



Sex differences in lumbar degenerative disc disease



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ARTICLE INFO

Article history:

Received 23 February 2016

Received in revised form 4 April 2016

Accepted 8 April 2016

Available online 8 April 2016

Keywords:

Sex differences

Timed-up-and-go test

Functional impairment

Health-related quality of life

Degenerative disc disease

ABSTRACT

Objectives: A growing number of studies focus on sex differences in the pre- and postoperative setting in patients with degenerative disc disease (DDD). The exact pathomechanism behind this phenomenon, however, remains unclear. The objective of this study was to investigate pre- and postoperative sex differences in patients with lumbar DDD.

Patients and methods: In a prospective two-center study, back and leg pain (Visual Analogue Scale (VAS)), functional disability (Oswestry Disability Index (ODI) and Roland-Morris Disability Index) and health-related quality of life (HRQoL) (EuroQoL 5D and Short-Form (SF12)) were collected for patients scheduled for lumbar spine surgery. In addition to the subjective functional impairment (SFI), objective functional impairment (OFI) was estimated using age- and sex-adjusted cut-off values for the timed-up-and-go (TUG) test. The 6-week responder status was defined using minimally clinically important differences of the ODI, SF12 PCS, VAS back and leg pain in all patients. Six months and one year follow-up (FU) was available in $n = 127$ and $n = 87$ patients, respectively.

Results: The patient cohort comprised of $n = 214$ patients (41.6% females). Preoperatively, female patients scored significantly worse on VAS back and leg pain, ODI and SF12 PCS ($p < 0.033$), while OFI was similar ($p = 0.334$). At the 6 week FU, sex-related differences had resolved for SFI and OFI was similar as well ($p = 0.333$). There were no sex differences in the mean improvement after 6 weeks for all measures of pain intensity, functional impairment and HRQoL ($p > 0.182$). Male and female patients profited equally on measures of SFI and HRQoL up to six months and one year after surgery ($p > 0.091$).

Conclusion: Preoperatively, female patients scored worse in terms of SFI, while OFI was similar. Consecutively, OFI appears to be less prone to sex bias and may thus serve as a valuable surrogate-marker of disability. The disadvantageous preoperative SFI-status did not translate into worse postoperative results, as no sex differences were present at the 6-week, 6-months and 1-year follow-up.

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1. Introduction

A growing number of studies for patients with lumbar degenerative disc disease (DDD) focus on sex differences in terms of experience and perception of pain, functional impairment and health-related quality of life (HRQoL) [1–7]. Correspondingly, sex-related differences have been reported in postoperative outcome and satisfaction in patients after spine surgery [8–13]. Katz et al. found that females had worse functional status than males prior

to laminectomy for lumbar spinal stenosis (LSS) [11]. However, females had comparable or even greater functional improvement after surgery compared to males. Häkkinen et al. studied changes of the Oswestry Disability Index (ODI) in 38 females and 60 males pre- and postoperatively for lumbar disc herniation (LDH) with a 1-year follow-up (FU) [3]. The authors reported significantly higher preoperative mean ODI for females compared to males. The ODI decreased by 38% in females and by 34% in males at the 1-year FU. Interestingly, the greatest improvement for both sexes was observed during the first 6 postoperative weeks. Thus, the authors concluded that the early (6 week) postoperative outcome appears to be a reliable indicator for the overall postoperative outcome. Strömquist et al. reported sex differences in 136 females and 165 males undergoing LDH surgery [14]. Preoperatively, females had more back pain and functional disability, as well as lower HRQoL.

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At the 1-year FU, females reported a higher rate of analgesics use, a higher degree of postoperative back and leg pain and less improvement regarding disability and HRQoL. More recently, the same group reported a sex difference analysis in a national register study including 15'631 patients scheduled for LDH surgery [7]. Females reported inferior walking ability, consumed more analgesics, reported higher level of Visual Analogue Scale (VAS) leg pain and had higher functional disability and inferior HRQoL.

Correspondingly, also our group found significant sex differences in respect to pain intensity, subjective functional disability and HRQoL in a study with 127 females and 178 males scheduled for lumbar spine surgery [2]. Female patients reported higher VAS back and leg pain, higher functional disability and reduced HRQoL than male patients. We recently proposed the introduction of the timed-up-and-go (TUG) test as a novel measure of objective functional impairment (OFI) to evaluate female and male patients [2,15,16]. Using previously validated age- and sex-adjusted cut-off values for OFI, no sex-related differences were found at baseline [2,15]. It appeared that OFI allowed for an objective patient evaluation without sex-bias.

In view of the contradictory data on outcome in male and female patients undergoing surgery for lumbar DDD, the aim of the current work was to investigate postoperative sex differences in subjective and objective outcome measures including measures of pain intensity, functional impairment and HRQoL.

2. Methods

2.1. Study design

Prospective two-center study (University Hospital Geneva (HUG) and Cantonal Hospital St.Gallen (KSSG)) on consecutive patients scheduled for lumbar spine surgery between September 2013 and May 2015 for the following diagnoses: (1) LDH, (2) LSS and (3) lumbar DDD with or without instability requiring lumbar fusion (transforaminal lumbar interbody fusion (TLIF), posterior lumbar interbody fusion (PLIF) or extreme lateral interbody fusion (XLIF)). Exclusion criteria for study participation were age < 18 years, pregnancy, known rheumatic disease and severe neurological deficits (unable to perform the TUG test, thus walk a 3 m distance twice and sit down again).

2.2. Recorded parameters

General demographic data, comorbidity as defined by the Charlson Comorbidity Index (CCI) and the American Society of Anaesthesiologists (ASA) score, smoking status and body mass index (BMI) were assessed in all patients. A comprehensive patient evaluation was performed before surgery, as well as 3 days (D3) and 6 weeks (W6) after surgery. Intensity of back and leg pain was measured with the visual analogue scale (VAS). Functional impairment was assessed with the validated disease-specific questionnaires ODI and Roland-Morris Disability Index (RMDI), whereas HRQoL was assessed with the Euro-Qol 5D (EQ5D) index score and the 12-Item short-form health survey (SF12) including the two physical and mental composite scores PCS and MCS. OFI as defined by age- and sex-corrected cutoff-values, using the TUG test, was measured for all patients at baseline and on D3 postoperatively [15]. For a subgroup of n=100 patients, OFI was also measured at W6 after surgery in the outpatient clinic. Long-term follow-up (FU) using the ODI, RMDI, EQ5D and SF12 questionnaires, as a mailed survey, was available for all patients operated at KSSG.

2.3. Ethical considerations

The study was approved by the local institutional review boards (HUG: 14-079 and KSSG: 14/049). All patients gave written informed consent.

2.4. Statistical considerations

Demographic baseline data were described using frequencies and percentage. Imbalances of categorical variables between male and female patients were tested using Pearson Chi² test. The Mann-Whitney *U* test was used to test for imbalances between the sex groups for variables that are continuous. Using the TUG test raw times, z- and t-scores were calculated according to the following formulas: z-score=(TUG test time – mean normal TUG test/standard deviation (SD) of normal TUG test) and t-score= 10 × z-score + 100. The following age- and sex-adjusted means and SDs of normal TUG test times (in seconds (s)) were used: males ≤ 60 years: mean 4.75 s, SD 1.22 s; males > 60 years: mean 6.45 s, SD 3.11 s; females ≤ 60 years: mean 6.00 s, SD 1.63 s; females > 60 years: mean 7.57 s, SD 3.14 s z- and t-scores were compared at each study visit using two-sided student's *t*-tests [15].

No, mild, moderate or severe OFI was determined using the previously determined age- and sex-adjusted cutoff-values for upper limit of normal (males, ≤ 60 years: 7.58 s; males, > 60 years: 13.69 s; females, ≤ 60 years: 9.80 s; females, > 60 years: 14.89 s) as well as for the 33rd percentile (males, ≤ 60 years: 8.97 s; males, > 60 yrs: 15.56 s; females, ≤ 60 yrs: 13.30 s; females, > 60 years: 19.00 s) and 66th percentile (males, ≤ 60 years: 11.92 s; males, > 60 years: 21.95 s; females, ≤ 60 years: 17.22 s; females, > 60 years: 25.22 s) [17].

Presence and degree of OFI at each study visit were compared using Pearson Chi²-tests. We estimated the effect size of the relationship between sex and moderate/severe OFI or the responder-status of subjective measures of pain, functional impairment and HRQoL, respectively. Thus, OFI was additionally transformed into a binary variable indicative of no OFI or mild to severe OFI. The W6 responder status for subjective functional impairment (SFI) was calculated using previously published minimal clinically important differences (MCID) for ODI (12.8), SF12 PCS (4.9), VAS back pain (1.2) and VAS leg pain (1.6) [18]. Following the binary transformation, logistic regression analysis was used. First, a univariate model was built to assess relationships without adjustment, and then a multivariate model was built using forced-entry methodology without stepwise or other automated variable selection methods. Multivariate analysis was corrected for baseline group differences (age, working status and ASA grade). Effect size before and after adding further variables to the multivariate model were tested for changes in effect size of the current model.

The software used for the statistical analysis was Stata v14 (StataCorp LP, College Station, Texas, USA). P values < 0.05 were considered statistically significant.

3. Results

The complete patient cohort with available FU information included 214 patients (89 females, 41.6%) with a mean age of 59.2 years (SD 15.4). Baseline demographic and surgical parameters are shown in Table 1. Before hospitalization, 87 (40.7%) patients worked full- or part-time, 25 (11.7%) were not working, 9 (4.2%) were disabled and 93 (43.4%) were retired. The full cohort showed significant differences in the work status and procedure type with significantly more males working full- and part-time than females (p=0.018). A total of 108 (50.5%) patients underwent microdiscectomy for LDH or recurrent LDH, 76 (35.5%) patients had uni- or

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