Original Investigation

Surgery for lumbar spinal stenosis in patients with rheumatoid arthritis: A multicenter observational study

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Abstract

Objective: To compare clinical outcomes following microdecompression surgery or laminectomy for central lumbar spinal stenosis (LSS) between patients with rheumatoid arthritis (RA) and patients without rheumatic disease.

Material and Methods: Data were collected from the Norwegian Registry for Spine Surgery. The primary outcome was change in the Oswestry Disability Index (ODI) score at 1 year. The secondary endpoints were health-related quality of life that was measured using the Euro-Qol-5D (EQ-5D), back pain numerical rating scale (NRS), leg pain NRS, and complications.

Results: A total of 1433 patients were included (1396 controls and 37 patients with RA). For all the patients, there was an improvement in ODI score 16.7 points; 95% confidence interval (CI), 15.7, 17.7; p<0.001). There were no differences between controls and patients with RA with respect to the mean changes of ODI scores (−2.5 points; 95% CI, −9.0 to 4.1; p=0.462), EQ-5D (p=0.295), back pain NRS (p=0.194), leg pain NRS (p=0.927), and complications within 3 months of surgery (12.8% vs. 13.5%, p=0.806). At 1 year, 68.6% (n=775) of controls had achieved a minimal clinically important difference (≥8 points ODI score improvement) compared with 65.5% (n=19) of patients with RA (p=0.726).

Conclusion: Patients with RA experienced similar and large improvements in patient-reported outcomes following surgical decompression for LSS compared with patients without rheumatic disease. There was no increased risk of complications in patients with RA.

Keywords: Rheumatoid arthritis, spinal stenosis, spondylosis, quality of life, neurosurgical procedures

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Introduction

Lumbar spinal stenosis (LSS) is a highly prevalent condition that often results from a degenerative aging process. The clinical syndrome of LSS is often characterized by low back pain and lower extremity pain and numbness, and it is a frequent source of impaired walking and disability in the elderly. There is a growing evidence that surgical decompression offers an advantage over non-surgical management for selected patients with persistent severe symptoms (1). LSS is the most frequent indication for spinal surgery in the elderly, and as the oldest segment of the population continues to grow, the prevalence is likely to increase (2, 3). Rheumatoid arthritis (RA) is a potentially devastating disease that is associated with reduced physical function and impaired quality of life, which may have a negative impact on outcome after surgery. Knowledge regarding outcomes after surgery for LSS in patients with RA is missing. This multicenter observational study aimed to compare clinical outcomes following microdecompression surgery or laminectomy for central LSS between patients with RA and patients without rheumatic disease.

Material and Methods

Patients were identified from a study comparing two different surgical methods for LSS (ClinicalTrials.gov: NCT02006901) (4).

Study population

Data were retrieved from the Norwegian Registry for Spine Surgery (NORspine), which is a comprehensive registry for quality control and research. In total, 36 of 40 hospitals performing lumbar spine surgery in Norway report to NORspine. Follow-up duration after surgery was 1 year.

Inclusion criteria

1. Included in the NORspine registry between October 2006 and December 2011
2. Diagnosis of central LSS
3. Operation in ≤2 levels with open laminectomy or microdecompression surgery

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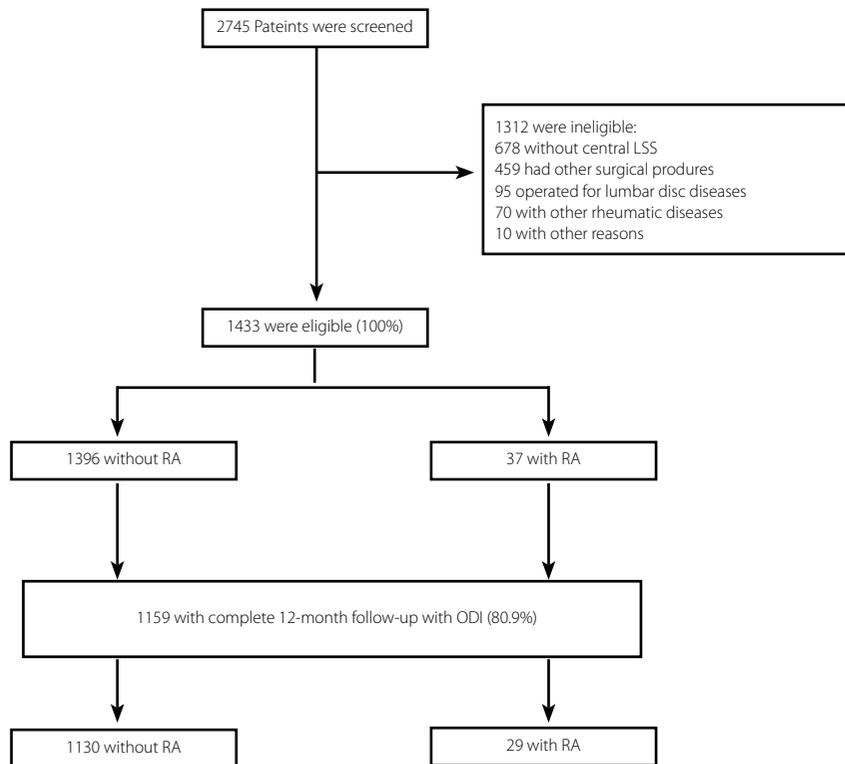
Figure 1. Study enrollment and follow-up

LSS: lumbar spinal stenosis; RA: rheumatoid arthritis; ODI: Oswestry Disability Index

Exclusion criteria

1. Discectomy or fusion
2. Rheumatic diseases other than RA

Ethics

The Regional Committee for Medical Research in Central Norway approved the study (ID2013/643), and all participants provided written informed consent.

Outcome measures

The primary outcome was the change in disease-specific functional outcome between baseline and 1-year follow-up that was measured using the Oswestry Disability Index 2.0 (ODI) (5, 6). Oswestry Disability Index is used to quantify the disability for degenerative conditions of the lumbar spine and examines the intensity of pain, ability to lift, ability to care for oneself, walking, sitting, standing, traveling, sexual function, ability to stand, social life, and sleep quality. The index is scored from 0 to 100. Zero means no disability, while 100 reflects maximum disability.

Secondary outcome measures were

1. Health-related quality of life (HRQL) that was measured using the Euro-Qol-5D (EQ-5D)
2. Low back pain and leg pain measured with numeric rating scales
3. Complications

Data collection using NORspine

Patients completed the baseline questionnaire, including questions regarding demographics and lifestyle. Surgeons recorded data concerning diagnosis, comorbidity, American Society of Anesthesiologists (ASA) grade, imaging, surgery, and complications. NORspine distributed patient questionnaires by mail at 3 and 12 months.

Surgical procedures

Patients underwent either laminectomies or microdecompression surgery. A recent study demonstrated equal results with the two surgical techniques (4). Microdecompression surgery using smaller skin incisions can be performed using a bilateral or unilateral approach depending on the surgeon's preference and the individual patient's anatomy and symptoms. Unlike a laminectomy, the spinous process and supra- and interspinous ligaments are left intact when performing a microdecompression surgery (7).

Statistics

Analyses were performed with SPSS 18.0. (IBM Corp.; Chicago, IL, USA) Statistical significance level was defined as $p \leq 0.05$, with no adjustments for multiple comparisons. Continuous variables were analyzed using an unpaired two-tailed t-test for normally distributed data. Continuous data with skewed distribution were analyzed using the Mann–Whitney U test. Discrete variables were compared using χ^2 analysis. The minimal clinically important difference (MCID) for a change in ODI score is considered to be 8–10 points (4, 8), and we used MCID value of 8 points. A multiple linear regression model was applied to assess the relationship between ODI score change at 1 year and RA, controlling for potential confounders.

Missing data

For missing data, we excluded cases pairwise. This method excluded patients only if they were missing the data that was required for the specific analysis. They were still included in any of the analyses for which they had the necessary information. The management of missing data is supported by a study in an equivalent patient population from NORspine that found no difference in outcomes between responders and non-responders (9).

Results

Baseline characteristics

Figure 1 demonstrates the inclusion and exclusion process, with a total of 1433 eligible patients (37 patients with RA and 1396 controls). As shown in Table 1, there were differences between groups for certain baseline characteristics (sex, ASA grade, baseline ODI score, and baseline EQ-5D). The total loss to follow-up was 19.1% at 1 year. The loss to follow-up at 1 year was 21.6% (n=8) in patients with RA and 19.1% (n=266) in controls (p=0.695).

Primary outcome

Primary outcomes are presented in Table 2. For both groups, combined mean ODI score at baseline was 40.6 and 23.9 at 1 year follow-up (difference, 16.7; 95% confidence interval (CI), 15.7, 17.7; p<0.001). In a complete case analysis (n=1159), there was no difference in ODI score change between controls and patients with RA at 1 year follow-up (mean difference, −2.5; 95% CI, −9.0 to 4.1; p=0.462). Among patients with complete 1 year follow-up, 68.5% (n=794) achieved MCID that was predefined as an improvement of ≥8 points in ODI score from baseline. At 1 year, 68.6% (n=775) of controls had achieved MCID compared with 65.5% (n=19) of patients with RA (p=0.726).

Secondary outcomes

Overall, there was an improvement in EQ-5D from baseline to 1 year follow-up from 0.36 to 0.64 (p<0.001). This represents a large clinical change (effect size, 0.89). No differences were found between the groups for any of the patient-reported outcomes (Table 2).

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Table 1. Demographic characteristics, coexisting illnesses, and measures of health status for both patient groups

Variable	Control group	Rheumatoid arthritis	p
No (%)	1396 (97.4)	37 (2.6)	-
Age, year (SD)	67.7 (±10.0)	68.2 (±6.9)	0.773
Female sex, no. (%)	675 (48.4)	28 (75.7)	0.001
Married or partner, no. (%)	994 (71.2)	26 (70.3)	0.856
Attended college, no. (%)	339 (24.3)	7 (18.9)	0.561
Mean body mass index (SD)	27.6 (±4.3)	27.3 (±5.3)	0.780
Current smoker, no. (%)	322 (23.4)	6 (16.2)	0.429
Coexisting spondylolisthesis or scoliosis	146 (10.5)	6 (16.2)	0.273
Previous lumbar spine surgery in operated level(s), no. (%)	131 (9.5)	2 (5.4)	0.571
Comorbidity, no. (%)	688 (49.3)	18 (48.6)	1.000
Cardiovascular disease	257 (18.4)	9 (24.3)	-
Cerebrovascular disease	26 (1.9)	1 (2.7)	-
Vascular claudication	10 (0.7)	0 (0)	-
Chronic lung disease	81 (5.8)	2 (5.4)	-
Hypertension	265 (19.0)	9 (24.3)	-
Osteoporosis	21 (1.5)	0 (0)	-
Chronic neurologic disease	41 (2.9)	0 (0)	-
Cancer	58 (4.2)	2 (5.4)	-
Diabetes mellitus	103 (7.4)	2 (5.4)	-
Other endocrine diseases	34 (2.4)	1 (2.7)	-
ASA grade >2†	312 (22.9)	17 (45.9)	0.002
Mean preoperative ODI‡	40.8 (±15.3)	46.6 (±12.1)	0.022
Mean preoperative EQ-5D	0.35 (±0.32)	0.23 (±0.27)	0.026
Preoperative diagnostic imaging			
Preoperative MRI, no (%)	1345 (96.3)	36 (97.3)	1.000
Preoperative CT, no (%)	128 (9.2)	6 (16.2)	0.149

SD: standard deviation; EQ-5D: Euro-Qol-5D; MRI: magnetic resonance imaging; CT: computed tomography; ASA: American Society of Anesthesiologists; ODI: Oswestry Disability Index

†ASA Grade I-V. Grade V is the worst indicating a life-threatening condition.

‡ODI ranges from 0 to 100, lower scores indicating less severe symptoms.

Table 2. Complete data analysis for outcomes at one year in patients with central LSS

	Control group			With RA			Difference in mean change between groups (95% CI)	p
	Baseline	One year	Mean change	Baseline	One year	Mean change		
ODI	40.8	23.8	16.6	46.6	26.7	19.1	- 2.5 (- 9.0, 4.1)	0.462
EQ-5D	0.35	0.64	0.28	0.23	0.56	0.35	- 0.07 (- 0.21, 0.07)	0.295
Back pain	6.6	3.8	2.7	7.3	4.0	3.5	- 0.8 (- 1.9, 0.4)	0.194
Leg pain	6.6	3.6	3.1	7.3	4.3	3.0	0.1 (- 1.2, 1.3)	0.927

CI: confidence interval; RA: rheumatoid arthritis; ODI: Oswestry Disability Index; EQ-5D: Euro-Qol-5D; CI: confidence interval

Details regarding surgical treatments are presented in Table 3. The proportion of patients experiencing one or more complications at ≤3 months after surgery was 12.8% (n=184). There were no differences in the overall complication rates (p=0.806), perioperative complications (p=0.435), or patient-reported complications within 3 months (p=1.000) between the groups.

In a multiple regression analysis, smoking (p=0.002), prior surgery in the operated level(s) (p<0.001), ASA grade of >2 (p=0.021), and obesity (p<0.001) were associated with a decreased ODI score change at 1 year (Table 4). Increasing preoperative ODI score (p<0.001) and college education (p=0.001) were associated with increased ODI score change, whereas no association was found for RA (p=0.456), microdecompression (p=0.054), age (p=0.268), or spondylolisthesis and/or scoliosis (p=0.562).

Discussion

This study demonstrates that patients with RA experienced similar and large improvements in patient-reported outcomes following surgical decompression for central LSS compared with patients without rheumatic disease.

Although special considerations are necessary for patients with RA undergoing surgery we found no increased risk of complications in this group. Moreover, there were no surgical site infections in patients with RA. In accordance with previous observational studies (1, 4), secondary outcome analyses demonstrated major improvements of HRQL in both groups. This may be surprising because RA is a potentially devastating disease causing reduced physical function and impaired QOL. However, in the new millennium, clinical outcomes in RA have significantly improved because of new medical treatment options and strategies aiming for remission (10).

Not all patients with LSS are candidates for surgery, and a non-surgical approach is often selected for patients with mild symptoms, sparse motivation for surgery, or when the risk of surgery outweighs potential benefits. We believe that the surgeons' threshold for surgery is higher in patients with RA, and this may be reflected by their higher baseline ODI scores. Still, the majority of symptomatic patients who are managed without surgery report no substantial change over the course of 1 year (11, 12). For non-surgical approaches, such as physical exercises, patient education, corsets, and analgesics, there are no high-quality trials to assess efficacy. Long-term results from a randomized trial suggest that non-operative measures are

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Table 3. Surgical treatments, complications, and events

Variable	Control group	Rheumatoid arthritis	Difference (95% CI)	p
Surgical procedure				
Microdecompression no. (%)	781 (55.9)	20 (54.1)	-	0.868
Laminectomy no. (%)	615 (44.1)	17 (45.9)	-	
Levels decompressed –no. (%)				
Single	816 (58.5)	21 (56.8)	-	0.867
Two	580 (41.5)	16 (43.2)	-	
Operated in level L2-L3	129	3	-	1.000
Operated in level L3-L4	703	14	-	0.138
Operated in level L4-L5	1024	30	-	0.349
Operated in level L5-S1	120	6	-	0.131
Days in hospital no.				
Single-level microdecompression	2.3	2.3	0.0 (- 1.1, 1.2)	0.926
Two-level microdecompression	2.7	4.7	- 2.0 (- 4.0, 0.1)	0.068
Single-level laminectomy	4.4	4.2	0.2 (- 1.4, 1.8)	0.812
Two-level laminectomy	4.6	4.4	0.2 (- 1.8, 2.2)	0.849
Patients with complications -no. (%)	179 (12.8)	5 (13.5)	-	0.806
Perioperative complications -no. (%)	71 (5.1)	3 (8.1)	-	0.435
Dural tear or spinal fluid leak	59 (4.2)	3 (8.1)	-	0.213
Nerve injury	1 (0.1)	0 (0)	-	1.000
Blood replacement or postoperative hematoma	8 (0.6)	0 (0)	-	1.000
Cardiovascular complications	2 (0.1)	0 (0)	-	1.000
Respiratory complications	0 (0)	0 (0)	-	-
Anaphylactic reaction	2 (0.1)	0 (0)	-	1.000
Wrong level surgery	1 (0.1)	0 (0)	-	1.000
Patient-reported complications within 3 months -no. (%)	116 (8.3)	3 (8.1)	-	1.000
Wound infection	50 (3.6)	0 (0)	-	0.637
Urinary tract infection	58 (4.2)	3 (8.1)	-	0.206
Pneumonia	10 (0.7)	0 (0)	-	1.000
Pulmonary embolism	2 (0.1)	0 (0)	-	1.000
Deep venous thrombosis	1 (0.1)	0 (0)	-	1.000

CI: confidence interval

associated with lesser improvement in functional outcome and provide an equivalent improvement only in back pain and radiating leg pain (13). A recent study demonstrated that the common practice of epidural injections is of no benefit to patients with LSS (14). Another randomized trial demonstrated that in intention-to-treat analyses, a physiotherapy program can have the same effects as surgery (15). However, the interpretation of results is hampered by the fact that 57% of patients who were randomized to physiotherapy crossed over to surgery, leaving only 35 patients in the physiotherapy group of which only 15 patients achieved MCID. Some surgeons have shifted towards more complex fusion procedures for LSS believing this will improve stability and long-term outcomes. This trend is backed by scarce evidence, and complex procedures are generally more invasive and can involve greater risks of complication and longer hospital stays, which in turn lead to higher healthcare costs (16). In light of our favorable results, upfront decompression and fixation in patients may appear overly aggressive, particularly in patients with RA.

Study strengths and limitations
The major strengths are the study design that was based on a prospective registry data with high external validity and the large sample size. Still, the cohorts are not balanced for all baseline characteristics. The main limitation was the loss to follow-up (19.1%). Validation of RA diagnoses was not possible, and measures of disease activity and medication history were unavailable.

In conclusion, patients with RA experienced similar and large improvements in patient-reported outcomes following surgical decompression for LSS compared with patients without rheumatic disease. There was no increased risk of complications in patients with RA.

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Table 4. Multiple regression analysis with difference in ODI one year after surgery as the dependent variable.

Variable	Parameter estimate	95% CI	p
Intercept	- 0.4	- 9.5, 8.8	0.937
RA	2.4	- 3.9, 8.7	0.456
Microdecompression	2.0	- 0.04, 4.1	0.054
Age	- 0.1	- 0.2, 0.1	0.268
Baseline ODI score	0.5	0.5, 0.6	<0.001
Smoker	- 3.9	- 6.4, - 1.4	0.002
BMI≥30	- 4.6	- 7.0, - 2.2	<0.001
ASA grade>2	- 2.9	- 5.5, - 0.5	0.021
Previous surgery in operated level(s)	- 7.7	- 11.2, - 4.3	<0.001
Spondylolisthesis and/or scoliosis	1.0	- 2.3, 4.2	0.562
Attended college	4.2	2.0, 6.8	0.001
Life partner	1.6	- 0.7, 3.9	0.167

RA: rheumatoid arthritis; ODI: Oswestry Disability Index; BMI: body mass index; ASA: American Society of Anesthesiologists; CI: confidence interval

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