



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. © 2016 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

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 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.

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