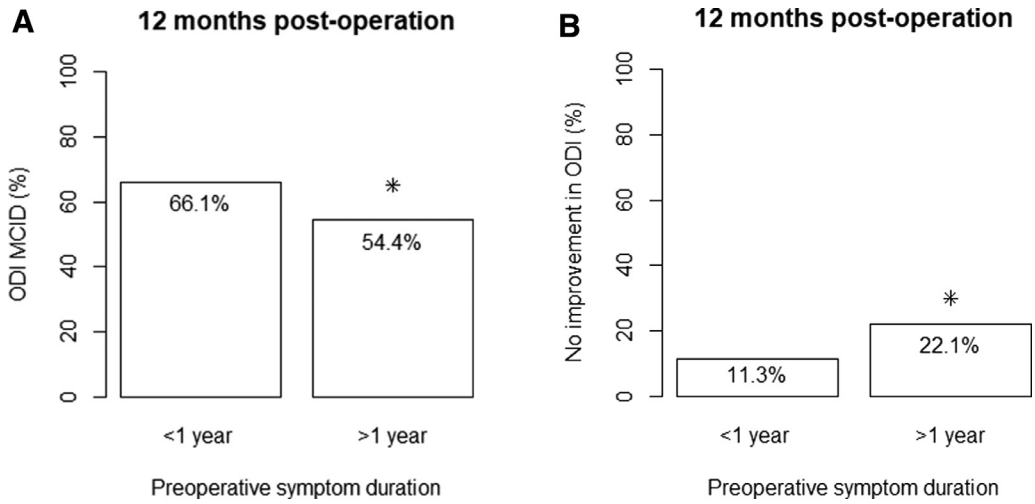


Fig. 2. Proportion of patients achieving the MCID in ODI between preoperative assessment and 1-year postsurgical decompression (A) and the proportion with no improvement or worsening of disability at 1-year postoperation (B) in lumbar stenosis. *p<.05.

priori as the primary outcome measure in this study rather than absolute ODI levels but an inverse correlation between ODI and symptom duration was present at baseline (rho=−0.11; p=.0006), but not postoperatively, which suggests that some of the difference in ODI may have been caused by differences in the groups at baseline. However, as noted in the multivariate analysis below, duration group remains significant even in controlling for baseline ODI levels. The mean wait between preoperative assessment, when symptom duration group was assigned (as defined by the CSORN registry protocol), and the surgical date was 67 days. On univariate analysis, patients with a longer wait than the mean had a less improvement in ODI at 12 months postoperatively (−14.5 [95%CI −17.6 to −11.4]) compared with those with a shorter wait (−19.2 [95%CI −21.3 to −17.1]; p=.01).

### *Multivariate analysis*

Multivariate regression analysis was used to identify factors associated with differential change in ODI between preoperative assessment and 1-year postoperatively. Factors in the final predictive model are shown in Table 2. Higher preoperative ODI and a level of education greater than high school were associated with a greater improvement in ODI, however symptom duration remained significant when controlling for these factors. Factors significantly associated with smaller improvements in ODI included duration of

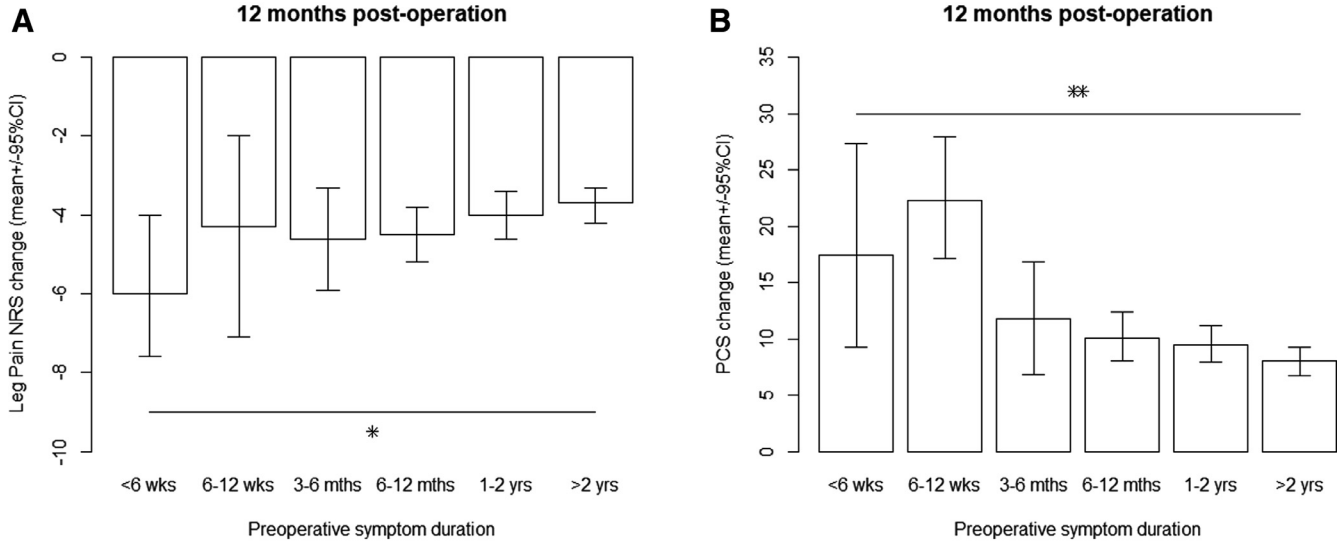


Fig. 3. Leg pain numeric rating scale (A) and short form 12 PCS (B) change between preoperative assessment and 1-year postoperative follow-up in lumbar degenerative lumbar stenosis. For leg pain more negative numbers represent greater improvement, whereas for PCS more positive values are favorable. Mean +/-95%CI. NRS, numeric rating scale. *p=0.03. **p<0.005

Table 2
Final multivariate regression model demonstrating variables that predicted change in ODI between preoperative and 12-month postoperative assessments

| Independent variable | Coefficient | 95%CI | p-value |
|---|---|---|---|
| Symptom duration> 12 months | 4.79 | 0.29–9.29 | .04 |
| Preoperative ODI* | −0.55 | −0.69 to −0.41 | <.0001 |
| No education past high school | 4.52 | 0.47–8.58 | .03 |
| Age† | 0.28 | 0.09– 0.48 | <.01 |
| Currently smoking | 8.44 | 2.57–14.31 | <.01 |
| BMI | 0.60 | 0.27–0.93 | <.001 |
| Worker's compensation claim | 12.40 | 3.03–21.76 | <.01 |
| Narcotic use | 4.74 | 0.60–8.88 | .02 |

CI, confidence interval.

All factors were independently significant and there were no interactions identified.

* Increments in ODI and BMI are per 1 unit.

† Increments in age are years.

symptoms greater than 12 months, greater age, current smoking status, workers compensation claims, narcotic use, greater BMI, and use of instrumented fixation during surgery. The factors not found to be independently predictive (all p>.1) on multivariate analysis were surgical wait time after the decision to operate, gender, preoperative leg, or back pain NRS, engagement of other health services preoperatively (emergency department, chiropractors, homeopaths, or specialist pain clinics), intraoperative blood loss, operative time, American Association of Anesthesiologist class, multiple surgical levels, fusion vs. no fusion, minimally invasive surgery, and enrolling site (all p>.1). After adjusting for potential confounding (Table 2), patients who had duration of symptoms greater than 1 year had a 4.79 point less improvement on ODI scores at 1 year.

## Discussion

In this study, shorter preoperative symptom duration was associated with a greater improvement in ODI in degenerative lumbar stenosis at the primary endpoint of 12 months postoperatively. Patients were also more likely to achieve the MCID in ODI and were less likely to have a failure to respond to surgery if they had less than a year of symptoms before receiving operative treatment. Radcliff et al. found a similar association between symptom duration and ODI in their secondary analysis of the SPORT trial; degenerative spinal stenosis participants with <12 months symptom duration exhibited greater improvement by ODI, SF36, and patient satisfaction rating, and had lower reoperation rates, compared with those with >12 months of symptoms [8]. Our SF12 PCS and leg pain NRS results were similar to our results with the ODI; greater improvements were seen with shorter symptom duration. In addition, the same results were also seen at 3 and 24 months after surgery indicating the effect was stable over time. Back pain NRS was not the primary complaint in these patients and did not vary with symptom duration. Nonetheless, patients reported a substantial improvement in back pain after surgery for their stenosis.

Bailey et al. (2016) in a single center study found that longer wait times for surgery were associated with worse postoperative ODI and leg pain outcomes in lumbar stenosis at 6 and 12 months after surgery but that the effect was not sustained at 2 years postoperatively [17]. Oswestry disability index is a patient reported outcome measure and is therefore of greatest value when comparing different time points for a single patient, rather than assessing improvement between patients. Change in ODI, rather than absolute value, was used as the primary measure in this study, thus obviating baseline differences. Multivariate analysis suggested higher preoperative disability was associated with larger improvements. In addition, Bailey et al.'s paper examined the surgical wait list time and attempted to control for duration of symptoms before the decision to operate. Preoperative surgical wait can be broken down into the wait before the decision to operate, the independent variable in this study, and the wait between the decision to operate and the surgical procedure. Our results demonstrated that longer symptom duration before the decision was associated with worse outcomes in stenosis patients. The time waiting for surgery after the decision to operate was significantly correlated with outcome on univariate but not multivariate analysis. It is possible that variance in the latter was not sufficient to demonstrate an effect.

Arguably, mean change outcome measures can be deceiving as there is a possibility for a change to be statistically but not clinically relevant; this has led to efforts to define MCIDs. Stenosis patients with more than a year of symptoms were more likely to not achieve the MCID improvement in ODI postoperatively and were twice as likely to have no improvement or even worsening of their score. A variety of MCID levels have been proposed for the ODI, depending on the derivation method, ranging from 2.92 to 15.36 [18]. The MCID level of 12.4 chosen for this study arose from a diagnosis specific derivation but it is possible that smaller improvements are still appreciated by patients. It is interesting to note that only 58.2% of stenosis patients in this study achieved a −12.4 change in ODI and yet 88.6% reported being somewhat or extremely satisfied with the surgery and, when asked at 12 months postoperatively, 92.2% said they would have the surgery again.

There are several limitations to this study which are largely those inherent in large, prospective surgical case registries. However, this is one of the largest lumbar stenosis cohorts in the literature and external validity is increased by the multicenter nature of the CSORN registry. This study design does not allow causation to be assigned and it is possible that a variety of other, unmeasured variables may be responsible for the association found between worse outcomes and longer symptom duration. However, a number of potentially important factors, related to

socioeconomic status (employment, education level), extent of disease/comorbidities (>1 level involved, ASA), mental state (MCS, antidepressant use), and substance use (narcotic use, smoking) did not differ between different duration groups and therefore do not explain the association.

Additionally, different aspects of outcome can be measured in other ways besides the patient reported outcomes measured in this study. The available data did not allow assessment of reoperation rate, complications, readmission, the economic societal impact of disability, or costs of different treatment approaches, all of which may be of importance when making decisions regarding patient care. The pathophysiology of why prolonged symptomatic stenosis is associated with worse outcome is not examined directly but possible explanations include the adoption of sick roles with chronic symptoms, deconditioning, loss of income or social supports, or permanent injury to the nerves themselves.

The long symptom duration seen in the majority of patients may be related to the single payer structure of the Canadian health care system which provides an opportunity, which may not be available in other jurisdictions, to study the effect of long symptom duration on outcome. For instance, the SPORT patients differed from our population in that 77% had surgery before 6 months of symptom duration whereas the CSORN patients waited considerably longer with 39% waiting >1 year and 18% >2 years. This study was not designed to uncover the underlying cause of surgical delay but this appears to represent an area of opportunity for outcomes improvement. Additionally, not all patients supplied follow-up data and could not be assessed at the final endpoint. However, none of the factors independently predicting worse outcomes differed in those with and without follow-up, except for smoking. The effect of smoking may therefore be underestimated in the final model.

All patients with >2 years of symptoms are grouped in one category in the registry and may represent a broad range of actual durations, creating the concern that these longer term, or "chronic" cases may overlap with other chronic pain conditions. However, the symptom duration category refers to the primary stenosis complaint of these patients, neurogenic claudication/radiculopathy, rather than other symptoms such as back pain. These symptoms improved in all duration groups after surgical decompression adding assurance that the symptoms were derived from the treated pathology (stenosis). The stenosis associated measures (ODI, leg pain) improved less with longer symptom duration but back pain change did not differ between groups suggesting that the differences between groups was not caused by another, unidentified, chronic pain disorder. Additionally, longer duration of symptoms before surgery was associated with worse outcomes but the reasons for the variable duration lengths may vary by individual and are not captured in the underlying data. Therefore, one cannot use this data to assess if one medical interventional technique or treatment duration is superior to another or better than no medical interventional treatment. However, that was not the goal of this study, which was instead designed to assess whether longer duration of symptomatic neural compression from degenerative stenosis was associated with worse outcomes. Current nonoperative management approaches cannot be expected to alleviate the underlying neural compression.

The difference in outcomes found at 12 months postoperation were also found at 3 and 24 months, indicating that the worse outcomes remained consistent over time. Glassman et al. did not find a significant difference in ODI or leg pain outcomes between 1 or 2 year postoperatively in lumbar spine surgery for any indication [19]. Elkan et al. describe 1 and 2 year ODI outcomes in the Swedish Spine registry and suggest that there is no added information gained by measuring at the longer time point in disc herniation patients [20]. Similarly, we did not find any difference in individual patient's ODI or leg pain NRS between 12 or 24 months postoperatively, regardless of initial symptom duration.

In conclusion, longer symptom duration was associated with less improvement in disability and leg pain in degenerative lumbar stenosis following surgical intervention. That association remained even after controlling for other factors influencing outcome, including preoperative ODI, workers compensation and smoking status, etc. These findings have potential ramifications for policy makers, patient counseling, and surgical planning.

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