Brain and Spine 4 (2024) 102802

Contents lists available at ScienceDirect

Brain and Spine

journal homepage: www.journals.elsevier.com/brain-and-spine

A propensity-matched study of patients with symptomatic lumbar spinal stenosis opting for surgery versus not

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ARTICLE INFO

Handling Editor: Prof F Kandziora

Keywords:
Lumbar spinal stenosis
Propensity-matching
Non-surgical treatment
Surgical treatment
Outcome measures

ABSTRACT

Introduction: Although most surgeons treating patients with lumbar spinal stenosis (LSS) believe that surgical treatment is superior to conservative measures, systematics reviews have concluded that no solid evidence support this.
Research question: To compare change at 1-year of walking ability, health-related quality of life, leg and back pain in patients with symptomatic LSS referred to a spine surgery clinic who opted for surgery and those who did not.
Material and methods: The study included 149 operated and 149 non-operated patients seen by spine surgeons and diagnosed with LSS. The non-operated patients were propensity-matched to a cohort retrieved from the Danish national spine registry. Matching was done on demographics and baseline outcome measures. The outcomes was walking improvement measured by item 4 of the Oswestry Disability Index, EQ-5D-3L, global assessment (GA) of back/leg pain, back and leg pain on the Visual Analogue Scale and the Short Form 36 transition item 2.
Results: Less than half of the non-operated reached MCID on EQ-5D-3L, VAS pain legs or VAS pain back where 2/3 of the operated did. The largest difference was VAS back pain where 27.5% of the non-operated reached an MCID of 12 points compared to 71.8% in the operated group.
Discussion and conclusion: Surgical treated patients improved better than non-operated on all outcome measures. However, further research is required to compare the effectiveness of surgical decompression with non-operative care for LSS patients.

1. Introduction

Lumbar spinal stenosis (LSS) is a common disease with a large impact on the quality of life of the patient (Otani et al., 2013). According to evidence-based guidelines from the North American Spine Society (NASS), degenerative LSS describes a condition in which there is diminished space available for the neural and vascular elements in the lumbar spine secondary to degenerative changes in the spinal canal (Kreiner et al., 2013). Patients present with radiating pain in the lower extremities from the buttocks to the knee or calf with or without low back pain. Pain intensifies with upright standing and walking, limiting routine daily activities and is relieved with spine flexion or sitting down.

Surgical decompression for LSS is the most common form of degenerative lumbar spinal surgery performed in Denmark accounting for 38% of all procedures (Andersen et al., 2021). The Danish national clinical guidelines for treatment of patients with LSS recommends surgical decompression in case of serious symptoms lasting longer than 3–6 months (Rousing et al., 2019). This recommendation is based on three Randomized Clinical Trials (RCTs) (Zaina et al., 2016a) comparing surgical decompression to non-surgical care. However, the Danish Health Authorities deemed that these RCTs do not provide strong evidence of recommending surgical over non-surgical treatment due to methodological limitations and high crossover rates predominantly from the non-surgical to surgical arm.

Taking into account the problems of RCTs have with retaining patients in the assigned groups (Delitto et al., 2015) (Rodrigues and

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https://doi.org/10.1016/j.bas.2024.102802
Received 8 January 2024; Received in revised form 8 March 2024; Accepted 4 April 2024
Available online 5 April 2024

Natour, 2021) (Weinstein et al., 2008) (Weinstein et al., 2010), we decided to utilize existing databases that included LSS patients who opted for surgical and nonsurgical treatment to shed light on the outcome of spinal decompression by propensity matching the cohorts. The objective of this retrospective propensity-matched case-control study of prospectively collected data was to compare change at 1-year of health-related quality of life, leg and back pain in patients with symptomatic lumbar spinal stenosis referred to a spine surgery clinic who opted for surgery and those who did not.

2. Methods

2.1. Patient sample

Patients referred to the Spine Centre of Southern Denmark and Elective Surgery Centre, Silkeborg from January 2019 to September 2021 with LSS who opted not to have surgery were identified. This cohort consisted of 387 patients diagnosed with central canal LSS with or without lateral or foraminal stenosis confirmed by MRI who consented to answer questionnaires on basic demographics and complete Patient Reported Outcome Measures (PROMs) during their initial consultation with a spine surgeon. For all patients referred with LSS symptoms a recent MRI was mandatory before the consultation in the outpatient clinic. The MRI was screened by a senior spine surgeon and only if the MRI was consistent with LSS did the patient receive an appointment in the outpatient clinic. The patients subsequently received follow-up questionnaires one year later. Of these 387 cases, 149 patients with complete baseline and follow-up data were identified (Fig. 1a). The absence of crossovers was confirmed by patients' statements, medical chart review and data queries from the National Danish Spine Registry (DaneSpine).

A total of 1.281 patients with complete baseline and follow-up data operated at Spine Centre of Southern Denmark or Elective Surgery Centre, Silkeborg from 2009 to 2020 with MRI confirmed LSS who opted for surgery were identified (Fig. 1b). Only patients with operative levels <3 and treated with decompression were included.

2.2. Outcome measures

The primary outcome was walking improvement reported by the patient in item 4 of the Oswestry Disability Index (ODI) (Fairbank and Pynsent, 2000). The score ranges from 0 (Pain does not prevent me walking any distance) to 5 (I am in bed most of the time). Improvement was defined as a decrease in the response scale from baseline to 1-year follow-up.

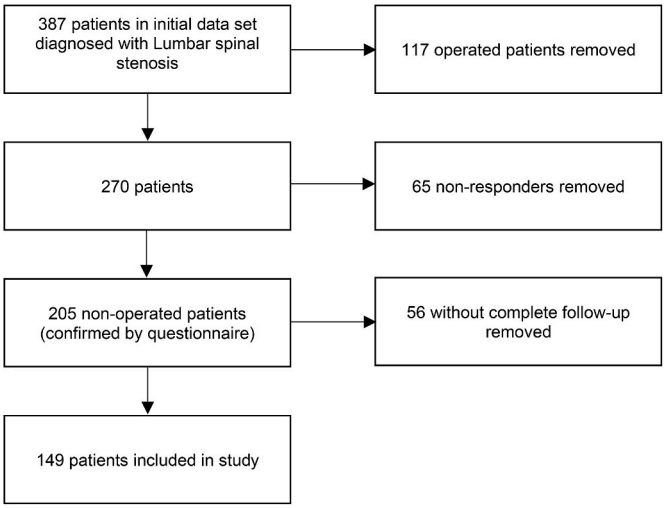

Fig. 1a. Identification of non-operated LSS patients (demander cohort).

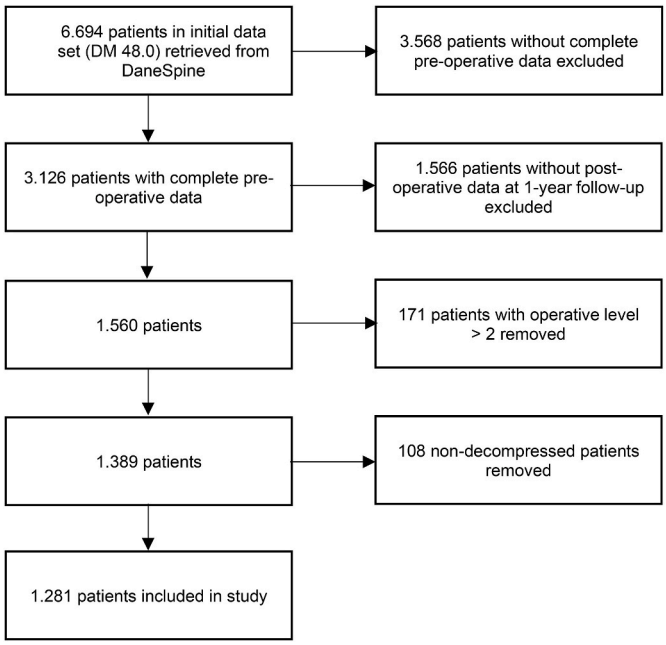

Fig. 1b. Identification of operated LSS patients (provider cohort).

Secondary outcomes were health-related quality of life measured by EQ-5D-3L (EuroQol Group, 1990) and the global assessment (GA) transition question: "How is your back/leg pain today as compared to one year ago?" GA is a Likert scale where 0 corresponds to no back/leg pain at baseline, and 1 = completely pain free, 2 = much better, 3 = somewhat better, 4 = unchanged, 5 = worse (Parai et al., 2018). In addition we included back and leg pain measured on the Visual Analogue Scale (VAS: 0–100) (Price et al., 1983) and the Short Form (36) (SF-36) (Ware and Sherbourne, 1992) Health Transition Item 2: "Compared to one year ago, how would you rate your health in general now?" Alternative answers are "much better", "somewhat better", "about the same", "somewhat worse" or "worse". Success was defined as patients who answered "much better" or "somewhat better".

Continuous outcome measures are presented as mean ± standard deviation and as proportions reaching a minimal clinically important difference (MCID). MCIDs were arrived at by applying the anchor-based Receiver Operator Characteristic curve (ROC) method on the provider cohort (n = 1.668). Cut-points were chosen by inspection of sensitivity and specificity using different estimators as guidelines weighting possible tradeoffs (Youden's J, EMGO, Sum of Squares, Farrar) (Froud and Abel, 2014). For EQ5D-3L an MCID of 0.105 was chosen using the SF-36 Health Transition Item as anchor (sensitivity: 76.1; specificity: 63.8). For VAS-leg an MCID of 16 points was found using the GA question on leg pain as anchor (sensitivity: 78.9; sensitivity: 80.5). An MCID of 12 points was chosen for VAS-back with the GA question of back pain as anchor (sensitivity: 73.4; specificity: 72.9). MCIDs for VAS leg and back pain were similar to the values reported by Copay et al. (2008). Data on curve coordinates and estimators are available here: https://github.com/ude9et/Spinal-Stenosis-supl. Improvement in walking distance, back and leg pain are given as frequencies (n) and proportions (%).

2.3. Data handling and statistical analysis

Data handling was performed in KNIME Analytics Platform version 4.4.2 (Berthold et al., 2007). All data analysis was done in IBM SPSS Statistics version 28.0 (IBM corp, 2021). Propensity matching was achieved by utilizing the SPSS Python extension FUZZY version 2.0.1 (FUZZY. JKP, 2014). The extension runs a logistic regression with the

case/control group indicator as the dependent variable and the selected confounding variables as predictors. The resulting probabilities of estimated case group membership are then used to match each case from the control group. If an exact match cannot be made, a fuzzy distance algorithm (nearest neighbor) calculates the closest match based on a user defined tolerance level set between 0 (only exact matches) and 1 (any control is a match). A control is deemed eligible to a **match** if the difference in the propensity scores is less than or equal to the tolerance level in absolute value. Comparable baselines with minimal differences were established by propensity matching the cohorts case-wise on the following baseline factors as predictors: age, sex, smoking status, BMI, walking distance, duration of pain in legs/back, VAS pain legs/back, EQ5D-3L and functional impairment (walking, ODI section 4). 2 exact matches and 147 fuzzy matches was identified with a tolerance level of 0.1. Sampling was performed without replacement and with randomized case orders.

Independent t-tests were used to compare mean differences between cohorts. On ordinal scales and when a parametric distribution of continuous data could not be assumed, Wilcoxon Two Sample Rank Sum tests were applied. Chi-square tests were used to compare nominal data. Level of threshold for statistical significance was set at $p < 0.0045$ following a Bonferroni correction for multiple comparisons with a desired alpha of 0.05 and 11 tested hypotheses.

3. Results

The propensity-matched operated and non-operated groups were similar in terms of demographics and baseline PROs (Table 1). A comparison of discarded unmatched operated and the non-operated is given in Table 2. There were improvements in all outcomes among both matched operated and non-operated groups (Table 3). Between groups however, there were highly significant differences. Measured as proportions less than half of the non-operated reached MCID on EQ-5D-3L, VAS pain legs or VAS pain back where 2/3 of the operated did. The largest difference in proportions was found to be VAS back pain where only 27.5% of the non-operated reached an MCID of 12 points. Similarly, 34–45% of the non-operated reported improvements on the transitional measures on leg pain, back pain and overall health as opposed to 66–76% in the operated group. Both measures on walking improvement revealed a mean of about 0.5 in scale difference in favor of the operated.

4. Discussion

LSS has a major impact on mobility, functioning and quality of life and is the main indication for lumbar surgery among the elderly in Scandinavia (Andersen et al., 2022) (Fritzell et al., 2020) (Solberg et al., 2019). Despite a prevalence of clinical symptomatic LSS in the general population of 11% a preferred treatment, surgical vs nonsurgical is still unclear and the natural disease course is largely unknown (Jensen et al., 2020).

In the present study on two propensity matched prospective cohorts comparing spinal decompression to non-surgical treatment in patients with clinical and MRI-verified LSS it was evident that the surgically treated patients improved compared to the non-surgically treated patients regarding pain, quality of life and walking distance. The magnitude of these differences was highly significant satisfying even the conservative significance level requirement of the Bonferroni correction. In addition, the non-surgically treated patients did not reach MCID for most of the PROMs.

This is in contrast to the conclusion of a Cochrane review published in 2016 (Zaina et al., 2016b) reporting no clear benefits with surgery versus non-surgical treatment based on 5 RCT's. The authors of the Cochrane review reached their conclusion to down grade the evidence because of selection bias, lack of blinding due to the nature of the interventions, incomplete outcome data due to crossovers or participant death at 10 years follow-up and no compliance monitoring in the nonsurgical group.

Several of these sources of bias are counteracted due to the design in the present study, such as selection bias and bias due to incomplete outcome data or crossovers. However, although case-control matching can improve confounding control a problem may arise if either of the groups are no longer representative of the population at large. Also, if

Table 1
Baseline Characteristics for patients diagnosed with Spinal stenosis as Mean (SD) or Proportions (matched cohorts).

Characteristic	Non-operated	Operated	Diff.	p-value
Number of patients, (n)	149	149	–	–
Age, years, mean (SD)	70.6 (9.5)	66.8 (10.4)	3.8	0.286 [a]
Gender, females, n (%)	72 (48.3)	71 (47.7)	1 (0.6)	0.908 [b]
Smoker, n (%)	18 (12.1)	21 (14.1)	3 (2.0)	0.606 [b]
BMI, mean (SD)	27.8 (4.2)	27.7 (4.3)	0.1	0.894 [a]
Number of Levels decompressed, n (%)				
One	0 (0.0)	90 (60.4)		
Two	0 (0.0)	59 (39.6)		
Quality of life (EQ-5D-3L), mean (SD)	0.485 (0.293)	0.469 (0.285)	0.016	0.859 [c]
Walking distance, 0–100 m, n (%)	36 (24.2)	36 (24.2)	0 (0.0)	0.115 [c]
Walking distance, 100–500 m, n (%)	42 (28.2)	59 (39.6)	17 (11.4)	
Walking distance, 0.5–1 km, n (%)	28 (18.8)	26 (17.4)	2 (1.4)	
Walking distance, >1 km, n (%)	43 (28.9)	28 (18.8)	15 (10.1)	
Duration of pain in legs, No pain, n (%)	10 (6.7)	2 (1.3)	8 (5.4)	0.377 [c]
Duration of pain in legs, <3 months, n (%)	8 (5.4)	6 (4.0)	2 (1.4)	
Duration of pain in legs, 3–12 months, n (%)	41 (27.5)	55 (36.9)	9.4 (3.3)	
Duration of pain in legs, 1–2 years, n (%)	25 (16.8)	39 (26.2)	14 (9.4)	
Duration of pain in legs, >2 years, n (%)	65 (43.6)	47 (31.5)	18 (12.1)	
Duration of pain in back, No pain, n (%)	21 (14.1)	13 (8.7)	8 (5.4)	0.296 [c]
Duration of pain in back, <3 months, n (%)	8 (5.4)	4 (2.7)	4 (2.7)	
Duration of pain in back, 3–12 months, n (%)	21 (14.1)	37 (24.8)	16 (10.7)	
Duration of pain in back, 1–2 years, n (%)	13 (8.7)	28 (18.8)	15 (10.1)	
Duration of pain in back, >2 years, n (%)	86 (57.7)	67 (45.0)	19 (12.7)	
Preoperative VAS pain (legs), mean (SD)	55.8 (25.9)	60.6 (23.7)	4.8	0.073 [c]
Preoperative VAS pain (back), mean (SD)	44.0 (29.6)	50.1 (25.4)	6.1	0.061 [c]
Functional impairment, Walking (ODI section 4)				
Pain does not prevent me walking any distance, n (%)	45 (30.2)	29 (19.5)	16 (10.7)	0.057 [c]
Pain prevents me from walking more than 1 km, *n (%)*	39 (26.2)	40 (26.8)	1 (0.6)	
Pain prevents me from walking more than 500 m, n (%)	32 (21.5)	41 (27.5)	9 (6.0)	
Pain prevents me from walking more than 100 m, n (%)	28 (18.8)	31 (20.8)	3 (2.0)	
I can only walk using a stick or crutches, n (%)	5 (3.4)	7 (4.7)	2 (1.3)	
I am in bed most of the time, n (%)	0 (0.0)	1 (0.7)	1 (0.7)	

Abbreviations: SD, standard deviation; ODI, Oswestry Disability Index; VAS, visual analogue pain scale.
[a] Independent *t*-test.
[b] Pearson's chi-squared test.
[c] Wilcoxon Two Sample Rank Sum test.

Table 2
Baseline Characteristics for non-matched operated patients diagnosed with Spinal stenosis as Mean (SD) or Proportions compared to the non-operated cohort.

Characteristic	Operated (non-matched)	Non-operated	Diff.	p-value
Number of patients, (n)	1.261	149	–	–
Age, years, mean (SD)	65.2 (10.8)	70.6 (9.5)	5.4	<0.000 [a]
Gender, females, n (%)	626 (49.6)	72 (48.3)	1.3	0.795 [b]
Smoker, n (%)	266 (21.1)	18 (12.1)	9.0	0.009 [b]
BMI, mean (SD)	27.5 (4.3)	27.8 (4.2)	0.3	0.374 [a]
Quality of life (EQ-5D-3L), mean (SD)	0.428 (0.309)	0.485 (0.293)	0.057	0.084 [c]
Preoperative VAS pain (legs), mean (SD)	64.5 (22.7)	55.8 (25.9)	8.7	<0.000 [c]
Preoperative VAS pain (back), mean (SD)	52.2 (27.4)	44.0 (29.6)	8.2	0.020 [c]
Walking distance, 0–100 m, n (%)	354 (28.1)	36 (24.2)	3,9	0.034 [c]
Walking distance, 100–500 m, n (%)	441 (35.0)	42 (28.2)	6.8	
Walking distance, 0.5–1 km, n (%)	223 (17.7)	28 (18.8)	1.1	
Walking distance, >1 km, n (%)	243 (19.3)	43 (28.9)	9.6	
Duration of pain in legs, No pain, n (%)	22 (1.7)	10 (6.7)	5.0	<0.000 [c]
Duration of pain in legs, <3 months, n (%)	81 (6.4)	8 (5.4)	1.0	
Duration of pain in legs, 3–12 months, n (%)	488 (38.7)	41 (27.5)	11.2	
Duration of pain in legs, 1–2 years, n (%)	305 (24.2)	25 (16.8)	7.4	
Duration of pain in legs, >2 years, n (%)	365 (28.9)	65 (43.6)	14.7	
Duration of pain in back, No pain, n (%)	92 (7.3)	21 (14.1)	6.8	<0.000 [c]
Duration of pain in back, <3 months, n (%)	45 (3.6)	8 (5.4)	1.8	
Duration of pain in back, 3–12 months, n (%)	307 (24.3)	21 (14.1)	10.2	
Duration of pain in back, 1–2 years, n (%)	228 (18.1)	13 (8.7)	9.4	
Duration of pain in back, >2 years, n (%)	589 (46.7)	86 (57.7)	11.0	
Functional impairment, Walking (ODI section 4)				
Pain does not prevent me walking any distance, n (%)	213 (16.9)	45 (30.2)	13.3	0.002 [c]
Pain prevents me from walking more than 1 km*, n (%)*	344 (27.3)	39 (26.2)	1.1	
Pain prevents me from walking more than 500 m, n (%)	355 (28.2)	32 (21.5)	6.7	
Pain prevents me from walking more than 100 m, n (%)	256 (20.3)	28 (18.8)	1.5	
I can only walk using a stick or crutches, n (%)	87 (6.9)	5 (3.4)	3.5	
I am in bed most of the time, n (%)	6 (0.5)	0 (0.0)	0.5	

Abbreviations: SD, standard deviation; ODI, Oswestry Disability Index; VAS, visual analogue pain scale.
[a] Independent *t*-test.
[b] Pearson's chi-squared test.
[c] Wilcoxon Two Sample Rank Sum test.

Table 3
Follow-up (1-year) Characteristics for patients diagnosed with Spinal stenosis as Mean (SD) or Proportions (matched cohorts).

Characteristic	Non-operated	Operated	Diff.	p-value
Number of patients, (n)	149	149	–	–
Δ Quality of life (EQ-5D-3L), mean (SD)	0.092 (0.364)	0.267 (0.319)	0.175	<0.000 [c]
Δ VAS pain (legs), mean (SD)	−14.6 (32.6)	−32.3 (35.5)	17.7	<0.000 [c]
Δ VAS pain (back), mean (SD)	−0.01 (28.6)	−28.8 (27.7)	28.8	<0.000 [c]
Quality of life (EQ-5D-3L) MCID, n (%)	61 (40.9)	94 (63.1)	33 (22.2)	<0.000 [c]
VAS pain (legs) MCID, n (%)	71 (47.7)	103 (69.1)	32 (21.4)	<0.000 [c]
VAS pain (back), MCID n (%)	41 (27.5)	107 (71.8)	66 (44.3)	<0.000 [c]
Improvement, Leg pain, n (%)	65 (43.6)	115 (80.4)	50 (36.8)	<0.000 [b]
Improvement, Back pain, n (%)	67 (45.0)	117 (86.0)	50 (41.0)	<0.000 [b]
Δ Walking distance improvement, mean (SD)	0.24 (1.14)	0.85 (1.17)	0.61	<0.000 [c]
Δ Improvement, Walking (ODI section 4), mean (SD)	−0.20 (1.3)	−0.85 (1.28)	0.65	<0.000 [c]
Proportion with self-reported health improvement, n (%)	51 (34.2)	110 (73.8)	59 (39.6)	<0.000 [b]

Abbreviations: SD, standard deviation; ODI, Oswestry Disability Index; VAS, visual analogue pain scale; MCID, Minimal clinically important difference.
a Independent *t*-test.
[b] Pearson's chi-squared test.
[c] Wilcoxon Two Sample Rank Sum test.

some of the matching variables are somehow associated with, or have affinity with the condition in question, the matched cohorts will be more similar than the actual distribution in the population. As such, selection bias cannot be completely eliminated by propensity matching (McKnight, 2018). As in the referenced RCT's blinding to the treatment is difficult when surgical and non-surgical treatments are compared due to the nature of the intervention.

In the present study, we were not able to monitor if the patients have received any type of non-surgical treatment and whether they were fully compliant, but we believe it mirrors other non-operative treatment regimens or even reflects the natural course of the disease. With approximately one third of the patients in our non-operated group improving clinical relevant regarding pain, quality of life, walking distance and self-reported health our findings are in line with the World Federation of Neurosurgical Societies (WFNS) Spine Committee stating, "Approximately 30% of patients with LSS are expected to worsen, but 30% may improve with conservative measures" (Zileli et al., 2020).

The task of counseling affected patients with clinical and MRI verified LSS is further complicated by the lack of moderate or high-quality evidence to recommend non-operative treatment (e.g. physiotherapy) as these treatments have failed to demonstrate an improvement in walking distance (Ammendolia et al., 2013).

This study is the largest published cohort of patients comparing non-operative treatment to spinal decompression. The quasi-experimental design circumvents the practical and ethical difficulties that may arise in an RCT, while retaining internal validity by equating known baseline variables. The clinical implications are evident and important for future treatment decisions concerning patients diagnosed with LSS.

4.1. Strength and limitations

Not being a RCT is the major weakness of this study. As RCTs, especially double blinded, are difficult to conduct in a surgical setting, we opted for a pseudo-randomized design. While a feasible alternative, this design is prone to confounding and selection bias (Reiffel, 2020). Consequently, establishing causal inference and generalizability is more challenging compared to RCTs.

It is a potential problem that we have no information on the MRI findings and how they might differ between the groups in question, specifically the extent of central canal stenosis (Schizas et al., 2010) and presence or absence of lateral or foraminal stenosis (Lee et al., 2010). However, the initial screening of the MRI by a senior surgeon ensures that the MRI's were showing pathological changes compatible with a radiographic diagnosis of LSS. The referrals were returned if the MRI was normal. Furthermore, we do not know whether either of the two

matched cohorts received any conservative treatment during the study period. The different types of decompression performed was not included in the analyses as several studies have shown that the type of decompression performed does not significantly impact clinical outcomes (Bouknaitir et al., 2021) (Hermansen et al., 2017) (Hong et al., 2011).

It is a strength of the study that the matched cohorts were diagnosed with LSS by surgeons and that they were very similar in terms of baseline characteristics. Furthermore, there were no crossovers in the studied sample. However, the absence of cross overs in the non-operated cohort could also suggests that this is not a generalizable group.

5. Conclusion

Compared to the non-operated, surgical treated patients diagnosed with LSS improved significantly better on all measured parameters including pain, health related quality of life, walking distance and overall perceived health improvement. The differences were not only significant in terms of minimal clinically importance measured as mean, but also as proportions of successful outcomes. This case-control matched study suggests that offering most patients spinal decompression might be the best option in the treatment of patients suffering LSS supporting the findings of previously published RCTs.

Funding

This research received no grant from any funding agency in the public, commercial, or not-for-profit sectors.

Funding disclosures

There are no financial conflicts of interest to disclose.

Data availability statement

The data used during the current study are available from the corresponding author upon reasonable request.

Declaration of competing interest

The authors declare no competing interests.

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