



Surgery for Lumbar Spinal Stenosis in Patients With Mild Leg Pain Levels Is Associated With Unsatisfactory Outcome

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Abstract

Study Design: Prospective register cohort study.

Objectives: The indication for surgery in patients with lumbar spinal stenosis (LSS) is considered to be leg pain and neurogenic claudication (NC). Nevertheless, a significant part of patients operated for LSS have mild leg pain levels defined as leg pain \leq minimally important clinical difference (MICD). Information is lacking on how to inform these patients about the probable outcome of surgery. The objective was to report the outcome of surgery for LSS in patients with a mild preoperative level of leg pain.

Methods: A total of 2559 patients operated upon for LSS with preoperative leg pain ≤ 3 NRS (Numerical Rating Scale) were evaluated for outcome at the 1-year follow-up. NRS for back pain, the Oswestry Disability Index (ODI), and the EuroQol (EQ-5D) were used.

Results: In the period 2007 to 2017, we identified 3239 patients (14%) who had mild leg pain (≤ 3 on the NRS). In this cohort, leg pain increased 0.40 (0.56–0.37) and back pain decreased 1.0 (0.95–1.2) at the 1-year follow up. ODI decreased 11.1 (10.2–11.4) and the EQ-5D increased 0.15 (0.17–0.14). A total of 31% reached successful outcome in terms of back pain, 43% in terms of ODI and 48% in terms of EQ-5D. 63% of the patients were satisfied with the outcome.

Conclusion: A minority of patients with mild leg pain levels operated upon for LSS attain MICD for back pain, ODI, and EQ-5D. The results from this study can aid the surgeon in the shared decision-making process before surgery.

Keywords

lumbar, stenosis, spondylosis, low back pain, leg pain, outcome, spinal stenosis

List of abbreviations

EQ-5D, EuroQol; HRQoL, Health Related Quality of Life; LSS, Lumbar Spinal Stenosis; MICD, Minimally Important Clinical Difference; NC, Neurogenic Claudication; NRS, Numeric Rating Scale; ODI, The Oswestry Disability Index; OR, Odds Ratio; PROMs, Patient Reported Outcome Measures; SD, Standard Deviation; SweSpine, The Swedish Spine Register

Introduction

Lumbar spinal stenosis (LSS) is the most frequent indication for elective spinal surgery.¹ The established indication for surgery in LSS is leg pain and neurogenic claudication.^{2–4} These indications may seem straightforward but close analysis of patients scheduled for LSS surgery shows the patients to have heterogenous symptoms.^{5–8} Leg pain is typically pronounced in patients scheduled for surgery but the percentage of patients having mild leg pain levels, defined as below or equal the minimal clinical difference, is not well-known and has, to our

knowledge, not been reported. As the main indication for surgery is considered to be leg pain and NC, the most common pain constellation in these patients is to have more pronounced

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Table 1. Preoperative Demographics (N = 2559).

Age, years, mean (SD)	67.9 (10.7)
Gender, men/women, %	64/36
Smoker	91% nonsmokers
Duration of leg pain (dichotomized) >1 year, %	48
Duration of back pain (dichotomized) >1 year, %	70
Type of surgery, %	
Central (facet sparing) decompression without preservation of midline structures	61.7
Central (facet sparing) decompression and uninstrumented posterolateral fusion	1.4
Decompression and instrumented fusion	6.2
Central decompression with preservation of midline structures (split spinous process laminotomy)	2.1
Microscopic decompression with preservation of the midline structures	26.1
Other	2.5
Previous spine surgery (includes any type of previous spine surgery)	20

leg pain than back pain, which is the situation in 50% of the patients and approximately 40% of the patients have more pronounced back pain than leg pain.⁶ Although the main indication for surgery in LSS is well established, studies have shown patients scheduled for LSS surgery to have heterogeneous pain profiles with significant burden of back pain that may influence the outcome of surgery.^{5,7,9-12} Previous outcome studies have mainly focused on the burden of back pain in surgery for spinal stenosis and have not explored the outcome in patients without significant leg pain.^{5,7,9-14} Understandably, patients with leg pain below the minimally important clinical difference (MICD) lack the potential to reach significant clinical improvements in terms of leg pain.¹⁵ The main objective of this study, from the Swedish Spine Register (SweSpine) was to analyze the outcome of surgery in patients with mild leg pain levels. Patients with mild leg pain levels are quite commonly encountered in the clinic and information on how to advice patients with these characteristics with regard to outcome is lacking. Information regarding the outcome can aid in the decision-making process when spinal surgeon's advice patients with mild leg pain on the probable outcome of LSS surgery.

Methods

Study Design

This study analyzed 3239 patients from the SweSpine database, operated upon for LSS without degenerative spondylolisthesis during years 2007 to 2017. All patients had mild levels of preoperative leg pain defined in this study as Numerical Rating Scale (NRS) ≤ 3 .

Data in SweSpine is prospectively collected and the coverage is currently (2020) approximately 98%. The SweSpine registry is a property of the Swedish National Board for Health and Welfare and the registry has previously been thoroughly described and validated.^{1,15-18} Surgical data as regards diagnosis, operated level/s, side, type of surgery, type of implant, and complications is registered by the surgeon. In SweSpine, the surgeon is obligated to select a predefined type of surgery that fits the performed surgery (Table 1). Postoperative follow-up questionnaires are mailed to the patients with a prepaid and

addressed return envelope. At the follow-up, same parameters as preoperative are registered. Preoperatively, the patients report demographics; age, gender, smoking habits, previous spine surgery (includes any type of spinal surgery for other reasons), and patient-reported outcome measures (PROMs). The PROMs used in SweSpine are the NRS for back and leg pain (0-10; higher is worse), quality of life by EuroQol (EQ-5D; -0.224 to 1.0 ; higher is better), and disability by Oswestry Disability Index (ODI; 0-100; higher is worse [more disability]). The outcome data of this study refers to the 1-year follow-up but PROMs used in SweSpine for LSS surgery are stabilized at the 1-year follow-up milestone.¹⁷

Back pain was the primary end point in this study. The secondary end points included the ODI and the EQ-5D. As the study is based on National Register data, detailed information on the decision making in individual cases is not available for analysis.

Mild leg pain level was defined as leg pain \leq MICD. A recent SweSpine study has set the MICD value for NRS leg pain MICD at 3.2.¹⁵ As these patients lack the ability to reduce their leg pain from a MICD perspective, the study focused on the ability of the surgery to achieve MICD for back pain, ODI, and EQ-5D. Furthermore, MICD values for back pain, ODI, and EQ-5D were obtained from a SweSpine study reporting MICD for ODI to be 14 and 0.1 for the EQ-5D.¹⁵ MICD for back pain was in the recent study determined to be 2.8, the cutoff in the present study was set at 3.¹⁵

Ethical Considerations

Participation in the register is voluntary for both patients and clinics and participation can be withdrawn at any time. The patients accept that data is used for clinical research and published in future studies. The database included no identifiable personal data. The study is approved by the regional ethical committee (Dnr. 2019-02 997).

Statistics

Results are presented as means with standard deviation (SD), otherwise as percent (%). In comparisons between groups mean values with 95% confidence intervals were presented. Logistic

Table 2. Preoperative PROMs and Outcome 1 Year After Surgery.

	Preoperative, mean, (95% CI)	One-year follow-up, mean (95%CI)	Difference, mean (95%CI)
Leg pain (NRS)	1.6 (1.5-1.6)	2.0 (1.9-2.1)	0.4 (0.56-0.37)
Back pain (NRS)	3.9 (3.8-4.0)	2.9 (2.7-2.9)	1.0 (0.95-1.2)
ODI	33.7 (33.1-34.2)	22.6 (21.9-23.4)	11.1 (10.2-11.4)
EQ-5D	0.52 (0.51-0.53)	0.67 (0.66-0.68)	0.15 (0.17-0.14)

Abbreviations: PROMS, patient-reported outcome measures; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index; EQ-5D, EuroQol.

Table 3. Percent of Patients Achieving MICD for the PROMs.

PROMs	Percent (%) reaching MICD at the 1-year follow-up
Back pain (NRS), threshold 3 NRS	31
ODI, threshold 14	43
EQ-5D, threshold 0.1	48

Abbreviations: MICD, minimal important clinical difference; PROMS, patient-reported outcome measures; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index; EQ-5D, EuroQol.

multivariable regression including, gender, duration of leg and back pain, type of surgery, smoking, and previous spinal surgery were used to calculate the Odds ratio for achieving MICD for back pain, ODI, and EQ-5D. We used the STATA14 statistical software.

Results

During the observed period, 29 117 patients went through surgery for lumbar spinal stenosis. A total of 23 426 reported their levels of leg pain on the NRS. During the period, 14% (n = 3239) had preoperative leg pain ≤ 3 on the NRS. The mean age of the patients was 67.9 years, 64% were men and 91% were nonsmokers (Table 1). Almost two-thirds of the patients underwent central decompression (laminectomy) without preservation of the midline structures and less than 7% underwent fusion surgery (Table 1).

A total of 2559 (79%) patients with leg pain \leq MICD had 1-year follow-up data for leg pain available. The mean NRS leg pain was preoperatively 1.6, which increased to 2.0 at the 1-year follow-up (Table 2). Back pain was reduced from 3.9 to 2.9 and ODI from 33.7 to 22.6 during the same follow-up period (Table 2). The EQ-5D increased from 0.52 to 0.67 during the same period (Table 2). All the changes from pre- to postoperatively were statistically significant (Table 2).

In all, 31% of the patients reached MICD for back pain, 43% of the patients reached MICD for ODI, and 48% of the patients reached MICD for EQ-5D (Table 3).

The odds ratio (OR) for reaching MICD for back pain were not influenced by type of surgery or previous surgery but duration of back pain exceeding one-year increased the OR for obtaining MICD for back pain while the duration of leg pain

Table 4. Odds Ratio for Reaching MICD in Back Pain, ODI, and EQ-5D: Results From the Adjusted Regression Analysis.

	Back pain, OR (95% CI)	ODI, OR (95% CI)	EQ-5D, OR (95% CI)
Gender	1.0 (0.90-1.21)	1.0 (0.88-1.19)	0.97 (0.84-1.13)
Smoking	1.2 (0.91-1.49)	0.94 (0.73-1.19)	0.85 (0.66-1.1)
Duration of back pain >1 year	1.2 (1.2-1.7)	0.92 (0.78-1.1)	0.78 (0.66-0.93)
Duration of leg pain >1 year	0.66 (0.56-0.77)	1.05 (0.90-1.23)	0.92 (0.79-1.1)
Previous spine surgery (any type)	1.0 (0.83-1.2)	0.8 (0.68-0.97)	0.66 (0.55-0.81)
Spinal fusion	1.2 (0.90-1.64)	1.4 (1.03-1.90)	1.5 (1.1-2.0)

Abbreviations: MICD, minimal important clinical difference; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index; EQ-5D, EuroQol.

had the opposite effect (Table 4). For ODI, fusion increased the OR for attaining MICD, while having previous spine surgery reduced the OR for attaining MICD for ODI (Table 4). For the EQ-5D, the duration of back pain more than 1 year and previous spine surgery reduced the OR for attaining MICD while fusion increased the OR for attaining MICD for EQ-5D (Table 4).

There was an association between satisfaction and outcome in terms of back pain, ODI and EQ-5D as high degree of satisfaction with the outcome was linked to reaching MICD for the PROMs utilized in the study (Figure 1).

Discussion

This study focuses on outcome of surgery in patients with mild leg pain level. Our results show that a majority of patients with leg pain \leq MICD fail to reach MICD in terms of back pain, ODI, and EQ-5D. In addition, the satisfaction rates with the surgical outcome is low in this group of patients. Using a somewhat different criteria for MICD, Khan et al¹¹ reported 50% of the patients achieving MICD for ODI, 57% for back pain and 49% for leg pain. In that study, 57% of the patients with prominent leg pain achieved MICD, which stands in contrast to our study of patients with mild leg pain where 43% reach MICD in terms of ODI. If one analyses all patients operated for LSS in SweSpine (not only those with mild leg pain levels) then marked improvements in leg and back pain are noted, even in patients with high back pain levels.^{1,7} The improvements in SweSpine are at the 1-year follow-up for all the patients is 16 points for ODI, 2.2 points for back pain and 0.25 points for EQ-5D. However, when leg pain is defined as mild then outcome in terms of pain, disability and HRQoL is inferior or 1 for back pain, 11 for ODI and 0.15 for EQ-5D.

What Reasons May Explain the Observed Unsatisfactory Outcome in This Group of Patients?

Surgery for LSS aims at alleviating radicular symptoms by decompressing nerves in the lumbar spine. Performing nerve

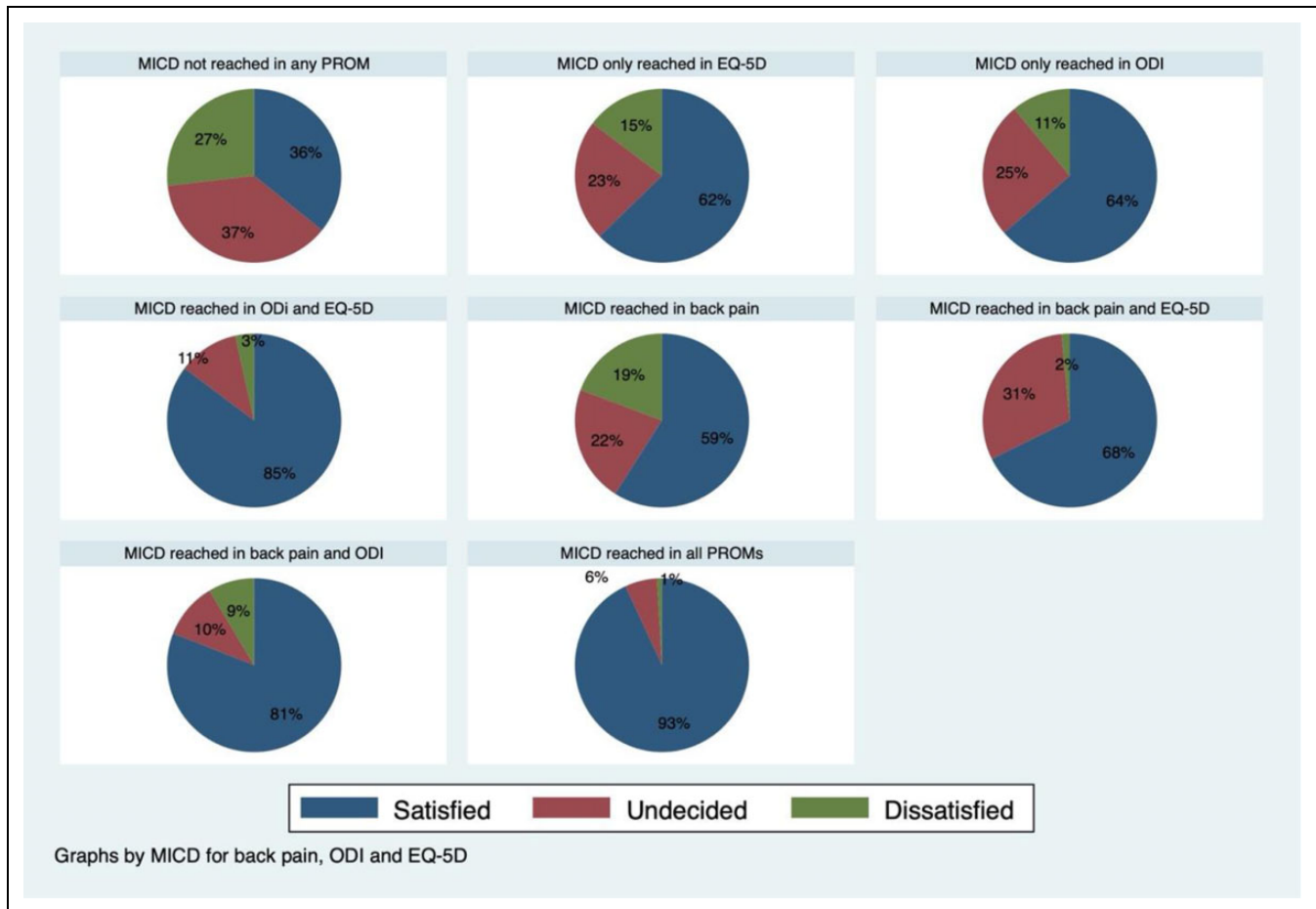


Figure I. Satisfaction with the 1-year outcome.

decompression for symptoms other than leg pain may not be entirely logical. Nevertheless, evaluating clinical symptoms in patients scheduled for spinal stenosis surgery is not consistently straightforward.¹⁹ As in many chronic pain disorders, the etiology of the pain is heterogenous and identification of the main pain generator may be challenging or impossible. The pain may be nociceptive, neuropathic, or mixed⁸ and other comorbidity such as diabetes neuropathy and other coexisting degenerative conditions of the hip and knee may present similarly.²⁰⁻²² Patients evaluated and operated for LSS usually have back pain and radiculopathy but the symptoms may be heterogenous and back pain and radiculopathy may have many different etiologies.^{5,7,9,14,22} Both neuropathic and nociceptive pain pathways may contribute to low back pain and the associated leg pain.²³ In one study, only a portion of the patients scheduled for LSS surgery had neuropathic pain and neuropathic pain was correlated to the visual analogue scores for leg pain and not back pain.⁸ Although most patients with LSS have back pain, the stenosis itself may not be exclusively responsible for the symptoms of back pain. The pain may be referred pain from degenerative joints in the spinal segment and will therefore not improve markedly with decompression. Subsequently,

while the patient may have a stenotic lumbar segment it may not be the main pain generator and the patient will be left unsatisfied with the result of surgery as the pain has not been adequately addressed with surgery. Further complicating the evaluation of patients scheduled for surgery for LSS is the great variation in the morphological disease as central, lateral recess and foraminal stenosis may coexist and be present in a varying degree in different spinal segments. Deciding which pathological morphology should be addressed with surgery and with which type of surgery can therefore be challenging.

In this study, we used recently developed criteria for MICD from the SweSpine.¹⁵ Previous reports have defined MICD for LSS surgery using different methods.²⁴⁻²⁶ In comparison, Copay et al²⁴ described MICD for ODI to be 12.8 and 1.2 points for back pain and 1.6 points for leg pain.²⁴ In another article, Solberg et al²⁵ described criteria for success after LSS surgery in terms of OD, NRS leg pain, and NRS back pain as well as EQ-5D and these criteria are much higher than those presented by Copay et al.²⁴ However, conducting MICD calculations is quite challenging and they can be performed in several ways yielding range of MICD values.^{15,24-26} The MICD values from SweSpine are based on a large database and may

therefore be considered reliable. However, the MICD in SweSpine is anchored to a retrospective single-item transition question, demanding that the patient recalls his or her health condition prior to the operation. This makes the set values for MICD in SweSpine vulnerable for recall bias and response shift.¹⁵ How to measure MICD is a matter of some controversy and there exist no universally acceptable method for calculating MICD.²⁴⁻²⁷ In view of this, we found it prudent to use MICD values established from the SweSpine, but detailed discussion regarding different ways to construct MICD is beyond the scope of this article.¹⁵

The populations studied in this article is heterogenous but represents “real-life” data. The common denominator is LSS, but it should be kept in mind that the register database includes no radiological data or information about why a certain surgical method was chosen in each case, that is, why fusion was performed in some cases. Instrumented fusion increased the OR for obtaining MICD for ODI in our study. These results have to be interpreted with caution as less than 7% of the cohort was fused. These patients undoubtedly had some distinguishing characteristics requiring spinal fusion, but these characteristics cannot be extracted from the database. The superior results for fusion are certainly afflicted by selection bias, which is an inherent limitation in register studies.

Type of decompressive surgery conducted depends on the surgeons training and level of skills. Almost two-thirds underwent a facet sparing decompression without preservation of the midline structures while about one-third underwent microscopic decompression. Type of decompressive surgery may influence the outcome of surgery but examining this question was not the objective of the present study. A recent Cochrane review failed to generate concrete recommendations regarding the optimal way to conduct decompression for LSS but advocated further research.²⁸ The results from our study show that conventional decompressive surgery, was during the study period, the most often performed surgery for LSS in Sweden.

The decision to offer surgery is sometimes complex and affected by numerous factors. The surgeons synthesize the decision to operate from many elements intrinsic to the consultation process, including clinical symptoms and radiological data. Undoubtedly, the spinal surgeons offered surgery to patients they thought would benefit from the operation. Even in patients with mild leg pain, improvements are certainly made but they are in more than half the patients below MICD for the PROMs. Patients with mild levels of leg pain should therefore be informed that the potential improvements that may be experienced in pain, disability and quality of life will most likely be modest and there is an inherent risk for dissatisfaction with the outcome.

Although surgery for LSS has the potential to relieve pain, restore function, and improve quality of life, it sometimes fails to do so for numerous reasons. Perhaps the well-known variability in indications may be a contributing factor and the results from our study may indicate this. The current literature suggests that patients with predominant leg pain achieve the best outcome after surgery for LSS and patients with mild leg pain

levels reach MICD in only minority of the patients. In times where resources are scarce and compensations for surgery often linked to improvements in PROMs and satisfaction rates, the results from the current study highlight the inferior outcome of patients with mild leg pain levels and may potentially reduce the number of dissatisfied patients and thus increase the value of surgery in LSS.

The main strengths of the present study are the prospective register follow-up with high levels of adherence at the 1-year follow-up and the validated PROMs. The limitations inherent to register studies include selection bias and heterogeneity of the cohort studied. In addition, what constitutes success after spine surgery is not well defined.

Conclusions

Patients with mild leg pain levels represent 14% of patients scheduled for surgery for LSS. A minority of these patients attain MICD for back pain, ODI and EQ-5D. The outcomes from this study can aid the spine surgeon when discussing probable outcome of spine surgery in patients with mild leg pain levels.

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Declaration of Conflicting Interests

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