The Spine Journal 19 (2019) 1633–1639

Clinical Study

Decompression alone vs. decompression plus fusion for claudication secondary to lumbar spinal stenosis

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Received 26 March 2019; revised 3 June 2019; accepted 4 June 2019

Abstract

BACKGROUND: Degenerative lumbar spinal stenosis is a common condition, predominantly affecting middle-aged and elderly people. This study focused on patients with neurogenic claudication secondary to lumbar stenosis without spondylolisthesis or deformity.

PURPOSE: To determine whether the addition of fusion to decompression resulted in improved clinical outcomes at 3, 12, and 24 months postsurgery.

STUDY DESIGN/SETTING: The Canadian Spine Outcomes and Research Network (CSORN) prospective database that includes pre- and postoperative data from tertiary care hospitals.

PATIENT SAMPLE: The CSORN database was queried for consecutive spine surgery cases of degenerative lumbar stenosis receiving surgical decompression for neurogenic claudication or radiculopathy. Neurogenic claudication patients with baseline and 2-year follow-up data, from four sites, formed the study sample (n=306). The sample was categorized into two groups: (1) those that had decompression alone, and (2) those that underwent decompression plus fusion.

OUTCOME MEASURES: Change in modified Oswestry Disability Index (ODI), numerical rating scale for back/leg pain, the EuroQol EQ5D, the SF-12 physical, and mental component scores. The primary outcome measure was the ODI at 2 years postoperative.

Author disclosures: ***KT:*** Nothing to disclose. ***PF:*** Nothing to disclose. ***GM:*** Nothing to disclose. ***SM:*** Nothing to disclose. ***EA:*** Consulting: Medtronic Canada (F); Grants: Medtronic Canada (F). ***CSB:*** Research Support (Investigator, Salary, Staff/materials) (E). ***JP:*** Grants: Medtronic Canada (E). ***DC:*** Nothing to disclose. ***WBJ:*** Consulting: Stryker (D); Speaking and/or Teaching Arrangements: Medtronic (B). ***YRR:*** Royalties: Medtronic (F); Consulting: Medtronic (B). ***NAM:*** Consulting: Medtronic Canada (E); Grants: Medtronic Canada (F). ***HH:*** Nothing to disclose. ***CGF:*** Royalties: Medtronic (F); Consulting: Medtronic, Nuvasive; Grants: OREF; Fellowship Support: Medtronic, AO Spine.

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https://doi.org/10.1016/j.spinee.2019.06.003

METHODS: We conducted a multicenter, ambispective review of consecutive spine surgery patients enrolled between October 2012 and January 2018.

RESULTS: Baseline characteristics were comparable between groups except for female sex and multilevel pathology (both with greater proportion in the decompression plus fusion group). The decompression plus fusion group had clinically meaningfully more operative time, blood loss, rate of perioperative complication, and length of hospital stay ($p<.05$). These differences were preserved following adjustment for baseline differences between the groups.

Both decompression and decompression plus fusion had a large clinically meaningful impact on generic and disease-specific patient-reported outcome measures within 3 months of surgery which was maintained out to 24-month follow-up. At any follow-up time point, there was no statistical evidence of a difference in these effects favoring decompression plus fusion over decompression alone.

CONCLUSIONS: The addition of fusion to decompression did not result in improved outcomes at 3-, 12-, or 24-month follow-up. The addition of fusion to decompression provides no advantage to decompression alone for the treatment of patients with neurogenic claudication secondary to lumbar stenosis without spondylolisthesis or deformity.

Keywords: Decompression; Degenerative stenosis; Fusion; Neurogenic claudication; Patient-reported outcome; Surgery; Treatment

Introduction

Degenerative lumbar spinal stenosis is a common condition, predominantly affecting middle-aged and elderly people [1]. Spinal stenosis is a pathoanatomical description commonly associated with the clinical symptom complex of neurogenic claudication. Intermittent neurogenic claudication is dominant reason that symptomatic patients seek a spine surgeon [2]. Neurogenic claudication causes symptoms ranging from pain and cramping to sensory deficit and motor weakness in the legs that limits walking ability and quality of life [2]. Misuse of diagnostic terminology and the failure to develop a precise definition makes it difficult to interpret and compare effectiveness studies [3]. As a result, the literature is fraught with conflicting research.

Deyo et al. [4] suggest that decompression surgery is more effective than nonoperative treatment for carefully selected patients with lumbar spinal stenosis. Bony decompression by laminectomy was first reported in 1893 [3,5]. Today, surgical options are largely divided into decompression only or decompression and fusion (with or without instrumentation) [6]. However, because of a lack of evidence, the most effective surgical option remains controversial [7–9].

In a review of recent literature (2006 to present), several authors have proposed that decompression alone is sufficient [2,7,9–16]. Conversely, some studies recommend adding fusion [17–20] to treat back pain; others advocate fusion only if the segment is unstable [8,21,22]. A lack of consensus suggests that the evidence is inconclusive and more research on this topic is required [2,12].

Our study focused on patients with neurogenic claudication secondary to lumbar stenosis without deformity or spondylolisthesis. The primary aim was to determine whether the addition of fusion to decompression resulted in improved patient reported outcomes at 3, 12, and 24 months postsurgery. Our hypothesis was that the patient-reported outcomes would not be different between those receiving decompression compared to those having decompression with fusion.

Methods

Study design

We conducted a multicenter, ambispective review of consecutive spine surgery patients enrolled in the Canadian Spine Outcomes and Research Network (CSORN) between October 2012 and January 2016. CSORN is a group of neurosurgical and orthopedic spine surgeons from academic and nonacademic hospitals across Canada that prospectively collects data on patients with spinal conditions. This database serves as a national registry created to answer research questions and to facilitate the implementation of best practices.

A national database research coordinator audits data quality and performance and sends reports to each contributing hospital site coordinator on a quarterly basis. Reports track data completion and follow-up rates to facilitate internal data validation at each site. A national privacy and security framework were created for CSORN that includes a governance structure, standard operating procedures, training processes, physical and technical security, and privacy impact assessments. This model ensures privacy and security of personal health information. Written informed consent is obtained from all participating patients. Patient identification is anonymized to ensure that patients in the registry cannot be individually identified. Data from the four sites with the highest volume of neurogenic claudication patients were used in this study. Each site obtained research ethics board approval from their local hospital prior to any data collection. Decisions regarding data

collection, storage, and analysis are independent of any company or commercial interest.

Patient sample

Local research coordinators enrolled patients at each site. All patients with spinal stenosis without a primary diagnosis of spondylolisthesis or deformity, with a significant complaint of neurogenic claudication and/or radiculopathy, and eligible for 2-year follow-up were included in this study. The definition of spine deformity was left to the discretion of the treating surgeon. Subjects less than 18 years of age and those who did not undergo surgery were excluded. The sample was categorized into two groups: (1) those that had decompression alone (D), and (2) those that underwent decompression plus fusion (D+F).

Patient variables

Baseline preoperative patient characteristics included sociodemographic factors such as age and sex in addition to clinical characteristics such as body mass index, presence of preoperative neurologic deficit, symptom duration/intensity, severity of baseline back pain, and smoking status.

Study measures

Surgeons recorded operative and postoperative data including type of procedure, American Society of Anesthesiologists (ASA) score, intraoperative blood loss, operating room (OR) time, and perioperative adverse events (utilizing the SAVES protocol). The research coordinator tabulated the length of hospital stay.

Research coordinators, unaware of the study hypothesis, collected patient-reported outcome measures (PROMs) in person, via post or from an online patient portal at preoperative baseline, as well as 3, 12, and 24 months postoperatively. PROMs included a modified Oswestry Disability Index (ODI) [23], numerical rating scale (NRS) for back/leg pain [24], the EuroQol EQ5D [25,26], the SF-12 physical (PCS), and mental component scores (MCS) [27]. The primary outcome measure was the ODI at 2 years postoperatively.

Study interventions

All patients underwent decompression alone or decompression plus instrumented fusion at one or more levels between levels L1 and S1. The surgery consisted of a minimally invasive (MIS) or open technique at the discretion of the treating surgeon.

Statistical analysis

Baseline patient characteristics, surgical characteristics, and PROMs were evaluated with descriptive statistics: *t* tests for continuous variables (means and standard deviations) and chi-square test or Fisher exact test for categorical variables (numbers and percentages). An a priori level of 5% was used to determine statistical significance. To judge for possible bias, we assessed baseline differences between those with and without follow-up data at 3, 12, and 24 months. Adjusted effects are from multivariable regression least squares fits adjusted for baseline values of age, sex, back pain, baseline PROM, and number of surgical levels.

Analyses were conducted using SPSS (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.)

Results

The study sample consisted of 306 patients from 4 participating CSORN hospital sites. Patients from a hospital site were included if a patient dataset included baseline and PROM data for greater than 10 consecutive patients with a 2-year follow-up rate of greater than 80%.

Table 1 reveals that the decompression plus fusion group had a greater proportion of females (53% vs. 33%), higher baseline NRS back pain (7.3 vs. 6.5), and a greater mean number of operative spinal levels. The decompression plus fusion group had significantly greater operative time, blood loss, and length of hospital stay ($p<.05$; Table 2 and Supplementary Fig. 1). Perioperative adverse events (intraoperative combined with in-hospital postoperative adverse events) were greater in the decompression plus fusion group (9.8% D vs. 33.0% D+F, $p<.001$).

Baseline differences between treatment groups were similar in those with observed vs missing 3-, 12-, and 24-month follow-up data (data not shown).

At 3-month follow-up (N=257, 84% follow-up), the decompression group had a statistically significantly greater beneficial change in SF 12 PCS (difference score 2.49, $p<.046$), which was not clinically significant (MCID for SF12 PCS=3.29). There were no observed differences at 3-month follow-up in ODI, EQ5D, NRS back pain, NRS leg pain, or SF 12 MCS.

At 12-month follow-up (n=251, 82% follow-up), there were no statistical differences between groups for change in ODI, NRS back pain, NRS leg pain, EQ-5D, or SF-12 PCS and MCS.

At 24-month follow-up (N=248, 81% follow-up), there were no differences for any PROs in the unadjusted analysis between treatment groups, except for EQ5D which was statistically different and favored decompression alone (Table 3), although this difference was not clinically significant (when considering MCID for EQ5D=0.2). NRS back pain change score was −3.0 in the decompression alone group and −2.9 in the decompression plus fusion group. NRS leg pain change score was −3.5 in the decompression alone group and −3.6 in the decompression plus fusion group.

Multivariate linear regression, adjusting for baseline differences, did not demonstrate any differences between treatment groups at any follow-up except for SF12 PCS at 3- and 24-month follow-up which favored decompression alone (Table 3). Supplementary Fig. 2 summarizes the

Table 1
Baseline characteristics of decompression alone and decompression plus fusion patients

Baseline measure		D	D+F	p Value
n		199	107	
Age mean (SD)		65.5 (11.6)	63.2 (9.9)	.072
Female sex		32.7%	53.3%	**<.001**
BMI		29.2 (5.6)	29.5 (5.6)	.675
Neurologic deficit		33.2%	34.6%	.902
Mean surgical levels		1.3 (0.6)	1.6 (0.9)	**.004**
Symptoms>2 years		54.3%	52.8%	.905
NRS back pain mean (SD)		6.5 (2.6)	7.3 (2.0)	**.006**
NRS leg pain mean (SD)		7.3 (2.1)	7.6 (2.0)	.285
Smoker		21.3%	26.4%	.389
ASA score mean (SD)		2.3 (0.6)	2.3 (0.7)	.638
Number surgical levels	1	77.4%	64.5%	**<.001**
	2	17.6%	16.8%	
	3	4.5%	13.1%	
	4	0.5%	5.6%	
Chief complaint	Back pain	5.5%	4.7%	.972
	Neurogenic claudication	57.8%	57.9%	
	radiculopathy	33.7%	35.5%	
	Other	3%	1.8%	
ODI mean (SD)		44.7 (15.3)	47.7 (14.8)	.102
EQ5D mean (SD)		0.7 (0.1)	0.7 (0.1)	.178
SF12 PCS mean (SD)		32.9 (8.2)	31.7 (8.4)	.232

BMI, body mass index; NRS, numeric rating scale; ASA, American Society of Anesthesiologists; ODI, Oswestry Disability Index; EQ5D, EuroQol; SF-12 PCS, Short Form-12 physical component score; D, decompression alone; D+F, decompression plus fusion.

Means were compared using *t* tests, percentages for binary (yes/no) variables were compared using Fisher exact test, and percentages for categorical variables were compared using chi-square tests.

Bolded p values indicate statistcially significant differences.

adjusted mean PROs at baseline, 3-, 12-, and 24-month follow-up. There were clinically meaningful differences from baseline noted at 3 months, in both treatment groups, which was sustained out to 24 months.

Discussion

This study compared decompression alone to decompression plus fusion in those with neurogenic claudication secondary to lumbar stenosis without deformity or spondylolisthesis. Using data from the CSORN, the decompression plus fusion group had significantly greater operative time, blood loss, and length of hospital stay. The rate of in-hospital perioperative adverse events was three times higher in the decompression plus fusion group. Both decompression and decompression plus fusion had a large clinically meaningful impact on generic and disease-specific PROMs within 3 months of surgery which was maintained out to 24-month follow-up. At any follow-up time point, there was no statistical evidence of a difference in these effects favoring decompression plus fusion over decompression alone. It is worth noting that all statistical differences favored decompression alone; however, none of the differences were clinically significant differences. Baseline NRS back pain was greater in the decompression plus fusion group which may suggest that Canadian surgeons consider back pain as an indication for fusion. However, the adjusted analysis controlling for initial back pain demonstrated no difference in the change in NRS back pain with the addition of fusion as compared to decompression alone which questions the utility of fusion in treating low back pain. Importantly, in response to our primary research question, the addition of fusion to decompression did not result in improved patient-reported outcomes.

Table 2
Comparison of mean perioperative outcomes between patients with decompression and those with decompression plus fusion

Variable	D	D+F	p Value
Blood loss (mL)*	75.0 (50.0, 200.0)	400.0 (200.0, 668.8)	**<.001**
OR time (min)*	91.0 (71.2, 118.0)	178.0 (121.8, 220.8)	**<.001**
LOS (d)*	1.0 (0.0, 3.0)	4.0 (3.0, 5.0)	**<.001**
AE	9.8%	33.0%	**<.001**

mL, milliliters; OR, operating room; LOS, length of stay; AE, adverse events; D, decompression alone; D+F, decompression plus fusion.

Bolded p values indicate statistcially significant differences.

* Median (Q1, Q3).

In the decompression plus fusion treatment group, there was a greater proportion of patients that had three or four levels of stenosis (Table 1). This observation may suggest that some surgeons feel compelled to add fusion with a greater number of decompressed lumbar levels.

The frequency of fusion surgery has been steadily increasing for treatment of degenerative lumbar conditions [2]. Decompression can significantly alter spinal anatomy and biomechanics [8], thereby prompting some spine surgeons to include fusion to treat real or perceived iatrogenic

Table 3
Comparison of outcome changes from baseline

Comparison of PROM changes from baseline							
Measure	Time	Model	D mean (N)	D+F mean (N)	Difference	95% CI	p
ODI*	Baseline	Un-adjusted	44.73 (198)	47.69 (107)	2.96	(−0.62, 6.54)	.105
		Adjusted	45.63 (195)	45.72 (105)	0.10	(−3.22, 3.41)	.954
	Baseline to 3 months	Un-adjusted	−18.69 (175)	−15.41 (100)	3.28	(−1.13, 7.69)	.144
		Adjusted	−18.90 (172)	−14.87 (98)	4.02	(−0.33, 8.38)	.070
	Baseline to 12 months	Un-adjusted	−18.25 (167)	−15.35 (101)	2.90	(−1.81, 7.61)	.227
		Adjusted	−18.45 (165)	−15.17 (99)	3.28	(−1.49, 8.05)	.177
	Baseline to 24 months	Un-adjusted	−17.09 (164)	−13.85 (100)	3.24	(−1.24, 7.71)	.156
		Adjusted	−17.21 (161)	−13.67 (99)	3.54	(−0.94, 8.03)	.121
EQ5D†	Baseline	Un-adjusted	0.74 (199)	0.73 (107)	−0.01	(−0.03, 0.01)	.195
		Adjusted	0.75 (195)	0.74 (105)	−0.01	(−0.03, 0.00)	.149
	Baseline to 3 months	Un-adjusted	0.07 (181)	0.06 (101)	−0.02	(−0.04, 0.01)	.144
		Adjusted	0.07 (177)	0.06 (99)	−0.02	(−0.04, 0.01)	.196
	Baseline to 12 months	Un-adjusted	0.08 (168)	0.06 (100)	−0.01	(−0.04, 0.01)	.337
		Adjusted	0.08 (165)	0.06 (98)	−0.02	(−0.04, 0.01)	.204
	Baseline to 24 months	Un-adjusted	0.07 (168)	0.05 (101)	−0.03	(−0.05, −0.00)	.042
		Adjusted	0.07 (164)	0.05 (100)	−0.02	(−0.05, 0.00)	.095
SF12_PCS†	Baseline	Un-adjusted	32.93 (195)	31.72 (104)	−1.21	(−3.19, 0.77)	.229
		Adjusted	32.56 (193)	32.47 (103)	−0.09	(−2.03, 1.84)	.926
	Baseline to 3 months	Un-adjusted	10.04 (172)	7.54 (96)	−2.49	(−4.95, −0.04)	.046
		Adjusted	10.08 (170)	7.14 (95)	−2.95	(−5.10, −0.79)	.008
	Baseline to 12 months	Un-adjusted	9.79 (162)	8.05 (95)	−1.74	(−4.29, 0.81)	.180
		Adjusted	9.85 (161)	7.67 (94)	−2.18	(−4.51, 0.15)	.066
	Baseline to 24 months	Un-adjusted	9.61 (161)	7.68 (96)	−1.92	(−4.55, 0.70)	.150
		Adjusted	9.87 (159)	7.33 (96)	−2.54	(−4.91, −0.17)	.036
NRS Back*	Baseline	Un-adjusted	6.52 (195)	7.26 (105)	0.74	(0.17, 1.30)	.011
		Adjusted	6.55 (195)	7.19 (105)	0.64	(0.05, 1.23)	.033
	Baseline to 3 months	Un-adjusted	−3.52 (174)	−3.76 (99)	−0.24	(−1.00, 0.52)	.535
		Adjusted	−3.71 (174)	−3.43 (99)	0.28	(−0.36, 0.92)	.386
	Baseline to 12 months	Un-adjusted	−3.08 (164)	−3.13 (99)	−0.05	(−0.77, 0.66)	.886
		Adjusted	−3.29 (164)	−2.78 (99)	0.51	(−0.14, 1.15)	.123
	Baseline to 24 months	Un-adjusted	−2.96 (164)	−2.94 (98)	0.02	(−0.74, 0.79)	.950
		Adjusted	−3.14 (164)	−2.64 (98)	0.50	(−0.18, 1.18)	.151
NRS Leg*	Baseline	Un-adjusted	7.33 (195)	7.59 (106)	0.26	(−0.23, 0.75)	.296
		Adjusted	7.44 (194)	7.39 (105)	−0.05	(−0.51, 0.42)	.837
	Baseline to 3 months	Un-adjusted	−4.27 (176)	−4.08 (100)	0.19	(−0.61, 0.99)	.646
		Adjusted	−4.33 (175)	−4.00 (99)	0.33	(−0.42, 1.09)	.387
	Baseline to 12 months	Un-adjusted	−3.98 (162)	−3.66 (100)	0.32	(−0.52, 1.15)	.457
		Adjusted	−4.05 (162)	−3.55 (99)	0.49	(−0.31, 1.29)	.226
	Baseline to 24 months	Un-adjusted	−3.50 (165)	−3.63 (98)	−0.13	(−0.96, 0.70)	.759
		Adjusted	−3.60 (164)	−3.47 (97)	0.13	(−0.66, 0.91)	.751

PROM, patient-reported outcome measures; ODI, Oswestry Disability Index; EQ5D, EuroQol; SF-12 PCS, Short Form-12 physical component score; D, decompression alone; D+F, decompression plus fusion.

Un-adjusted effects are equivalent to *t* tests comparing change scores at each time. Adjusted effects are from least squares fits adjusted for baseline values: age, sex, back pain at baseline, and number of levels.

* Positive effects for ODI, NRS back pain and NRS leg pain favor D over D+F.

† Negative effects for EQ5D and SF12 PCS favor D over D+F.

instability when decompressing lumbar stenosis [25,27]. In a recent Cochrane Library systematic review, Machado et al. [2] posed an important question: "is the tendency towards more extensive fusions and more and more metal of value to patients?" Our results contribute to the growing list of studies that suggest the answer is "no" for those without deformity or spondylolisthesis.

Forsth et al. have written on this topic [7,12]. In their Swedish registry study [7], they concluded that the addition of fusion to decompression was not associated with improved outcome, much like the CSORN study. This Swedish registry study differed from the current study in that the enrolment years were approximately one decade earlier, surgical spine levels were limited to one or two adjacent motion segments, follow-up at 2 years was less than 66% and the sample included those with or without spondylolisthesis. The current CSORN study was more homogeneous in that there was a 2-year follow-up rate of 81%, and it did not include patients with spondylolisthesis.

In a randomized trial concerning fusion surgery for lumbar stenosis [12], Forsth et al. concluded that adding fusion did not result in better clinical outcomes than decompression alone. Patients with spondylolisthesis were stratified within the randomization scheme. The study design and methodology were excellent, and the study was well executed with only 2% loss to follow-up. Our results were similar to the RCT subgroup without spondylolisthesis, where differences were noted in operating time and blood loss favoring decompression alone and no differences in patient-reported outcomes were observed, both suggesting that fusion does not provide additional benefit beyond decompression alone.

There were limitations to our study. First, the 2-year follow-up rate was 81% (248/306). The loss of follow-up data may have influenced the results. However, analysis of possible confounding baseline variables revealed that there were no statistically significant differences between those with observed vs missing 3-, 12-, and 24-month follow-up data. Second, by design, we were only able to control for known confounders. It is possible that a randomized controlled trial could yield different results. There was heterogeneity of baseline patient factors, which may not have been full accounted for and heterogeneity of surgical technique reflecting the pragmatic design. Spine registries have the potential to provide outcome data with greater external validity than what is often obtained in controlled trials. The CSORN was designed based on these principles of generalizability. Registries allow for aggregation of larger sample sizes in a more cost effective and time efficient manner than controlled trials.

There were several strengths of our study. This study had a well-defined clinically relevant sample, patients with neurogenic claudication secondary to lumbar stenosis without deformity or spondylolisthesis. Many published studies which address the topic of stenosis do not separate patients with and without deformity. Having a well-defined study sample facilitates interpretation of the data and comparison with other patient samples. The study data were from four hospitals across Canada representing four provinces. The inclusion of multiple sites with a geographical spread provides enhanced generalizability of our findings.

Conclusion

The addition of fusion to decompression in the stable stenotic lumbar spine did not result in improved patient-reported outcomes at 3, 12, or 24 months' follow-up. Fusion did not provide any advantage over decompression alone, suggesting that decompression is the treatment of choice in this well-defined patient population.

Acknowledgments

The authors thank all of the subjects who participated in the study and the support/research coordinator staff and investigators from the Canadian Spine Outcomes and Research Network (CSORN) contributing sites:

Foothills Medical Centre: Calgary AB; Canada East Spine Centre: Saint John NB; Hospital de L'enfant Jesus: Quebec City QC; Victoria Hospital - London Health Sciences Centre: London ON.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.spinee.2019.06.003.

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