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Clinical Study

Women do not fare worse than men after lumbar fusion surgery

Two-year follow-up results from 4,780 prospectively collected patients in the Swedish National Spine Register with lumbar degenerative disc disease and chronic low back pain

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Abstract

BACKGROUND CONTEXT: Proper patient selection is of utmost importance in the surgical treatment of degenerative disc disease (DDD) with chronic low back pain (CLBP). Among other factors, gender was previously found to influence lumbar fusion surgery outcome.
PURPOSE: This study investigates whether gender affects clinical outcome after lumbar fusion.
STUDY DESIGN: This is a national registry cohort study.
PATIENT SAMPLE: Between 2001 and 2011, 2,251 men and 2,521 women were followed prospectively within the Swedish National Spine Register (SWESPINE) after lumbar fusion surgery for DDD and CLBP.
OUTCOME MEASURES: Patient-reported outcome measures (PROMs), visual analog scale (VAS) for leg and back pain, Oswestry Disability Index (ODI), quality of life (QoL) parameter EQ5D, and labor status and pain medication were collected preoperatively, 1 and 2 years after surgery.
METHODS: Gender differences of baseline data and PROM improvement from baseline were analyzed. The effect of gender on clinically important improvement of PROM was determined in a multivariate logistic regression model. Furthermore, gender-related differences in return-to-work were investigated.
RESULTS: Preoperatively, women had worse leg pain (p<.001), back pain (p=.002), lower QoL (p<.001), and greater disability than men (p=.001). Postoperatively, women presented greater improvement 2 years from baseline for pain, function, and QoL (all p<.01). Women had better chances of a clinically important improvement than men for leg pain (odds ratio [OR]=1.39, 95% confidence interval [CI]: 1.19–1.61, p<.01) and back pain (OR=1.20,95% CI:1.03–1.40, p=.02) as well as ODI (OR=1.24, 95% CI:1.05–1.47, p=.01), but improved at a slower pace in leg pain (p<.001), back pain (p=.009), and disability (p=.008). No gender differences were found in QoL and return to work at 2 years postoperatively.
CONCLUSIONS: Swedish women do not have worse results than men after spinal fusion surgery. Female patients present with worse pain and function preoperatively, but improve more than men do after surgery.

Keywords: Chronic low back pain; Degenerative disc disease; Gender; Quality of life; Sex; Spinal fusion; Surgical outcome

FDA device/drug status: Not applicable.

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The regional ethical review board of Uppsala, Sweden, approved the study (2009/164/1).

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Introduction

Even though lumbar fusion surgery improves back pain and health-related quality of life (QoL) in a well-selected subgroup of patients with chronic low back pain (CLBP) [1], the improvement rates are sobering, and nowadays even the most enthusiastic surgeons consider alternatives to surgical treatment before engaging in spinal fusion [2]. In this context, identification of predictors for surgical outcome is of significant importance.

Women are often thought of as having more pain and reporting more pain than men [3–5].

Several clinical trials found a better global and functional outcome after lumbar spine fusion for men than for women. In a retrospective study of 112 patients, Gehrchen et al. [6] report female gender to be an independent risk factor for nonoptimal outcome after lumbar fusion, and the randomized controlled trial of 164 patients by Ekman et al. [7] observes female gender to be associated with worse postoperative results [8].

The cross-sectional study of patients with CLBP by Chenot et al. [3] finds a lower pain threshold (p=.04) and greater chronicity (p<.001) in women (n=1,310). There are multiple environmental and sociocultural factors influencing gender role perception and expectations of pain, which may have a significant effect on sex-specific results after lumbar fusion surgery [4]. Robinson et al. [4] observe that both sexes strongly indicate that they expect the typical man to be far less willing to report pain than the typical woman. Wise et al. [5] find men to have a higher threshold for thermal pain (p<.001) and a greater pain tolerance (p<.001) than do women. Thus, men may report lower pain even though they experience similar pain stimuli as women—biasing most previously published results assessing pain after lumbar fusion surgery.

It is still unclear why women should do worse after lumbar fusion surgery. Some suggest that women are more affected by CLBP and tend to protract functional recovery [9]. Others blame a greater prevalence of depression in the female population for worse postoperative results [10]. Furthermore, both sociocultural and physiological influences on pain perception have to be taken into account [4,11]. Beyond that, a surgeon-related gender-specific patient selection can hardly be denied [12–15].

Recently, the analysis of a cohort of 1,518 patients by Pochon et al. [16] treated for multiple spinal disorders questions the widespread belief that women fare worse than men after lumbar spinal surgery.

The aim of our cohort study was to investigate if women have worse results after lumbar spinal fusion regarding pain, function, QoL, and return to work.

Methods

Study population

The Swedish National Spine Register (SWESPINE) was founded in 1993. Since then, virtually all patients who undergo spine surgery in Sweden are registered. About 90% of clinics performing spine surgery in Sweden report to the SWESPINE. Until 2015, more than 90,000 patients were registered, and the 2-year follow-up rate with patient-reported outcome measures (PROMs) is between 65% and 70% for surgically treated degenerative lumbar spine disorders [17].

Preoperatively, all patients report background data in terms of age, sex, smoking habits, working conditions, sick listing, consumption of analgesics, and walking distance. Patient-reported outcome measurements (PROMs) in the register include pain on a visual analog scale (VAS) for back and leg pain, and since January 2000, also include Oswestry Disability Index (ODI) and EuroQol (EQ5D). A follow-up questionnaire is completed 1 and 2 years postoperatively. The follow-up questionnaire evaluates the same parameters assessed preoperatively but also includes questions that reveal information about patient satisfaction with the surgical outcome. The follow-up questionnaire is sent to the patients' home along with a prepaid envelope. Surgical data are recorded by the surgeon and include diagnosis and possible surgical complications. All PROMs included have been validated, and the current protocol of the register has been validated in a test-retest situation [18].

In this study, all patients in the Swedish Spine Register who underwent surgical fusion for degenerative disc disease with CLBP from June 2001 to August 2011 were included. Of the registered 5,290 entries, 449 had incomplete information on gender. The 4,841 remaining patients in the register were treated in 46 different hospitals. Some hospitals operated on fewer than three patients each, and patients operated

EVIDENCE & METHODS

Context

In this Swedish national registry cohort study, the authors found that women undergoing fusion for low back pain / degenerative disc disease had worse preoperative status than men, but improved more after surgery.

Contribution

The registry provides solid outcomes data using accepted measures for quality of life, pain, return to work, and disability.

Implications

The study provides some insight into what might have been a prior bias against women during surgical decision-making over concerns that they might not do well. Limitations of the study include: (a) response rates at follow-up in the 60% range and (b) cultural and genetic differences between the cohorts that may limit comparability between groups and also limit generalizability beyond Sweden. Also, the role of fusion for LBP / DDD is now unclear. So, while "new," the information may not be useful.

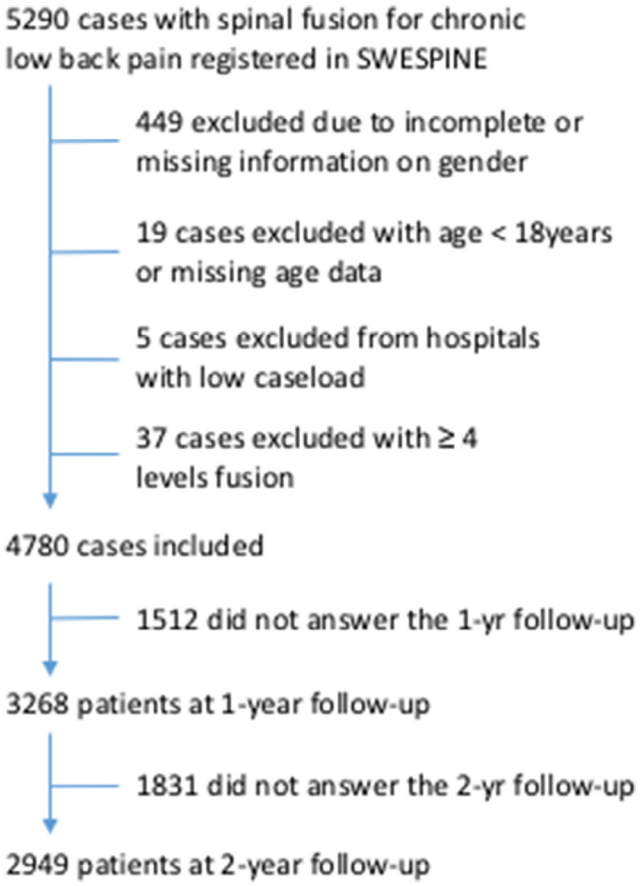

Fig. 1. Inclusion flow diagram.

on at these low-volume hospitals were excluded (n=5). Pediatric cases (age <18 years) were also excluded (n=19). Of the remaining patients, 37 were operated on four or more levels and were therefore excluded, leaving 4,780 patients to be included in the baseline cohort (90% response rate). The inclusion flowchart is shown in Fig. 1.

Statistics

All statistical analyses were performed using R version 3.3.0 (The R Foundation for Statistical Computing, Vienna, Austria).

Mean differences in age, smoking status, previous surgery, use of analgesics, VAS, EQ5D, ODI, and labor status between men and women were tested. The chi-square test was applied to test proportional group differences. A parametric *t* test was used if the variable was normally distributed (VAS back, ODI), and a nonparametric Mann-Whitney *U* test was used if the variable was not normally distributed (VAS leg, EQ5D).

To compare the time to improvement during the first two postoperative years between the genders, the area under the curve was calculated for VAS back, VAS leg, ODI, and EQ5D. The treatment effect in each gender was analyzed using a paired *t* test for normally distributed data and a Wilcoxon test for skewed data.

Working status was treated as a dichotomous variable. Part-time and full-time sick leave were considered as decreased working capacity.

Furthermore, the association between sex and VAS, ODI, and EQ5D was analyzed by multivariable logistic regression to assess odds ratios (OR) with 95% confidence intervals (CI). The minimally clinically important difference (MCID) was used as cutoff value for creating dichotomous variables for the logistic regression. Minimally clinically important difference values used in this study were previously determined with an anchor-based method (change difference) using the Global Assessment Score of the SWESPINE database as anchor [19]. An MCID ≥14 for VAS, ≥8 for ODI, and ≥0.2 for EQ5D was considered clinically important. A p-value <.05 was considered as statistically significant. In the model were included age, smoking, sickness retirement, and intake of analgesics at baseline, which are all associated with postoperative outcome and QoL [20,21]. Goodness of fit of the investigated models was tested according to Hosmer and Lemeshow [22] and presented with pseudo-r^2 according to McFadden [23].

The dropout analysis included a logistic regression of possible covariates predicting dropout at 1- and 2-year follow-up. In the model were included male gender, age, smoking, body mass index, working status, intake of analgesics at baseline, and previous spine surgery, which all have been found responsible for dropout in previous studies [1]. Predicted values were tested for goodness of fit according to Hosmer and Lemeshow and with the area under the receiver operating characteristic curve.

Results

Baseline characteristics including group differences by sex are described in Table 1.

Table 1
Baseline values of included patients with regard to gender (data presented as count, proportions, and mean±standard deviation)

	Male	Female	p
n	2,251	2,529	
Age (y)	46±10	46±11	.42
Smoker	16%	20%	<.001
BMI (kg/m^2)	27±3	25±4	<.001
Not working	68%	75%	<.001
Analgesic medication	49%	59%	<.001
Previous spine surgery	33%	33%	.02
IBF	41%	39%	.15
IPLF	34%	38%	<.001
TDR	15%	14%	.73
NPLF	5%	5%	.22
Number of levels	1.4±0.6	1.4±0.6	.33

BMI, body mass index; IBF, interbody fusion; IPLF, instrumented posterolateral fusion; TDR, total disc replacement; NPLF, noninstrumented posterolateral fusion.

Group differences were tested with chi-square test, and mean value differences were tested with Student t test.

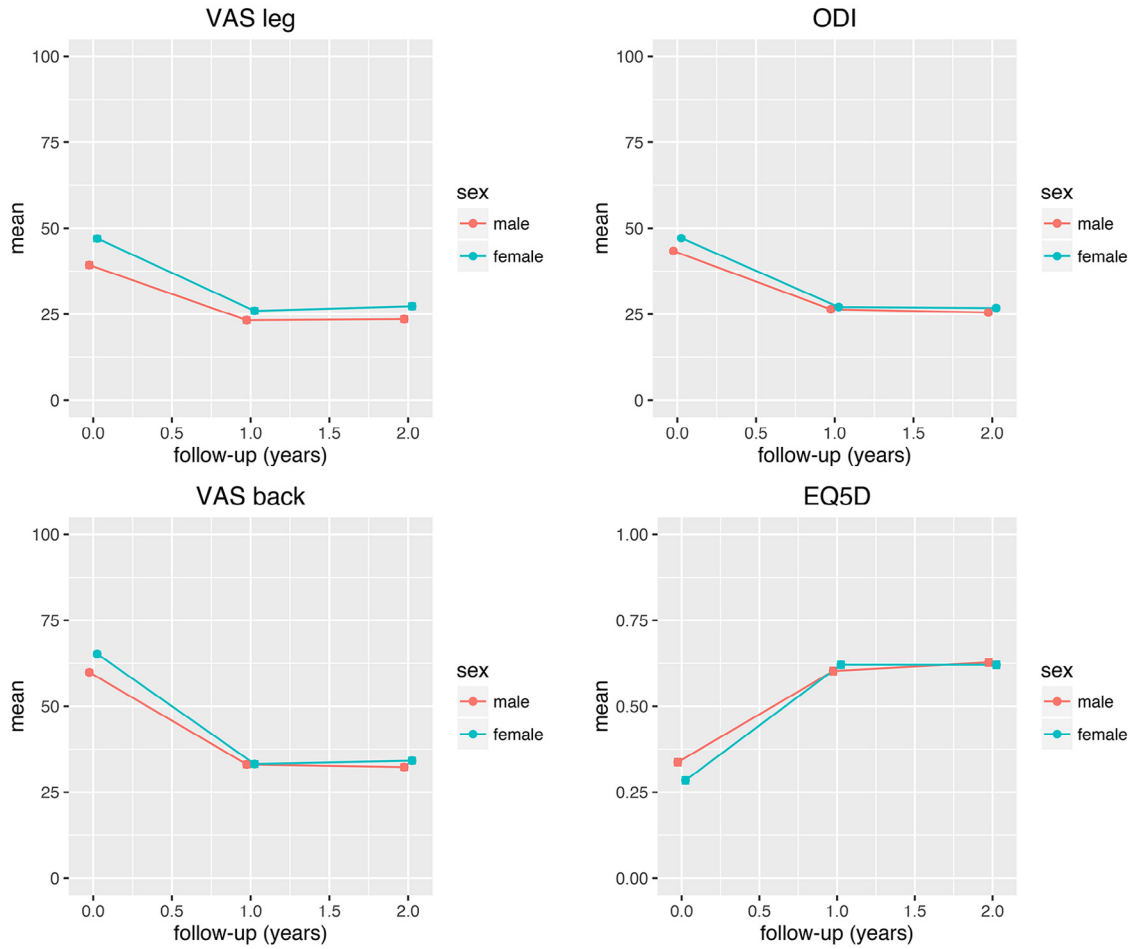

Fig. 2. Improvement in leg pain (visual analog scale [VAS] leg), back pain (VAS back), function (Oswestry Disability Index [ODI]), and health-related quality of life (EQ5D) of male and female patients from baseline up to 2 years after lumbar fusion surgery for degenerative disc disease and chronic low back pain.

Women were more frequently smokers than men (20% vs. 16%), were consuming more analgesics (59% vs. 49%), and were at a higher rate not working preoperatively (73% vs. 67%). Women reported at baseline higher pain both in the leg (p<.001) and the back (p=.002), lower QoL (p<.001), and higher disability (p<.001) (Fig. 2). At 1-year follow-up, the only variable that differed between the sexes was leg pain (p=.001).

Women had a higher rate of improvement from baseline to follow-up in leg pain (p<.001), back pain (p=.009), QoL (p=.002), and disability (p=.001). Both sexes improved to an extent that is of clinical importance with regard to the MCID. Women had a slower improvement than men, as can be seen in the area under the curve of the improvement for leg pain (p<.001), back pain (p=.009), and disability (p=.008).

The logistic regression analysis presented in Table 2 revealed that, when adjusted for age, smoking, working status, and analgesics, women had higher odds of clinically important improvement than do men for leg pain (OR=1.39, 95% CI: 1.19–1.61, p<.01) and back pain (OR=1.20, 95% CI:1.03–1.40, p=.02), as well as ODI (OR=1.24, 95% CI:1.05–1.47, p=.01).

After 1 year, 29% of preoperatively not working men returned to work, whereas 25% of women returned to work. In a logistic regression model including age, smoking, and analgesics, female gender was not a significant predictor for return to work at 1-year follow-up (OR=0.87, 95% CI: 0.75–1.02, p=.08) (Table 3). At 2-year follow-up, 29% of preoperatively not working men have returned to work, whereas 28% of women returned to work, leaving no gender effect in the logistic regression model (OR=0.99, 95% CI: 0.85–1.15, p=.90).

Dropouts were defined as those who did not answer the follow-up questionnaire. At 1-year follow-up, the dropout was 32%; at 2-year follow-up it was 38%. The logistic regression analysis revealed that age, not working, and previous spine surgery were associated with dropout 1 year after surgery (Table 4). At 2-year follow-up, additionally, smoking and a higher body mass index were associated with dropout (Table 4).

Discussion

This study found three major gender-related outcomes before and up to 2 years after spinal fusion surgery: (1) women were referred to surgery for DDD with worse symptoms and

Table 2
Logistic regression of covariates of clinically important improvement for leg and back pain, ODI, and EQ5D

	VAS leg (improvement >14)				VAS back (improvement >14)				ODI (improvement >8)				EQ5D-index (improvement >0.2)			
		95% CI				95% CI				95% CI				95% CI		
	OR	2.5%	97.5%	p	OR	2.5%	97.5%	p	OR	2.5%	97.5%	p	OR	2.5%	97.5%	p
Female gender	1.39	1.19	1.61	<.01	1.20	1.03	1.40	.02	1.24	1.05	1.47	.01	0.83	0.61	1.13	.24
Age	1.00	0.99	1.01	.88	1.00	0.99	1.00	.36	0.99	0.98	1.00	.07	1.00	0.98	1.01	.73
smoking	0.92	0.76	1.12	.43	0.79	0.65	0.97	.03	0.69	0.55	0.86	<.01	1.45	0.98	2.09	.06
Sickness retired	0.95	0.86	1.06	.40	0.78	0.70	0.87	.00	0.79	0.70	0.89	<.01	1.01	0.80	1.27	.91
Analgesics	1.11	0.88	1.41	.37	0.82	0.63	1.05	.12	0.84	0.64	1.11	.22	1.11	0.69	1.91	.68
r^2	0.03			.29	0.05			.76	0.06			.11	0.06			.43

Dichotomization with minimally clinically important difference according to the SWESPINE annual report as cutoff value for relevant improvement. Odds ratios (OR) are presented with 95% confidence intervals and p-values for significance. Post-regression diagnostics are presented McFadden pseudo-r^2 and p-value of the Hosmer-Lemeshow test.

lower QoL than men; (2) improvement by surgery was higher in women; and (3) women return to work at a similar rate as do men after lumbar fusion surgery.

Women have higher baseline values for pain and lower function and QoL than do men before lumbar disc herniation surgery [24]. Our study confirmed this finding even for patients with lumbar fusion. Interestingly, our finding from the SWESPINE that women improved at the same rate as men did after lumbar fusion stands against several previously published study results. Ekman et al. [8] report that the main determinant of favorable patient outcome after lumbar fusion is patient work status (p<.001), followed by male gender (p=.004) and exercise (p=.025). They suggest that it seems reasonable to inform not working female patients who do not exercise on the less than optimal chances of an excellent outcome. The retrospective analysis of 127 patients who underwent fusion surgery because of isthmic spondylolisthesis by Gehrchen et al. [6] find that female gender is related to a less satisfactory outcome (p=.012).

There are several possible explanations for the less favorable results of spinal fusion in women and for our finding that women have worse pain and function preoperatively:

Table 3
Logistic regression of return to work at 1 and 2 years postoperatively with regard to gender, age, smoking, and analgesics at baseline

	1-year follow-up				2-year follow-up			
		95% CI				95% CI		
	OR	2.5%	97.5%	p	OR	2.5%	97.5%	p
Female gender	0.87	0.75	1.02	.08	0.99	0.85	1.15	.90
Age	0.98	0.97	0.99	<.01	0.97	0.97	0.98	<.01
Smoking	1.08	0.88	1.31	.48	1.11	0.90	1.35	.33
Analgesics	1.10	0.87	1.41	.42	0.93	0.74	1.18	.53
r^2	0.02			.28	0.02			.39

Odds ratio (OR) presented with 95% confidence interval. Post-regression diagnostics are presented with McFadden pseudo-r^2 and p-value of the Hosmer-Lemeshow test.

Table 4
Logistic regression of dropout after 1 and 2 years

	1-year follow-up				2-year follow-up			
		95% CI				95% CI		
	OR	2.5%	97.5%	p	OR	2.5%	97.5%	p
Male gender	1.19	0.98	1.43	.07	1.17	0.99	1.38	.06
Age	0.98	0.97	0.99	<.01	0.98	0.97	0.99	<.01
Smoking	1.25	0.99	1.59	.06	1.31	1.06	1.61	.01
BMI	1.02	0.99	1.04	.20	1.02	1.00	1.05	.02
Not working	1.29	1.05	1.59	.02	1.20	1.01	1.44	.04
Analgesics	1.01	0.76	1.38	.93	1.01	0.78	1.32	.92
Previous spine surgery	1.30	1.07	1.57	.01	1.27	1.07	1.50	.01
r^2	0.51			.31	0.44			.20

Odds ratio (OR) presented with 95% confidence interval. Post-regression diagnostics are presented with McFadden pseudo-r^2 and p-value of the Hosmer-Lemeshow test.

Women have lower nociceptive pain thresholds. Myers et al. [25] report that even though being a predictor of pain tolerance, gender does not explain the observed sex-related difference in pain reactivity, which they determined with systolic blood pressure reaction to nociceptive pain stimulation. It is still unclear which underlying mechanisms control estrogen-related pain modulation, and endocrinological pain modulation will be a hot topic in future neurophysiology research [26]. If estrogen reduced the pain threshold in our female patients, their greater improvement in leg and back pain 2 years postoperatively weighs even more in comparison with men.

Women have more perioperative complications. The retrospective cohort of 1,518 patients by Pochon et al. [16] finds a higher rate of surgical complications for women (10% vs. 4% in men, p<.0001), most of which were due to a higher rate of dural tears. The general complication rate was also higher in women than in men (9% vs. 5%, p=.002), partially explained by more prevalent urinary tract infections in women (3% vs. 1%).

Women are more reluctant to undergo surgery and are therefore operated on in a later stage of their disease. Karlson et al. [27] report that men set up for a knee replacement have greater trust in the competency of doctors, whereas women have greater fear of bad outcomes and are willing to wait longer until surgery despite their functional deficit. This finding stands in contrast to the study from Hawker et al. [28], who do not observe any gender differences in willingness to undergo surgery, but find women instead to be less risk averse than men. Still, women seem to gather more information on risks and benefits than do men before hip or knee arthroplasty (p<.001) [29]. The only study on patients with spinal surgery in this regard is published by Bono et al. [30], where patient's acceptance of surgical complication risks in lumbar fusion has no association to female gender (n=118). In our study, we do not have information about duration of pain, and therefore this issue was not addressed.

Surgeon gender affects gender-discriminating patient selection and outcome measurement. Another possible variable influencing gender-related patient outcome is the surgeon's gender, being predominantly male in Sweden. Robinson and Wise [31] find female nurses to rate observed pain 8–10 points higher on a 100-point VAS scale than their male colleagues (p<.05). The pain reported by female individuals is treated more often with psychological and psychopharmacological measures compared with the pain reported by men (p<.05), irrespective of the investigator's gender [14]. This is supported by the finding that surgeons are less willing to offer arthroplasty to a female patient with hip or knee osteoarthritis than to a male patient (OR 0.63, p<.01) [28]. Similar findings are observed for patients with lumbar spinal stenosis, where female patients have worse odds of being treated surgically (OR 0.64, p=.21) [15].

Which influence the surgeon's gender role perception has on patient selection is not well understood. Lattig et al. [32] describe a tendency for spine surgeons to overestimate the global outcome (compared with the patient's rating) more often in women (27.7%) than in men (22.8%), but the difference fails to reach significance (n=1,113, p=.13), and no surgeon gender–related outcome is assessed.

In the presented prospective investigation, we could not assess surgeon gender–associated differences in functional outcome, because these data were not available in the SWESPINE. Because follow-up was performed with standardized forms without patient-surgeon interaction, no postoperative surgeon-gender bias can be expected in our study.

The strength of our study is the nationwide design of the SWESPINE. Results from the registry can be considered representative for all patients in Sweden. The unique personal identification number ensured that loss to follow-up is relatively low because all patients can be traced and contacted for follow-up. The patients submitted a preoperative questionnaire, which allowed us to compare preoperative and postoperative pain and QoL without the risk of recall bias. By using validated PROMs for which MCID have been previously determined, the value of the collected data increases, and the usefulness of this information clinically must be stressed.

The major limitation of our study was the response rate of 68% at the 1-year follow-up and 62% at the 2-year follow-up. A higher response rate would have been preferable and would have increased the power of the study. However, our main variable of interest—gender—was not associated with dropout. Similar to other registry studies, lower age was related to dropout [33]. The uni-national registry design has an inherent population bias, which weighs strong with regard to highly subjective variables as pain and QoL, being modulated by cultural and genetic factors [34]. Therefore, the conclusions of this study cannot be generalized and should be reinvestigated in various topographic and socioeconomic contexts.

Because of the noncomprehensive dataset in the SWESPINE database, not all variables of interest were available for inclusion in the regression models. Important covariates, that is, depression [35] or comorbidity [36], could not be included owing to the registry design, even though they could have added to the predictive value of our models. Additionally, the inclusion of covariates in the regression models was based on researcher consensus. With automated (ie stepwise) methods for variable inclusion, this important covariate selection bias could have been reduced [37].

In our cohort of Swedish men and women, gender did not seem to be of importance in the decision whether to operate on a patient, which may lead to undertreatment of female patients. These data add to the available knowledge and must be followed by a constructive discussion on our decision making with regard to lumbar fusion.

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