Patient are satisfied one year after decompression surgery for lumbar spinal stenosis

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ABSTRACT

INTRODUCTION: Lumbar spinal stenosis (LSS) is a clinical syndrome of buttock or lower extremity pain, which may occur with or without back pain. The syndrome is associated with diminished space available for the neural and vascular elements in the lumbar spine. LSS is typically seen in elderly patients, its prevalence is estimated to be 47% in people over the age 60 years. LSS is the most common reason for spine surgery in Denmark and the number of surgical procedures is likely to increase due to demographic changes. The purpose of this study was to evaluate the patient-reported outcomes and perioperative complications of spinal decompression surgery in LSS patients.

METHODS: This study is a retrospective study based on prospectively collected data from 3,420 consecutive patients with clinical and magnetic resonance imaging confirmed LSS. Patients were treated with posterior decompression surgery without fusion. Data were obtained from the DaneSpine register and collected pre- and post-operatively after a minimum interval of one year. The outcome measures were Oswestry Disability Index (ODI), European Quality of Life 5D (EQ-5D), visual analogue score (VAS), 36-Short Form Mental Component Summary (MCS), 36-Short Form Physical Component Summary (PCS) and self-reported walking distance.

RESULTS: Of 3,420 cases enrolled, 2,591 (75%) had complete data after a minimum interval of one year. The mean ODI scores were 39.8 and improved to 24. The mean EQ-5D score was 0.40 and improved to 0.66. The mean VAS-leg improved from 54 to 36. The mean VAS-back improved from 46 to 34. The mean MCS improved from 28 to 36, and, finally, the mean PCS improved from 40 to 45. All p-values were 0.0000.

CONCLUSION: Surgery improved all the patient-reported outcome measures and 82% of patients were satisfied.

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Lumbar spinal stenosis (LSS) is currently recognised as a clinical syndrome of buttock or lower extremity pain, which may occur with or without back pain. The syndrome is associated with diminished space available for the neural and vascular elements in the lumbar spine [1]. Symptoms often worsen during walking or prolonged standing [2]. LSS is typically seen in elderly patients. The exact prevalence remains unknown, but is estimated to be 9% in the general population and up to 47% in people over the age of 60 years [3]. According to the Danish National Spine Database (DaneSpine), 5,807 lumbar spine surgeries were performed in 2015 of which 42.2% were for LSS [4]. Even though DaneSpine does not reflect all spinal surgeries in Denmark, the distribution makes LSS reliable as the most common indication for spine surgery in Denmark. The number of surgical procedures is thought to be increasing due to a considerable growth of the elderly population.

According to the Danish national guidelines, patients have to complete non-surgical treatment regimens such as physiotherapy, medication or lifestyle modifications prior to surgery. Unfortunately, the evidence supporting the effectiveness of non-surgical treatments for LSS is inadequate. A Cochrane review published in 2013 [5] about non-surgical treatments in patients with neurogenic claudication and LSS concluded that there was insufficient evidence to recommend any specific type of conservative treatment.

The gold standard surgical treatment for LSS is decompression of the involved neural structures. Decompression can be performed using different surgical techniques including various types of laminotomies and laminectomies. However, no clear evidence supports the superiority of either technique [6]. Ideally, the facets should be preserved, but they may ultimately be resected to achieve an adequate decompression [7-9]. Fusion surgery can be added if segmental instability is discovered.

Two recent systematic reviews evaluated surgical versus non-surgical treatments for LSS [10, 11]. However, clear evidence of either treatment option is lacking and high-quality randomised clinical trials are needed. No conclusion could be made as to whether surgical or nonsurgical treatment is preferable for individuals with LSS. However, current systematic reviews have difficulties comparing the available RCTs due to insufficient description of the non-surgical treatment, large crossover rates and heterogeneity of reported outcomes. Despite the insufficient evidence from the systematic reviews, additional studies showed both short and long-term benefits from surgical treatment [12-14].

ORIGINAL ARTICLE

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TABLE 1

Baseline data comparing respondents and non-respondents.

	Respondents	Non-respondents	p-value
Male, n (%)	1,202 (48.9)	406 (42.2)	0.018
Age, yrs, mean (SD)	66.20 (10.97)	64.68 (12.47)	0.00
EQ-5D, mean (SD)	0.40 (0.31)	0.38 (0.31)	0.05
ODI, mean (SD)	39.80 (15.13)	42.10 (15.52)	0.00
VAS, mean (SD)			
Back	45.96 (31.11)	38.44 (33.31)	0.00
Leg	54.91 (31.10)	45.37 (34.81)	0.00
SF-36, mean (SD)			
PCS	41.08 (12.46)	37.80 (12.46)	0.00
MCS	29.01 (7.36)	27.90 (7.34)	0.00

EQ-5D = European Quality of Life 5D; ODI = Oswestry Disability Index; SD = standard deviation; SF-36 = Short Form-36; MCS = Mental Component Summary; PCS = Physical Component Summary; VAS = visual analogue score.

In line herewith, our clinics have experienced good results from decompression surgery in LSS patients. This study presents outcome data from 2,591 consecutive LSS patients treated with posterior decompression surgery with a minimum one-year follow-up period.

METHODS

This is a retrospective study of prospectively collected data from 3,420 consecutive patients with clinical symptoms of LSS confirmed by magnetic resonance imaging. Patients were treated with posterior decompression surgery between 2009 and 2014 at three regional centres in Denmark (Middelfart, Silkeborg, and Køge). All techniques of posterior lumbar decompression were included, both with and without the use of a microscope. Patients treated with concomitant fusion were excluded.

Patient-reported outcome measures (PROMs) obtained from the national spine database, DaneSpine, were used to evaluate the effect of the surgical intervention. Relevant approvals for the use of DaneSpine data were obtained from the Danish Data Protection Agency. PROMs included pre- and post-operative Oswestry Disability Index (ODI), EuroQoL (EQ-5D), visual analogue score (VAS) for back and leg pain, Short Form-36 (SF-36) and self-reported walking distance. Two domains of the SF-36 questionnaire were used for evaluation of mental health; the mental component summary (MCS) and for evaluation of physical health, the physical component summary (PCS).

ODI is commonly used to evaluate low-back disability. The questionnaire scores range from 0 (no disability) to 100 (total disability). It is estimated that the minimum clinically important difference (MCID) for this measure is 12-15 points [15-18]. EQ-5D measures health-related quality of life on a scale where 0.0 equals death and 1.0 equals perfect health. MCID for this questionnaire is considered approximately 0.17 [19]. VAS was obtained for both back and leg pain on a 0 (no pain) to 100 (severe pain) point scale. MCID is considered to be approximately 16 points for VAS-leg and 12 points for VAS-back. MCID for PCS is considered to be approximately four points [18].

Patient satisfaction was registered at the one-year follow-up and was divided in two groups according to satisfaction: satisfied/acceptable or dissatisfied.

Data from VAS, SF-36, ODI and EuroQoL are presented as means with standard deviations. Pre-operative and one-year post-operative scores were compared using paired t-tests. Self-reported walking distance was divided into four categories: 0-100 m, 100-500 m, 500-1,000 m and above 1,000 m. Fisher's exact test was used to compare the proportion of patients in each category from pre-operatively and one year post-operatively. All statistical analyses were performed using STATA with the p-value threshold set at 0.01.

Trial registration: Danish Data Protection Agency.

RESULTS

Among the 3,420 cases enrolled, a total of 2,591 (75%) had complete data after a minimum interval of one year. Non-responders were typically 1.5 years younger than responders, but had a similar gender distribution. Non-responders had statistically significantly better baseline PROM scores than the responders (**Table 1**), but these differences were not clinically relevant. Mean ODI scores were 39.85 preoperatively, which improved to 24.09 one year post-operatively. The mean EQ-5D score was 0.40 preoperatively, which improved to 0.66 one year post-operatively. The VAS-leg improved from 54 preoperatively to 36 one year post-operatively. The VAS-back improved from 46 preoperatively to 34 after one-year follow-up. The mean MCS improved from 28 preoperatively to 36 after one-year follow-up. The mean PCS improved from 40 preoperatively to 45 after one year of follow-up. All comparisons were statistically significant with p-values of 0.0000 (**Table 2**).

The percentage of patients with a walking capacity below 100 m decreased from 38% preoperatively to 15.6% after one year. The percentage of patients with a walking distance in the 100-500 m range decreased from 34.9% preoperatively to 22.3% after one year. The percentage of patients with a walking capacity in the 500-1,000 m range increased from 14.9 preoperatively to 18.8% after one year. The percentage of patients with a walking distance exceeding 1,000 m increased from 12% preoperatively to 43.4% after one year (**Table 3**).

In total, 82% were satisfied with surgery at the one-year follow-up.

A total of 250 patients sustained complications during surgery (**Table 4**). The complication rate was 7.3% and was distributed among various causes. The most common complication was dural tears with 182 incidents.

DISCUSSION

Data from our study showed that all outcome parameters were significantly improved after surgery. However, not all data were available for one-year follow-up (75%) and this is a weakness of this study and could potentially indicate information bias. All outcome parameters except for VAS-back showed improvements of clinical relevance one year after surgery. The improvements in VAS-back did not reach MCID. This finding may be explained by the fact that the primary indication for decompression is leg symptoms and not back pain alone. Back pain can originate from multiple structures in the back and might not be relieved by decompression surgery.

Our analysis of baseline data between the responders and non-responders showed that the non-responders were generally 1.2 years younger and had better baseline data than the responders. However, the differences were small and not clinically relevant.

Walking distance was improved as more patients were able to walk more than 500 m after surgery and fewer patients had a walking capacity below 500 m. However, walking distance was a self-reported outcome measure which may give rise to information bias.

As this study only has one-year follow-up, the improvements will not necessarily be sustained for longer follow-up periods. A recent study [20] concluded that patients with symptomatic LSS show diminishing benefits of surgery between four and eight years post-operatively. Given the fact that LSS is a degenerative disorder, degeneration may occur on same or adjacent levels with time. This could potentially explain some of the diminishing benefits of surgery at longer-term follow-up.

Our study found that 82% of the patients were satisfied after one year. Even though the majority of patients are satisfied after surgery, we still recorded that 18% were dissatisfied. Due to the relatively high percentage of dissatisfied patients, it would be interesting to investigate for possible prognostic factors of a poor

TABLE 2

Baseline and one-year post-operative patient-reported outcomes. The values are mean (standard deviation); p = 0.00.

	Baseline	Follow-up
EQ-5D	0.40 (0.31)	0.66 (0.29)
ODI	39.85 (15.14)	24.09 (17.93)
VAS		
Back	46.14 (31.04)	34.52 (30.19)
Leg	54.81 (31.19)	36.22 (31.73)
SF-36		
PCS	40.73 (12.21)	45.75 (12.28)
MCS	28.96 (7.38)	36.74 (11.37)

EQ-5D = European Quality of Life 5D; ODI = Oswestry Disability Index; SF-36 = Short Form-36; MCS = Mental Component Summary; PCS = Physical Component Summary; VAS = visual analogue score.

TABLE 3

Parts of patients within each walking distance category at baseline and one year post-operatively; p = 0.00.

Walking distance, m	Baseline, %	Follow-up, %
0-100	38	15.6
100-500	34.9	22.3
500-1,000	14.9	18.8
> 1,000	12	43.4

TABLE 4

Complications.

	n	Rate, %
Death	5	2.0
Pulmonary embolism	0	0.0
Thrombosis	1	0.4
Urinary infection	13	5.2
Urinary retention	10	4.0
Spinal haematoma	19	7.6
Wound infection	2	0.8
Nerve root lesion	4	1.6
Cauda equina	2	0.8
Dural lesion	182	72.8
Other	12	4.8
Total	250	7.3

outcome. The authors of this manuscript will investigate this matter based on similar data in the future.

Regarding surgical complications in our cohort, we found a total rate of 7.3%, which is consistent with reports from previous studies [21]. As expected, dural lesions account for up to 70% of the total complications registered, and the more serious complications such as death, cauda equina syndrome and nerve root damage were relatively rare. The complications were reported by the surgeon post-operatively and this could potentially lead to information bias. In addition, complications such as infections, haemorrhage and urinary retention may be underreported as these may present later in the hospitalisation. Other complications such as death, nerve injury and dural lesion will be detected during or shortly after surgery and these data are considered valid.

This article presents a cohort study, and therefore no control group is available, e.g. a cohort receiving sham surgery or nonsurgical treatment. Thus one could argue that we cannot distinguish a true clinical effect from a potential placebo effect.

Evidence regarding the different treatment options of LSS is generally poor. Recent reviews [2, 5, 10] conclude that no strong evidence of either treatment option exists and that treatments should be chosen on a shared decision approach between patient and physician. High-quality RCTs are needed to produce stronger evidence, but as some studies reported [21, 22] a large amount of up to 57% of patients cross-over to surgical intervention during these studies of conservative versus operative treatments. Such crossover rates complicate the comparison of outcomes. Further, most RCT studies are too heterogeneous in terms of reported outcomes and the description of the conservative treatment types. This makes pooled statistical analyses difficult in the systematic reviews [10].

CONCLUSION

Improvements of clinical relevance were seen in all evaluated PROMs except VAS-back. 82% of patients were satisfied at their one-year follow-up. Future RCT studies should compare a homogenous group of patients undergoing either surgical or well-defined conservative treatment to generate a stronger evidence base for the effect of surgical treatment.

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