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Clinical Study

Predictors for failure after surgery for lumbar spinal stenosis: a prospective observational study

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Abstract

BACKGROUND/CONTEXT: Some patients do not improve after surgery for lumbar spinal stenosis (LSS), and surgical treatment implies a risk for complications and deterioration. Patient selection is of paramount importance to improve the overall clinical results and identifying predictive factors for failure is central in this work.

PURPOSE: We aimed to explore predictive factors for failure and worsening after surgery for LSS.

STUDY DESIGN /SETTING: Retrospective observational study on prospectively collected data from a national spine registry with a 12-month follow-up.

PATIENT SAMPLE: We analyzed 11,873 patients operated for LSS between 2007 and 2017 in Norway, included in the Norwegian registry for spine surgery (NORspine). Twelve months after surgery, 8919 (75.1%) had responded.

OUTCOME MEASURES: Oswestry Disability Index (ODI) 12 months after surgery.

METHODS: Predictors were assessed with uni- and multivariate logistic regression, using backward conditional stepwise selection and a significance level of 0.01. Failure (ODI>31) and worsening (ODI>39) were used as dependent variables.

RESULTS: Mean (95%CI) age was 66.6 (66.4−66.9) years, and 52.1% were females. The mean (95%CI) preoperative ODI score was 39.8 (39.4−40.1). All patients had decompression, and 1494 (12.6%) had an additional fusion procedure. Twelve months after surgery, the mean (95%CI) ODI score was 23.9 (23.5−24.2), and 2950 patients (33.2%) were classified as failures and 1921 (21.6%) as worse. The strongest predictors for failure were duration of back pain > 12 months (OR [95%CI]=2.24 [1.93−2.60]; p<.001), former spinal surgery (OR [95%CI]=2.21 [1.94−2.52]; p<.001) and age>70 years (OR (95%CI)=1.97 (1.69−2.30); p<.001). Socioeconomic variables increased the odds of failure (ORs between 1.36 and 1.62). The strongest predictors for worsening were former spinal surgery (OR [95%CI]=2.04 [1.77−2.36]; p<.001), duration of back pain >12 months (OR [95%CI]=1.83 [1.45−2.32]; p<.001) and age >70 years (OR [95%CI]=1.79 [1.49−2.14]; p<.001). Socioeconomic variables increased the odds of worsening (ORs between 1.33−1.67).

CONCLUSIONS: After surgery for LSS, 33% of the patients reported failure, and 22% reported worsening as assessed by ODI. Preoperative duration of back pain for longer than 12 months, former spinal surgery, and age above 70 years were the strongest predictors for increased odds of

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failure and worsening after surgery.

Keywords: Failure; Patient selection; Predictors; Spinal stenosis; Spine registries; Worsening

Introduction

Lumbar spinal stenosis (LSS) is a common condition and represents an increasing burden for our health care system. Surgical treatment for LSS is a good option for patients failing nonoperative care [1−6].

Although the results after surgical treatment can vary, many studies report good results in 62%−75% of patients [7−13]. Furthermore, even though the surgical techniques constantly develop toward less invasiveness, the clinical results seem stable [7,14].

Of note, surgery also implies a risk for complications and deterioration, which underlines the importance of proper patient selection for surgery. It is tempting to consider a clinician's experience and judgment as the best prerequisite to selecting suitable patients for surgery. However, complex and subtle clinical pictures are difficult to perceive, and expert surgeons may overestimate the benefit of surgery and underestimate the risk of unfavorable outcomes [15]. Furthermore, risk factors may be positively or negatively associated with results, interact, and be subject to confounding. It may be challenging to overview a range of predictors in a clinical setting and assess their combined clinical relevance. However, previous studies have shown that a combined set of predictors perform better than one single in predicting outcomes and that predictors are superior to clinical judgment. Hence predictor analyses are central for informing and improving patient selection and clinical decision-making before surgery [16−19].

Many patients seem to understand the uncertainty regarding clinical outcomes and that not everybody improves. The risk of getting worse may be harder to accept. Former predictor studies are based on different databases (mandatory registers, voluntary registers, or a few treating centers) and include different variables or definitions of variables. Hence, the results are not necessarily transferable to other settings. Some former studies focus on improvement rather than failure or worsening. Risk assessment concerning unfavorable outcomes is crucial for informing patients and making clinical decisions and could aid in reducing the adverse effects of spine surgery [20].

We aimed to explore predictors for failure and worsening after surgery for LSS in a national comprehensive spine registry.

Material/method

This retrospective study on prospectively collected data includes adult patients operated on for lumbar spinal stenosis (LSS) between 2007 and 2017 in Norway. The Norwegian registry for spine surgery (NORspine) is a mandatory register with a coverage of 70% at the case level and 100% at the surgical unit level [21]. The registration process includes a preoperative form on socio-economical items and standard PROMs filled by the patients at admission for surgery (baseline). The surgeon fills out one postoperative form on diagnosis and surgical details. The patients complete two follow-up forms, one at three months and one at 12 months. They include common PROMs and a global perceived effect (GPE) transition scale. The PROMs are the Norwegian translation of the Oswestry Disability Index (ODI), a pain-related disability score ranging from 0 (no impairment) to 100 (bedbound) [22−23], and Numerical Rating Scales (NRS) for back and leg pain (ranging from 0 = no pain to 10 = worst pain imaginable) [24]. The GPE scale have seven steps (1=completely recovered, 2=much improved, 3=somewhat improved, 4=unchanged, 5=somewhat worse, 6=much worse, 7=worse than ever) [25].

Primary outcome: We defined failure as ODI final score >31 points and worsening as ODI >39 points, in accordance with a recent study [26].

Sensitivity analysis: To evaluate the robustness of the prediction we defined an ODI change of less than 8 points as failure and less than 4 points as worsening [26]. Finally, we also used GPE to assess the effect after surgery.

Statistics

We report central tendency in terms of mean (95% CI) for continuous data with normal distribution and number and proportions (%) for categorical data. We assessed predictors using uni- and multivariate logistic regression, with backward conditional stepwise selection with an entry and removal threshold of 0.01.

ODI score 12 months after surgery of 31 for failure and 39 for worsening were used as dependent variables (outcome). Covariates in the predictor analyses were chosen according to previous literature: age, gender, smoking, ASA classification, BMI, educational level, civil status, Norwegian speakers, disability benefit, former spinal surgery, MRI findings, preoperative ODI score, duration of symptoms, multilevel surgery [27−29]. Among the covariate variables, some were dichotomized to improve the data-to-model fit and facilitate interpretation of the analyses (age, BMI, ASA classification, and educational level). There was no strong (<0.7) correlation between the covariates, and linearity between continuous variables was checked against logit failure. Only preoperative ODI had nonlinearity, as displayed in Figure. Covariates were tested

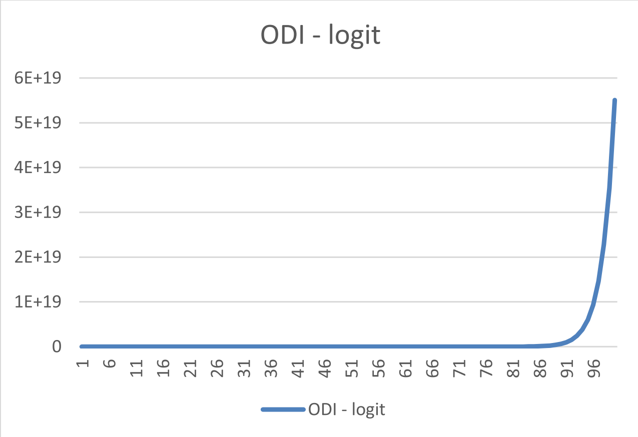

Figure. Non linear realtionship between preoperaitve ODI and logit failure.

for relevant interactions using multivariate logistic regression, and no interactions had a statistically significant association with the outcomes.

Subgroup analyses

To explore the role of preoperative back pain, we dichotomized the population into those who reported more back than leg pain (yes/no). We reported the number (%) of failures in patients who received decompression and fusion versus those who received decompression only. We also explored the role of the number of levels operated by analyzing the number (%) of patients reporting failure who were operated on at one, two, three, and four levels. We performed subgroup analyses of patients with previous surgery at the same or another level. For secondary explorative analyses, we used simple crosstabulations.

We did not impute any missing data. All statistical analyses were done with SPSS version 26 (IBM Corp. released in 2017. IBM SPSS Statistics for Windows, Version 25. Armonk, NY, USA).

Ethics

Participation in the registry is voluntary and includes written consent. The study was also approved by The Norwegian Regional Committee for medical and health research ethics ((2017/2157). The study was conducted in accordance with the Helsinki declaration and is presented according to the STROBE statement [30].

Results

Baseline

We identified 11,873 patients operated for LSS between January 2007 and April 2017, 8,863 (74.6%) had completed three months follow-up, and 8,919 (75.1%) had completed 12 months follow-up. Table 1 displays patient characteristics at baseline for all patients and patients with treatment categorized as "failure" and "worsening" subgroups. The mean (95%CI) age was 66.6 (66.4−66.9) years, and 4,644 (52.1%) were females. The mean (95%CI) ODI was 39.8 (39.4−40.1). Patients with failure and worsening were elder, more often ASA >2, and had higher BMI and preoperative ODI. In addition, they more often had low education, comorbidities, disability benefit, and former surgery (Table 1). Patients lost to follow-up at 12 months were younger, more often smokers, and had higher preoperative ODI scores (Appendix Table 1). Table 2 displays the type of surgical treatment given. All patients had some kind of decompression, bilateral foraminotomy was the largest group, and 1,494 (12.6%) patients had an additional fusion procedure.

Clinical results

Twelve months after the operation, 2950 (33.2%) patients were categorized as "failures," including 1,921 (21.6%) classified as "worse" according to the ODI final score cut-offs. When we used the ODI change score cut −offs, , (32.8%) reported failure, and 2,132 (24.2%) reported worse. The mean (95%CI) ODI 12 months after surgery was 23.9 (23.5−24.2) and the mean (95%CI) improvement in ODI was 15.9 (15.5−16.3) points. When patients graded the effect of surgery by GPE, 1,829 (20.6%) perceived themselves as "unchanged" or any degree of worsening, and 521 (5.9%) reported "much worse" or "worse than ever."

Predictors

Table 3 shows the results of the uni- and multivariate logistic regression analyses.

Failure

The strongest independent risk factors for failure identified in the multivariate model were duration of back pain >12 months (OR=2.24 [1.93−2.60]; p<.001), former spinal surgery (OR=2.21 [1.94−2.52]; p<.001) and age >70 years (OR=1.97 [1.69−2.30]; p<.001). Socioeconomic variables, that is, receiving disability benefits, low educational level, not being a native Norwegian speaker, and living alone, all increased the odds of failure (OR between 1.36−1.62). Variables concerning general health, that is, smoking, BMI >30, and ASA>2, also increased the odds of failure (OR 1.32 −1.40). The spine-related disability (ODI) and pain medication increased the odds (OR 1.06−1.29). Of the radiological variables, only the finding of degenerative olisthesis showed an effect on the odds for failure with decreased odds (OR=0.75).

Worsening

The strongest independent risk factors for worsening identified in the multivariate model were former spinal

Table 1
Patient characteristics of 11,873 Norwegian patients with surgically treated lumbar spinal stenosis in a 10 years period (2007−2017)

	All patients, n=11,873 Mean (95%CI), or n (%)	Failure (ODI>31), n=2,950 Mean (95%CI), or n (%)	S
Age (cont)	65.8 (65.6−66.0)	67.8 (67.2−68.0)	67.8 (67.3−68.3)
Age > 70 years	4,442 (37.5%)	1,352 (45.8%)	1,016 (52.9%)
Gender female	6,204 (52.3%)	1,714 (58.1%)	1,115 (58.0%)
Civil status, living alone	3,169 (26.8%)	937 (31.9%)	619 (32.4%)
Native Norwegian speaker	11,353 (96.0%)	2,796 (95.4%)	1,910 (95.3%)
ASA grade >2*	2,462 (21.0%)	848 (29.1%)	601 (31.7%)
Body mass index (cont)	27.6 (27.5−27.7)	28.0 (27.9−28.2)	28.1 (27.9−28.3)
Body mass index >30	2,920 (26.2%)	853 (31.1%)	573 (32.1%)
Smoking	2,518 (21.4%)	682 (23.3%)	470 (24.7%)
Level of education below college	8,209 (70.4%)	2,281 (79.1%)	1,501 (80.1%)
Any comorbidity	7,243 (67.2%)	2,031 (75.2%)	1,347 (76.0%)
Receives disability benefit (all types)	4,007 (34.8%))	1,082 (38.1%)	726 (39.3%)
Previous lumbar spine surgery	2,968 (25.3%)	1,025 (35.3%)	703 (37.1%)
MRI central stenosis	8,288 (69.8%)	2,104 (71.3%)	1,372 (71.4%)
MRI lateral stenosis	6,796 (57.2%)	1,616 (54.8%)	878 (45.7%)
MRI foraminal stenosis	1,225 (10.3%)	337 (11.4%)	218 (11.3%)
X-ray degenerative olisthesis	1,854 (15.6%)	416 (14.1%)	281 (14.6%)
Leg pain > 12 months duration	7,115 (65.1%)	1,940 (72.9%)	1,295 (73.8%)
Back pain > 12 months duration	8,415 (75.4%)	2,267 (82.3%)	1,507 (83.7%)
Preoperative ODI†	40.3 (40.1−40.6)	48.1 (47.6−48.6)	50.8 (50.2−51.4)
Preoperative leg pain (NRS)‡	6.59 (6.55−6.63)	7.05 (6.97−7.12)	7.22 (7.12−7.32)
Preoperative back pain (NRS)‡	6.53 (5.49−6.57)	7.24 (7.17−7.31)	7.44 (7.35−7.52)
Preoperative EQ-5D§	0.363 (0.357−0.369)	0.253 (0.241−0.265)	0.205 (0.191−0.219)

All patients, and patients reported as failure and worse.
* ASA = American Society of Anesthesiologists classification (1−5).
† ODI = Oswestry Disability Index (0−100), indicating increasing disability.
‡ NRS = Numeric Rating Scale (0−10), indicating increasing pain.
§ ED-5D = EuroQol's quality of life, (-0.60 to 1.00), indicating increasing quality of life.

surgery (OR=2.04 [1.77−2.36]; p<.001), duration of back pain >12 months (OR=1.83 [1.45−2.32]; p<.001), and age >70 years (OR=1.79 (1.49−2.14); p<.001). Socioeconomic variables, that is, receiving a disability benefit, low educational level, and living alone, increased the odds of worsening (OR between 1.33 and 1.67). Variables concerning general health, that is, as BMI >30 and ASA >2 increased the odds for worsening (OR 1.28−1.38), and spine-related disability (ODI) and duration of leg pain > 12 mths increased the odds for worsening (OR 1.07−1.30). None of the preoperative radiological variables influenced the odds of worsening, except the finding of a degenerative olisthesis, which decreased the odds of failure (OR=0.76 [0.64 −0.89]; p<.001)).

Table 2
Surgical treatment for 11,873 Norwegian patients with lumbar spinal stenosis in a 10 years period (2007−2017)

	Completed 12 months follow up (n=8,919) Mean (95%CI), or n (%)	Lost to follow up (n=2,954) Mean (95%CI), or n (%)
Fusion surgery	1,125 (12.6%)	369 (12.5%)
Fusion, TLIF*	309 (3.5%)	120 (4.1%)
Fusion, PLIF†	38 (0.4%)	6 (0.2%)
Fusion, PLF‡	769 (8.6%)	241 (8.2%)
Fusion, other	9 (0.2%)	2 (0.1%)
Decompression		
Unilateral foramenotomy	1,973 (22.1%)	732 (24.8%)
Bilateral foraminotomy	3,485 (39.1%)	1,120 (37.9%)
Cross over / "over the top"	1,388 (15.6%)	544 (18.4%)
Laminectomy	2,199 (24.7%)	622 (21.1%)
More than one level operated	3,255 (36.9%)	975 (33.3%)

Patients completed 12 months follow-up, and patients lost to follow-up.
* Transforaminal Lumbar Interbody Fusion.
† Posterior Lumbar Interbody Fusion.
‡ Posterolateral Lumbar Fusion.

Table 3
Logistic regression for 8,919 patients operated for lumbar spinal stenosis and registered in NORspine during 2007−2017, using failure (ODI>31) and worsening (ODI>39) as dependent variables and potential predictors as explanatory variables

	Failure (ODI>31 points)				Worsening (ODI>39 points)			
Variables	Univariate OR (95%CI)	p value	Multivariate OR (95%CI)	p value	Univariate OR (95%CI)	p value	Multivariate OR (95%CI)	p value
Age >70 years	1.50 (1.37−1.64)	<.001	1.99 (1.71−2.31)	<.001	1.50 (1.36−1.66)	<.001	1.93 (1.62−2.31)	<.001
Gender (female)	1.44 (1.32−1.57)	<.001			1.36 (1.23−1.51)	<.001		
Smoking	1.46 (1.31−1.63)	<.001	1.40 (1.21−1.62)	<.001	1.52 (1.35−1.71)	<.001	1.53 (1.31−1.80)	<.001
Body mass index >30	1.54 (1.39−1.70)	<.001	1.34 (1.18−1.53)	<.001	1.53 (1.36−1.71)	<.001	1.33 (1.15−1.54)	<.001
ASA grade >2 *	2.05 (1.85−2.28)	<.001	1.34 (1.16−1.54)		2.14 (1.91−2.40)	<.001	1.39 (1.19−1.62)	<.001
Education level below college	1.99 (1.79−2.21)	<.001	1.54 (1.35−1.75)	<.001	1.95 (1.72−2.21)	<.001	1.51 (1.29−1.76)	<.001
Civil status, living alone	1.62 (1.46−1.78)	<.001	1.33 (1.17−1.52)	<.001	1.52 (1.37−1.71)	<.001	1.26 (1.09−1.45)	.002
Not Native Norw speakers	1.58 (1.26−2.00)	<.001	1.66 (1.23−2.23)	.001	1.49 (1.16−1.92)	<.001		
Disability benefit (all types)†	1.46 (1.33−1.60)	<.001	1.67 (1.44−1.94)	<.001	1.47 (1.32−1.63)	<.001	1.66 (1.40−1.98)	<.001
Former lumbar spine surgery (any)	2.26 (2.05−2.50)	<.001	2.21 (1.94−2.51)	<.001	2.19 (1.96−2.44)	<.001	2.00 (1.74−2.30)	<.001
MRI central stenosis	1.05 (0.95−1.15)	.358			1.05 (0.94−1.17)	.428		
MRI lateral stenosis	0.91 (0.83−1.00)	.040			0.90 (0.81−1.00)	.044		
MRI foraminal stenosis	1.18 (1.02−1.36)	.024			1.14 (0.97−1.34)	.120		
RF degen olisthesis	0.85 (0.75−0.97)	.013	0.76 (0.64−0.89)	.001	0.92 (0.80−1.06)	.255		
Pre opr ODI (cont)‡	1.06 (1.06−1.07)	<.001	1.06 (1.05−1.06)	<.001	1.07 (1.07−10.7)	<.001	1.07 (1.06−1.07)	<.001
Duration leg pain >12 months	1.68 (1.52−1.86)	<.001			1.74 (1.55−1.96)	<.001	1.29 (1.06−1.56)	.010
Duration backpain >12months	1.87 (1.68−2.10)	<.001	2.17 (1.88−2.50)	<.001	1.95 (1.70−2.24)	<.001	1.85 (1.47−2.32)	<.001
Multilevel surgery§	1.21 (1.11−1.33)	<.001			1.19 (1.07−1.32)	.001		

* ASA = American Society of Anesthesiologists classification (1−5).
† All types of disability benefit, both full and partly supported.
‡ ODI = Oswestry Disability Index (0−100), indicating increasing disability.
§ more than one level operated.

Sensitivity analyses

Appendix Table 2 displays the multiple regression using ODI change score to define failure and worsening; there were minor differences from the primary analysis.

Subgroup analyses

Predominant preoperative back pain was reported by 1968 patients, of which 307 (16%) received decompression and fusion and 1,661 (84%) received decompression only. In the decompression and fusion group, 125 (41%) reported failure compared to 581 (35%) in the decompression only group. In the predominant leg pain group, 292 (36%) reported failure in the decompression and fusion group versus 1,921 (32%) in the decompression only group. Patients with predominant back pain had an increased risk ((RR) of 1.11 (1.04−1.19); p=.002) of failure.

Appendix table 3 displays failure rates according to the number of levels operated. The proportion of patients that reported treatment failure increased by numbers of spinal levels operated. There were 48% failures reported by patients who had previously received surgery at the same spinal level, compared to 47% for those who were previously operated at another spinal level.

Discussion

In this register study, 33% of patients operated for lumbar spinal stenosis, were classified as failure after surgery, including 22% classified as worse. The strongest predictors for failure were preoperative duration of back pain for at least 12 months, previous spinal surgery, and age above 70 years. Both socioeconomic variables, general health variables, and spine-related variables affected the odds for failure. The same patterns were seen regarding the odds for worsening.

The proportion of patients reported as failure and worsening seemed relatively high and may be partially explained by different outcome measures. For instance, the proportion of patients that perceived themselves as unchanged or worse was lower when patients used GPE, rather than ODI, to assess the effect of surgery. Similar results are reported in the literature. This is not surprising as GPE is conceptually different from a disease specific outcome measure. Previous studies reported success rates of about 62%−75% or failure rates of 25%−31% [7−13,31]. Moreover, the effect of surgery in our study with a mean ODI final score of 24, and a mean ODI improvement of 16 points is also in line with other studies [7−8].

Socioeconomics

A short education, living alone, not being a native Norwegian speaker, and receiving disability benefits increased the odds of failure. The findings of associations between socioeconomic factors and odds for failure and worsening are known from the literature [20]. The effect of these factors in our study was moderate (ORs between 1.33 and 1.67). One former study reported socioeconomic factors as more important than factors related to spine surgery and general health regarding return to work after spine surgery [32]. The impact of socioeconomics on the results of surgical treatment may seem surprising, but pain and disability are subjective feelings and functions. Hence, they may be affected by patient-related factors. Furthermore, communication is crucial in deciding on surgical treatment for a condition of pain and during clinical follow-up. Consequently, socioeconomic factors may impact the shared decision-making process between patients and health care personnel [33].

Our findings of associations between socioeconomic factors and failure and worsening may contribute to a higher threshold to receive surgical treatment for some patients with socioeconomic challenges. Nevertheless, it is essential to consider equal rights to health care for all patients.

General health

Age >70 years was associated with almost doubled odds for failure and worsening (ORs between 1.93 and 1.99). However, the literature on the effect of age on clinical results after surgery for LSS is conflicting. Some studies find no or minimal association between age and clinical results [34−37]. In contrast, others find decreased risk for success with increased age, or age <75 as a predictor of satisfaction [8,38]. Possible reasons for conflicting results include different outcomes, different ways of defining age groups (continuous data, age groups, or specific cut-offs), or differences in study populations. In addition, high age may be correlated with increased prevalence of other illnesses (ie, osteoarthritis), contributing to the association between age >70 years and increased odds for failure.

Smoking, ASA>2, and BMI>30 also showed associations with failure and worsening (ORs between 1.33 and 1.53). Other studies have found ASA>2 more likely to have poor outcomes [13]. The effect of BMI on the results is more uncertain in the literature. Mauro et al. reported worse outcomes with high BMI, while Onyekwelu et al. reported similar results for patients with BMI > 30 and BMI <30 [39−40].

Using the final ODI score as the outcome, it seems natural that variables concerning general health (smoking, ASA>2, BMI>30) affect the outcome as they presumably reduce function.

Some studies report frailty as a composite variable on general health, and frailty has shown an apparent effect on clinical results and complications after spine surgery and surgery in general [41−42]. We believe the general health condition impacts the clinical outcome and disability after surgery for LSS. However, grading and recording this can be done in different ways. Hence, detecting it can be challenging, especially in a registry setting.

Disease-related factors

Duration of symptoms of >12 months strongly predicted both failure and worsening. Still, long-lasting back pain had a more negative impact than prolonged leg pain. In the multivariate analyses, leg pain > 12 months was either not detectable or moderated. We found an increased risk for failure for patients with preoperative predominant back pain. Surgery for LSS aims to increase the cross-sectional area of the spinal canal to relieve leg pain and improve walking capability. Patients who reporting predominately back prior to surgery could therefore be expected to benefit less of surgery. Previous studies have shown better outcomes among patients with short symptom duration [8,43]. One possible explanation is that prolonged symptoms may lead to biochemical differences in the nerve cells and chronic pain, hence poorer treatment effect [44−45].

Former spinal surgery was a significant predictor of failure and worsening, doubling the odds for these outcomes (ORs 2.00−2.21), dichotomized irrespective of level, that is, including surgery at the same or another segment. In the subgroup analysis, we analyzed previous surgery at the same spinal level versus previous surgery at another spinal level. Interestingly, we found no differences in failure rates between these subgroups. Nerland et al. reported similar ORs for worsening associated with previous surgery in the same segment [36?]. Furthermore, Aalto et al. reported an association between no previous surgery and increased odds for good results (OR=3.65) [8]. Possible explanations for this association can be that previous surgery may lead to scar tissue resulting in technical difficulties in surgery. In addition, patients undergoing repeated surgery may be non-responsive to surgical treatment, often achieving failure and worsening.

Preoperative ODI showed increased OR for failure and worsening. The effect may seem small (OR=1.06−1.07 per ODI point). However, marked differences in preoperative ODI will significantly affect the odds of failure and worsening. Association between preoperative ODI scores and clinical outcomes have been reported before [9,46]. As we define failure and worsening by final ODI scores, the preoperative ODI score seems as a natural predictive factor; it is less likely to achieve a postoperative cut-off with a higher preoperative disability.

Patients who had surgery in more than one level had slightly increased odds for failure and worsening (OR = 1.19−1.21), although not significant in the multivariate analyses. The proportion of patients reporting treatment failure increased by number of spinal levels operated. Two former studies reported no statistically significant differences in outcomes for one and multilevel LSS treated surgically [36,47]. If one level operation has a specific risk for failure, adding the chance for failure per level could be a reasonable way to estimate the risk for failure in multilevel surgery. However, our study did not support such findings.

In our study, radiological findings showed no or negligible associations with failure or worsening. That is in line with previous studies, showing no clinically relevant association between MRI findings and preoperative disability and no or minor association between MRI findings and clinical outcome [9,48]. Radiologic findings were only recorded as yes /no, and no grading of the radiologic findings was recorded. The validity of radiological data in NORspine has not been reported.

When we examined failure and worsening as defined by ODI change score in the sensitivity analysis, we found that previous surgery, preoperative back pain lasting longer than 12 months, and age above 70 years were the strongest predictors of failure and worsening (Appendix Table 2)

In patients with predominant back pain, fusion, in addition to decompression, did not improve the results.

Future perspectives

There is a need for better instruments predicting outcomes after surgery for LSS. Prediction models have been developed to assist in patient selection. However, Staartjes et al. reported only a moderate ability to identify patients likely to benefit from surgery for degenerative spine disorder. Therefore, they concluded that prediction models should only play a minor role in decision-making [49]. The Swedish spine registry (Swespine) has also developed a prediction tool based on a prediction model to aid in patient selection for spine surgery [39]. From a future perspective, it could be interesting to develop a parallel prediction model based on NORspine data. The prediction model might help select suitable patients for surgery.

Limitations

There are several limits to this study. One is whether the NORspine registry records relevant variables to predict clinical outcomes. The study design does not allow conclusions regarding causality; only associations can be discovered. Some associations might be confounders or mediators connected to causal variables left unobserved. For instance, the NORspine did not record data on spinal alignment during the study period.

Our study had a loss to follow-up of 24.9%; Appendix Table 1 and Table 2 display no significant differences between responders and nonresponders in baseline data or surgical treatment. Although according to former studies, loss to follow-up in national spine registers does not affect the clinical outcome, one of these studies examined the NORspine population [50−52].

One can discuss the choice of the cut-offs for failure and worsening. The cut-offs were assessed in a former study on LSS patients using a transitional scale as an anchor and are in concordance with another survey of cut-offs for success and with the PASS score of 22 proposed by van Hooff [26,53−54]. Our cut-offs result in proportions classified as failure and worsening, similar to other studies [7−13,31]. Failure and worsening have been defined differently in other studies, but the use of MCID regarding increasing ODI score and worsening is not well supported [36]. In the sensitivity analysis, our main findings were confirmed. There are, however, no explicit definitions of failure and worsening after spinal surgery.

Twelve months follow-up might be short for a chronic illness. On the other hand, several studies show no clinically significant differences between 12 and 24 months. We, therefore, consider 12 months as sufficient in LSS patients [50,55−58]. Twelve months follow-up is also recommended in a systematic review with recommendations for spine registries in 2015 [28].

Different surgical techniques were used in this study; both decompression methods and fusion methods varied. Naturally, this introduces heterogeneity in our material, but on the other hand, it reflects the everyday practice and increases the external validity.

Different findings between predictor studies can result from differences in patient selection, surgical techniques, and the selection and recording of possible predictive variables.

Strengths

The study population is large and recruited in a national register obligatory to all treating centers in Norway. Therefore, the patient population reflects everyday practice, and we consider the external validity good. The large sample size also allowed for strict thresholds for entry and removal of covariates into the model of 0.01, improving the power of the analyses.

Interpreting changes in PROM scores, that is, ODI, in groups is not straightforward, and especially in large datasets, one can find statistically significant findings that do not reflect clinical importance. Therefore, we chose to use dichotomous outcomes to define failure and worsening, emphasized in a review article as favorable regarding clinical important change [59].

Conclusion

In this prospective observational spine register study, 33% of patients reported treatment failure, including a worsening rate of 22%, after surgery for LSS. Associated with increased odds for failure and worsening were duration of back pain of more than 12 months, former spinal surgery, and age >70 years. This information can assist in patient information and patient selection for surgery.

Declaration of Competing Interest

The authors declare that they have no known potential conflicts of interest influencing the work with this paper. None of the authors have received financial support to complete this study.

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Appendix table 1
Patient characteristics of 11,873 Norwegian patients with surgically treated lumbar spinal stenosis in a 10 years period (2007-2017)

	Completed 12 months follow up (n=8919) Mean (95%CI), or n (%)	Lost to follow up (n=2954) Mean (95%CI), or n (%)
Age (cont)	66.6 (66.4−66.9)	63.2 (62.7−63.6)
Female sex	4,644 (52.1%)	1,560 (52.8%)
Civil status, living alone	2,282 (25.7%)	887 (30.2%)
Native Norwegian speaking	8,565 (96.5%)	2,788 (94.7%)
ASA grade >2*	1,840 (20.8%)	622 (21.3%)
Body Mass Index (cont)	27.5 (27.4−27.6)	27.8 (27.6−28.0)
Smoking	1,697 (19.2%)	2,100 (28.1%)
Education level below college	6,145 (70.1%)	2,064 (71.4%)
Comorbidity, any	5,410 (66.9%)	1,833 (68.0%)
Patient not working	7,443 (86.0%)	2,425 (85.1%)
Receives Disability benefit (uføret)	1,421 (15.9%)	511 (17.9%)
Previous spinal surgery, any level	2,173 (24.7%)	795 (27.3%)
Leg pain > 12 months duration	5,284 (64.3%)	1,831 (67.5%)
Back pain > 12 months duration	6,280 (74.9%)	2,135 (76.8%)
Preoperative ODI *	39.8 (39.4−40.1	42.1 (41.6−42.7)
Presoperative NRS leg pain†	6.57 (6.52−6.61)	6.7 (6.6−6.8)
Pre operative NRS back pain	6.50 (6.45−6.55)	6.6 (6.5−6.7)
Pre operative EQ-5D‡	0.376 (0.369−0.383)	0.323 (0.311−0.335)

Patients completed 12 months follow-up, and patients lost to follow-up.
* ASA = American Society of Anesthesiologists classification (1−5).
† ODI = Oswestry Disability Index (0−100).
‡ NRS = Numeric Rating Scale (0−10)****ED-5D = EuroQol‘s quality of life, (-0.60−1.00)

Appendix table 2
Sensitivity analysis, multivariable logistic regression for 8,919 patients operated for lumbar spinal stenosis and registered in NORspine during 2007−2017, using failure (ODI change <8 points) and worsening (ODI change <4 points) as dependent variables and potential predictors as explanatory variables

	Failure (ODI change <8 points)			Worsening (ODI change <4 points)		
	OR	95%CI	p	OR	95%CI	p
Age >70	1.68	1.47−1.93	<.001	1.61	1.39−1.87	<.001
Smoking	1.39	1.22−1.60	<.001	1.49	1.29−1.72	<.001
BMI>30	1.25	1.11−1.42	<.001			
ASA>2	1.37	1.19−1.56	<.001	1.49	1.22−1.63	<.001
Education level below college	1.45	1.28−1.63	<.001	1.53	1.34−1.75	<.001
Civil status, living alone	1.26	1.11−1.42	<.001	1.26	1.20−1-44	<.001
Disability benefit (all types)	1.49	1.30−1.71	<.001	1.50	1.29−1.75	<.001
Previous surgery,any	1,90	1.68−2.14	<.001	2.01	1.77−2.29	<.001
MRI: central stenosis	0.79	0.71−0.89	<.001	0.81	0.71−0.92	<.001
Degenerative olisthesis (x-ray)	0.69	0.59−0.81	<.001	0.70	0.59−0.84	<.001
Preoprerative ODI (cont)	0.96	0.96−0.97	<.001	0.96	0.96−0.97	<.001
Back pain >12 mnts	1.89	1.65−2.15	<.001	1.71	1.06−1.49	<.001
Leg pain >12 mhts				1.26	1.06−1.49	.008

Appendix table 3
Cross tabulation of number of levels operated and rates of treatment failure defined by ODI final score >31

Number of levels operated	Failure	Nonsssfailure	Total	Proportion failure
1	1,747	3,796	5,543	32%
2	941	1,740	2,681	35%
3	199	301	500	39%
4	23	35	58	39%

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