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The Influence of Sex on Clinical Outcomes in Minimally Invasive Lumbar Decompression

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ABSTRACT

Background: Research focused on postoperative outcomes among men and women undergoing minimally invasive lumbar decompression (MIS LD) spine surgery is sparse. This study aims to assess the influence of sex on postoperative patient-reported outcome measure (PROM) evaluations and achievement of a minimum clinically important difference (MCID).

Methods: A prospectively maintained surgical database was retrospectively queried for patients undergoing primary or revision, single or multilevel LD procedures from 2011 to 2019. Patients with incomplete visual analog scale (VAS) leg or back surveys were excluded. Demographic and operative variables were recorded, and a chi-squared analysis or *t* tests were used to compare by sex. PROMs were evaluated from preoperative to postoperative time points. PROM score differences and postoperative improvement were evaluated between sexes by a *t* test. Achievement of MCID by sex was compared using chi-squared analysis.

Results: The study cohort ($n = 572$) was 70% male ($n = 398$), had an average age of 47 years, and 42% were obese. Sexes differed in preoperative VAS leg, Oswestry Disability Index (ODI), and 12-item short form (SF-12)-physical composite score (PCS) scores (all $P < .05$) and in ODI at 6 and 12 weeks ($P = .048$; $P = .001$) and VAS back and leg scores at 6 months ($P = .039$; $P = .019$). Both sexes significantly improved ($P < .050$) all PROMs at all time points except for VAS back at 1 year for women and ODI at 6 weeks and 6 months for men. The only significant difference in achievement of MCID was for ODI at 6 months ($P = .008$).

Conclusions: Significant preoperative differences were observed among sexes with ODI, SF-12-PCS, and VAS leg scores. By 1 year, there were no significant sex differences for any PROM or for achievement of MCID. MIS LD has an equivalent role for both sexes in achieving MCID.

Level of Evidence: 3.

Clinical Relevance: Results demonstrate no sex difference in PROMs following LD.

Lumbar Spine

Keywords: LD, lumbar decompression, sex, MCID, minimum clinically important difference

INTRODUCTION

Degenerative pathology of the lumbar spine in the general adult population is incredibly common.^{1,2} An estimated 10 to 20% of adults, for example, will experience symptomatic lumbar spinal stenosis during their lifetimes.³ Decompressive surgery is the gold standard treatment for pathologies, such as herniated nucleus pulposus and stenosis that have not responded to conservative treatment.^{4,5} Furthermore, lumbar decompression surgery is the most commonly performed procedure by spine surgeons annually.⁶ Although the indications for surgery and surgical technique are similar, some groups have demonstrated different degrees of improvement in patient-reported outcome measures

(PROMs) in response to surgery.^{7,8} Given the frequency of the procedure and the demographic variability of this patient population, there has been much interest in discerning the relationship between these demographic factors and perioperative PROMs.

Sex is one demographic factor that has been proposed to play an important role in pathology, symptomatology, and response to treatment for degenerative pathology of the lumbar spine.^{9–11} While some research has suggested that men and women fare differently in response to surgery,^{11,12} other research has suggested there are no major differences.^{13,14} However, prior studies have either analyzed lumbar surgeries other than decompres-

sion^{12,14} or have assessed for statistical rather than clinical divergence between sexes.^{15–17}

Further research is necessary to grasp the true clinical impact of sex on perioperative outcomes for lumbar spine decompression surgery. Analysis of the minimum clinically important difference (MCID) in PROMs may provide greater clinical context to the numeric scales of widely used outcome measures. Surgeons can use these clinical findings to counsel their patients, set expectations, and provide more realistic data to healthcare payers. Thus, the aim of the present study was to elucidate the relationship between sex and the likelihood of achievement of MCID for several of the most commonly used PROMs in spine surgery today.¹⁸

METHODS

Patient Selection

Institutional review board approval (ORA 14051301) was granted for a prospective surgical registry of spine surgery patients under the care of one surgeon at a single institution. This registry was retrospectively reviewed from December 2011 to July 2019 for patients who underwent lumbar decompressions. Included patients were required to have undergone primary or revision, single or multilevel lumbar decompressions. Patients were excluded from the study if they did not complete the preoperative visual analog scale (VAS) back or VAS leg surveys.

Data Collection

Patient records were reviewed for preoperative demographic variables, including age, sex, disease burden as evaluated by the Charlson Comorbidity Index, American Society of Anesthesiology score, tobacco use, and preoperative medical and spinal pathology diagnosis. Evaluated operative variables included the number of vertebral levels decompressed, operative time, estimated blood loss, duration of inpatient stay following surgery, and day of discharge. PROMs were evaluated at pre- and postoperative time points (eg, 6 weeks, 12 weeks, 6 months, and 1 year). Administered surveys included VAS back, VAS leg, and Oswestry Disability Index (ODI), 12-item short form (SF-12)-physical composite score (PCS), and Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function (PF).

Statistical Analysis

Demographic and operative variables were evaluated for differences among male and female sex subgroups using a chi-squared or Student *t* test where appropriate. A *t* test analyzed PROM score differences among sexes, while a paired *t* test evaluated postoperative improvement within each subgroup. A chi-squared test compared sex proportions that achieved MCID following lumbar decompression. MCID values were used based on previous literature values for VAS back (2.2),¹⁹ VAS leg (5.0),¹⁹ ODI (8.2),¹⁹ SF-12-PCS (2.5),¹⁹ and PROMIS PF (4.5).²⁰ Statistical analysis was performed using Stata SE 16.1 (College Station, Texas), and statistical significance was set at $\alpha = .05$.

RESULTS

Study Cohort

In total, 572 eligible patients underwent lumbar decompression. The male to female ratio was 69.6% to 30.4%, respectively (Table 1). The average age was 46.8 years, and 42% of the cohort was obese (body mass index ≥ 30). The only significant differences among sexes were a greater proportion of male smokers than female smokers (16.4% versus 8.6%; $P = .014$), and females had a greater rate of arthritis (13.2% versus 6.3%; $P = .006$). The most common preoperative medical diagnoses was hypertension (23.7%), and the mean Charlson Comorbidity Index score was 1.4 ± 1.7 . The three most common spinal pathologies were herniated nucleus pulposus (76.2%), central stenosis (71.3%), and foraminal stenosis (44.4%).

Operative Characteristics

There were no significant differences in the evaluated operative variable among sexes (Table 2). The majority of procedures decompressed a single level (78.3%). The mean operative time was 46.6 ± 17.7 minutes, and mean estimated blood loss was 28.6 mL. The mean postoperative hospital stay was 29.9 hours, with the majority of patients being discharged on postoperative day zero (61.7%).

Patient-Reported Outcomes

At all time points, there were no significant differences among sexes for PROMIS PF (Table 3). Preoperative mean PROM score differences between sexes were observed for VAS leg ($P = .019$), ODI ($P =$

Table 1. Patient demographics and baseline characteristics by sex.

	Total, % (n)	Female, % (n)	Male, % (n)	P Value ^a
Participants	100.0 (572)	30.4 (174)	69.6 (398)	
Age, mean \pm SD, y	46.8 \pm 14.3	48.6 \pm 13.4	46.0 \pm 14.6	.051
BMI, kg/m ²				.461
Not obese (BMI < 30)	58.0 (332)	60.3 (105)	57.0 (227)	
Obese (BMI \geq 30)	42.0 (240)	39.7 (69)	43.0 (171)	
Smoking status				.014
Nonsmoker	86.0 (490)	91.4 (159)	83.6 (331)	
Smoker	14.0 (80)	8.6 (15)	16.4 (65)	
CCI, mean \pm SD	1.4 \pm 1.7	1.4 \pm 1.6	1.4 \pm 1.7	.973
ASA score				.204
1	35.5 (164)	29.6 (40)	37.9 (124)	
2	51.1 (236)	58.5 (79)	48.0 (157)	
≥ 3	13.4 (62)	11.9 (16)	14.1 (46)	
Preoperative medical diagnoses ^b				
Myocardial infarction	2.5 (14)	0.6 (1)	3.3 (13)	.054
AIDS	0.2 (1)	0.0 (0)	0.3 (1)	.507
Uncomplicated diabetes	5.8 (33)	5.2 (9)	6.1 (24)	.676
Complicated diabetes	0.4 (2)	0.0 (0)	0.5 (2)	.348
Congestive heart failure	0.4 (2)	0.6 (1)	0.3 (1)	.549
Hypertension	23.7 (135)	20.7 (36)	25.0 (99)	.265
Neurologic disease	0.2 (1)	0.0 (0)	0.3 (1)	.507
Arthritis	8.4 (48)	13.2 (23)	6.3 (25)	.006
Renal failure	0.4 (2)	0.6 (1)	0.3 (1)	.549
Metastasis	0.5 (3)	0.6 (1)	0.5 (2)	.916
Peripheral vascular disease	1.1 (6)	0.6 (1)	1.3 (5)	.459
Preoperative spinal pathology				
Spondylolisthesis	4.4 (25)	6.3 (11)	3.5 (14)	.131
Isthmic spondylolisthesis	2.4 (8)	4.0 (4)	1.8 (4)	.225
Retro-listhesis	0.4 (2)	0.6 (1)	0.3 (1)	.548
Lateral listhesis	0.2 (1)	0.0 (0)	0.3 (1)	.508
Herniated nucleus pulposus	76.2 (436)	73.6 (128)	77.4 (308)	.791
Degenerative disc disease	2.3 (13)	3.5 (6)	1.8 (7)	.212
Central/spinal stenosis	71.3 (408)	70.1 (122)	71.9 (286)	.671
Foraminal stenosis	44.4 (254)	43.1 (75)	45.0 (179)	.679

Abbreviations: AIDS, acquired immunodeficiency syndrome; ASA, American Society of Anesthesiology; BMI, body mass index; CCI, Charlson Comorbidity Index; SD, standard deviation.

^aP value was calculated using the Student *t* test (continuous), chi-square (categorical), or the Fisher exact test (categorical).

^bThere were no patients in our study with a recorded medical history of paraplegia or liver disease.

A bolded P value (<0.05) indicates a statistically significant difference between the two groups being compared.

.001), and SF-12-PCS ($P = .025$). Postoperative mean differences between sexes were observed for VAS back at 6 months ($P = .039$), VAS leg at 6 months ($P = .018$), and ODI scores at 6 and 12 weeks ($P = .048$; $P = .001$). Statistically significant improvements ($P < .05$) were observed for all PROMs at all time points

with the exception of VAS back at 1 year for women and ODI at 6 weeks and 6 months for men. There were no significant sex differences in achieving MCID for pain (VAS back, VAS leg) and physical function (SF-12-PCS, PROMIS PF) metrics at all time points (Table 4). At 6 months, there was a

Table 2. Operative characteristics by sex.

	Total, % (n)	Female, % (n)	Male, % (n)	P Value ^a
Number of operative levels				.888
1-level	78.3 (448)	79.3 (138)	77.9 (310)	
2-level	18.2 (104)	17.8 (31)	18.3 (73)	
3-level	3.3 (19)	2.9 (5)	3.5 (14)	
4-level	0.2 (1)	0.0 (0)	0.3 (1)	
Operative time ^b , mean \pm SD, min	46.6 \pm 17.7	45.9 \pm 16.3	46.9 \pm 18.3	.538
Estimated blood loss, mean \pm SD, mL	28.6 \pm 34.0	26.8 \pm 6.4	29.4 \pm 40.5	.401
Length of hospital stay, mean \pm SD, h	29.9 \pm 5.8	29.2 \pm 5.5	31.3 \pm 6.3	.055
Day of discharge				.966
POD 0	61.7 (340)	60.8 (104)	62.1 (236)	
POD 1	7.3 (40)	7.6 (13)	7.1 (27)	
POD 2	0.9 (5)	1.2 (2)	0.8 (3)	
POD ≥ 3	0.9 (5)	1.2 (2)	0.8 (3)	

Abbreviations: POD, postoperative day; SD, standard deviation.

^aP value was calculated using the Student *t* test (continuous), chi-square analysis (categorical), or the Fisher exact test (categorical).

^bOperative time was measured from skin incision to skin closure.

Table 3. Patient reported outcome comparison by sex.

	Female		Male		<i>P</i> value ^b
	Mean ± SD (<i>n</i>)	<i>P</i> Value ^a	Mean ± SD (<i>n</i>)	<i>P</i> Value ^a	
VAS back					
Preoperative	6.0 ± 2.6 (135)		6.1 ± 2.6 (298)		.937
6 week	2.7 ± 3.0 (135)	<.001	3.0 ± 3.1 (298)	<.001	.273
12 week	3.1 ± 3.2 (79)	<.001	3.3 ± 3.1 (183)	<.001	.527
6 month	3.0 ± 3.1 (65)	<.001	4.0 ± 3.1 (131)	<.001	.039
1 year	3.4 ± 2.8 (45)	.053	3.4 ± 3.2 (81)	.003	.980
VAS leg					
Preoperative	6.4 ± 2.6 (135)		6.1 ± 2.5 (298)		.019
6 week	2.9 ± 3.5 (135)	<.001	2.9 ± 3.2 (298)	<.001	.864
12 week	3.4 ± 3.9 (79)	<.001	2.8 ± 3.4 (184)	<.001	.184
6 month	2.6 ± 3.4 (64)	<.001	3.6 ± 3.4 (130)	<.001	.019
1 year	2.8 ± 3.5 (45)	<.001	2.9 ± 3.3 (81)	<.001	.723
ODI					
Preoperative	45.8 ± 17.7 (135)		41.9 ± 18.1 (299)		.001
6 week	25.2 ± 21.0 (135)	<.001	25.8 ± 19.3 (299)	.342	.048
12 week	27.8 ± 24.9 (80)	<.001	24.7 ± 21.0 (183)	<.001	.001
6 month	24.0 ± 22.8 (64)	<.001	37.0 ± 87.8 (132)	.483	.495
1 year	23.3 ± 24.6 (45)	<.001	24.1 ± 18.7 (81)	<.001	.357
SF-12 PCS					
Preoperative	30.2 ± 7.3 (99)		31.5 ± 8.5 (222)		.025
6 week	37.6 ± 10.6 (99)	<.001	38.2 ± 10.6 (222)	<.001	.096
12 week	39.9 ± 11.3 (63)	<.001	40.5 ± 12.0 (129)	<.001	.303
6 month	40.9 ± 11.7 (56)	<.001	39.0 ± 12.2 (110)	<.001	.490
1 year	43.3 ± 13.0 (48)	<.001	40.7 ± 12.2 (93)	<.001	.159
PROMIS PF					
Preoperative	35.9 ± 6.2 (75)		36.5 ± 7.7 (162)		.095
6 week	41.9 ± 8.0 (75)	<.001	42.6 ± 8.8 (162)	<.001	.460
12 week	43.9 ± 7.9 (47)	<.001	45.3 ± 10.2 (104)	<.001	.272
6 month	44.6 ± 9.1 (41)	<.001	42.6 ± 10.3 (89)	<.001	.284
1 year	44.8 ± 8.9 (35)	<.001	45.4 ± 12.1 (66)	<.001	.839

Abbreviations: ODI, Oswestry Disability Index; PROMIS PF, Patient-Reported Outcomes Measurement Information System Physical Function; SD, standard deviation; SF-12 PCS, 12-item short form physical composite score; VAS, visual analog scale.

^a*P* value was calculated using the paired *t* test (continuous) to compare each time point score with the preoperative value.

^b*P* value was calculated using the Student *t* test (continuous) to compare each time point among subgroups.

A bolded *P* value (<0.05) indicates a statistically significant difference between the two groups being compared.

Table 4. Achievement of minimal clinically important difference (MCID), percentage (*n*/total).

PRO	Preop to 6 wk	Preop to 3 mo	Preop to 6 mo	Preop to 12 mo	Overall met MCID
VAS back					
Female	70.1 (279/398)	78.6 (313/398)	83.9 (334/398)	91.2 (363/398)	97.5 (388/398)
Male	70.7 (123/174)	83.9 (146/174)	86.2 (150/174)	88.5 (154/174)	97.1 (169/174)
<i>P</i> value	.887	.146	.485	.314	.804
VAS leg					
Female	49.8 (198/398)	70.6 (281/398)	76.1 (303/398)	85.4 (340/398)	94.5 (376/398)
Male	51.7 (90/174)	67.8 (118/174)	79.3 (138/174)	86.2 (150/174)	93.7 (163/174)
<i>P</i> value	.664	.504	.405	.807	.708
ODI					
Female	73.4 (292/398)	84.2 (335/398)	85.2 (339/398)	93.5 (372/398)	98.2 (391/398)
Male	79.3 (138/174)	85.1 (148/174)	93.1 (162/174)	92.5 (161/174)	96.6 (168/174)
<i>P</i> value	.130	.788	.008	.682	.212
SF-12					
Female	54.3 (216/398)	73.6 (293/398)	76.6 (305/398)	79.4 (316/398)	94.2 (375/398)
Male	51.2 (89/174)	66.6 (116/174)	70.7 (123/174)	75.3 (131/174)	92.0 (160/174)
<i>P</i> value	.491	.090	.132	.274	.311
PROMIS					
Female	62.1 (247/398)	74.6 (297/398)	74.6 (297/398)	84.9 (338/398)	95.5 (380/398)
Male	60.3 (105/174)	74.1 (129/174)	74.1 (129/174)	81.0 (141/174)	90.8 (158/174)
<i>P</i> value	.698	.903	.577	.246	.030

Abbreviations: ODI, Oswestry Disability Index; PRO, patient-reported outcome; PROMIS, Patient-Reported Outcomes Measurement Information System; SF-12, 12-item short form score; VAS, visual analog scale.

A bolded *P* value (<0.05) indicates a statistically significant difference between the two groups being compared. Other bolded percentage values are associated with the statistically significant *P* value.

significant difference in the proportion of patients who achieved MCID among sexes for the disability metric ODI ($P = .008$).

DISCUSSION

Understanding the effect of demographic factors on outcomes following spine surgery has become critical and can enable surgeons to better counsel patients and guide expectations. The relationship between sex and perioperative outcomes has remained debated. The present study sought to discern the true clinical relationship between sex and PROMs for patients undergoing decompression surgery of the lumbar spine. Our cohort had a larger proportion of male patients (69.6%). Patients were generally young and otherwise healthy, with a mean age of 46.8 years and with 86.6% holding an American Society of Anesthesiology score of 2 or less. The cohort of female patients had a smaller proportion of active tobacco users and a higher prevalence of arthritis, with no additional demographic differences between the two groups. Regarding symptomatology, the female cohort reported worse preoperative leg pain, disability, and overall physical function (via SF-12) relative to men. However, the only significant differences in postoperative absolute outcome measures were ODI scores at 6 and 12 weeks and VAS back and leg scores at 6 months, with the differences disappearing by the 6-month and 1-year follow-up mark, respectively. Women had a lower likelihood of meeting the MCID for ODI at 6 months, but were equally likely to achieve this MCID at final follow-up. Moreover, there were no differences in the likelihood of achieving the MCID at 1 year postoperative for the five patient-reported outcomes that were recorded and analyzed.

These findings are consistent with previous research of patients undergoing lumbar decompression surgery. The predominance of male patients has been exhibited in similar studies^{4,21} and may be attributable to the greater degree of disc degeneration than in age-matched women⁹ or to sex-specific behaviors and referral patterns. Patients did generally well in response to surgery, with improvements in absolute PROMs that were similar to prior efforts, including the highly cited Spine Patient Outcomes Research Trials.^{4,5} Finally, the mean duration of surgery and length of stay were consistent with an experienced surgeon performing a standard minimally invasive decompressive surgi-

cal technique.^{22,23} These similarities to previous efforts support the generalizability of our findings.

There has been a limited effort to date to elucidate the relationship between sex and perioperative outcomes following lumbar decompression surgery. Strömqvist et al performed an analysis of 11 237 patients in the Swedish National Spine Surgical Register who underwent lumbar decompression surgery with a primary objective of comparing outcomes between men and women.¹⁶ Similar to the present study, they found no significant difference in the degree of absolute improvement in PROMs. Despite this, women did report significantly worse pre- and postoperative absolute PROM values. The reasons for this discrepancy are unclear, but the authors suggest it may be related to sex-specific delays in presentation or a willingness to attempt longer courses of nonoperative care.¹⁷ Similarly, Gulati et al retrospectively reviewed 3245 patients in the Norwegian Registry for Spine Surgery who had undergone single-level lumbar decompressions.¹⁵ Although their primary objective was to determine differences between the adult and adolescent population, they found that female sex was an independent risk factor for less improvement in ODI at 1 year postoperative (parameter estimate -1.8 , 95% confidence interval [CI] -3.1 to -0.4 , $P = .010$). Despite the statistical findings of the aforementioned studies, the clinical significance of sex on perioperative outcomes for lumbar decompression surgery has remained unclear.

Several groups have examined the role of sex on the likelihood of achieving an MCID in PROM following lumbar spine surgery. Siccoli et al, for example, analyzed 3279 patients undergoing a variety of surgical procedures for degenerative pathology of the lumbar spine, including discectomy, laminectomy, or fusion, for differences in outcome measures between sexes.¹² Similar to the present study, they found that women had a higher degree of functional disability (via ODI score) at 6 weeks and at 12 and 24 months after surgery than men. However, the team also reported that men and women had no difference in the likelihood of experiencing “clinical success”, which was defined as achieving a minimum of 30% improvement in ODI from baseline to follow-up (82% of men and 79% of women; $P = .34$). The likelihood of achieving MCID in any additional measures was not examined. Similarly, Triebel et al performed a

retrospective review of 2251 men and 2521 women in the Swedish National Spine Register who had undergone lumbar fusion for degenerative disc disease and chronic low back pain.¹⁴ Consistent with our findings, they too found that women reported more severe symptoms preoperatively. However, they reported that female sex was associated with an increased likelihood of achieving MCID in leg pain (odds ratio = 1.39, 95% CI 1.19–1.61, $P < .01$), back pain (odds ratio = 1.20, 95% CI 1.03–1.40, $P = .02$), and disability scores (odds ratio = 1.24, 95% CI 1.05–1.47, $P = .01$). Although these studies have further contributed to our understanding of this complex area, the effect of sex on achieving MCID for lumbar decompression surgery has yet to be publicized.

Despite a similar degree of improvement in response to surgery, the reasons for differences in absolute value of outcome measures between sexes remain debated. There have been multiple attempts at explaining sex-related differences in pain perception with no clear consensus.^{24,25} This is not isolated to the postoperative state, as the female cohort in the present study reported worse preoperative symptoms compared with men, including the degree of leg pain, disability, and overall function. These findings are consistent with those of Strömquist et al who first found that women were likely to report worse symptoms before lumbar decompression surgery.¹⁷ This could be attributable to an advanced stage of the disease in females at the time of intervention, a finding that has been supported for degenerative arthritis and other subspecialties of orthopedic surgery.²⁶ There may also be underlying physiological and hormonal differences in pain perception, but these remain poorly understood.^{24,25} Lastly, differences in inflammatory pathways and the relative effectiveness of analgesics may play an important role.²⁷ Further research is necessary to grasp the multifactorial nature of this topic.

The results of the present study should be considered within the context of some notable limitations. The minimum clinical follow-up necessary for inclusion was 12 months, and this was also the final time point for analysis of MCID achievement. Previous research has suggested that female patients may experience a drawn out recovery process for radicular and neurogenic claudication symptoms in response to both surgical and nonsurgical care.²⁸ Although 12 months has been suggested to be a sufficient duration to assess the true clinical

benefit following lumbar decompression surgery,²⁹ it is possible that female patients may experience even more clinical improvement between 12 and 24 months relative to their male counterparts. Triebel et al, for example, found that women experienced a slower recovery and a higher likelihood for achieving MCID than the male cohort but required a 2-year follow-up to appreciate this effect.¹⁴ In addition, the duration of preoperative symptoms was not known or analyzed. This may be a contributing factor to the generally worse preoperative pain, disability, and physical function scores for the female cohort that was not captured within our statistical analysis. Therefore, future prospective analysis may be beneficial.

CONCLUSION

The relationship between sex and perioperative outcomes remains debated. This is the first study to analyze the role of sex on the achievement of MCID in response to lumbar decompression surgery alone. We found that, although women may present with worse preoperative symptoms, there is no difference in the overall likelihood of achieving the MCID of five of the most commonly used PROMs (VAS back/leg, ODI, SF-12, PROMIS) in spine research today. Surgeons may use this information to appropriately counsel patients and guide expectations following surgical intervention.

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