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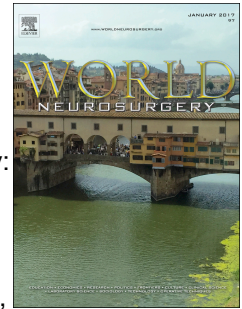
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Risk factors for negative global treatment outcomes in lumbar spinal stenosis surgery: a mixed effects model analysis of data from an international spine registry

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1 Abstract

2 **Objective:** To determine risk factors for negative global treatment outcomes (GTO) as self-assessed
3 by patients undergoing surgical treatment for lumbar spinal stenosis (LSS).

4 **Methods:** Patients from the Spine Tango registry undergoing first-time surgery for LSS were
5 analyzed. The primary outcome was GTO measured at the last available follow-up ≥ 3 months
6 postoperatively using a single question rating how much the operation had helped the patient's back
7 problem (negative=no change/operation made things worse). A 2-level logistic mixed effects model
8 with the treating department as the random effect was used to assess factors associated with a negative
9 outcome.

10 **Results:** 4,504 patients from 39 departments in ten countries were include. Overall, 14.4% of patients
11 reported a negative GTO after an average follow-up of 1.3 years. In patients with dominant leg pain,
12 negative outcome was associated with higher baseline back pain; in those with dominant back pain, it
13 was associated with higher baseline back pain, ASA ≥ 3 , lower age, not having rigid stabilization, not
14 having disc herniation, and the vertebral level of the most severely affected segment (L5/S1 vs L3/4).
15 Four departments had significantly higher odds of a negative outcome, while one department had
16 significantly lower odds. Three out of the four negative effects were related to two departments from
17 one country.

18 **Conclusions:** LSS surgery fails to help at least one in 10 patients. High baseline back pain is the most
19 important factor associated with a negative treatment outcome. Department-level and potentially
20 country-level factors of unknown origin explained a non-negligible variation in the treatment results.

21

22 Keywords

23 Spine Tango; lumbar spinal stenosis; negative outcome; mixed effect model

24 Introduction

25

26 Degenerative lumbar spinal stenosis (LSS) is one the underlying indications for 42% of all spine
27 surgeries recorded in the international Spine Tango registry¹. LSS is characterized by a narrowing of

1 the central canal and/or the intervertebral foramen due to degenerative changes, and possibly also
2 genetic factors, leading to compression of neural and vascular elements in the lumbar spine².
3 According to the Framingham population-based study, between 19-47% of people aged over 60 years
4 have radiological evidence of spinal stenosis on computed tomography, depending on the criteria
5 used³. With increasing life expectancy, the overall prevalence of LSS will continue to increase⁴.

6
7 The initial treatment approach is usually conservative. If conservative treatment proves unsuccessful,
8 surgery is advocated and has been shown to result in better outcomes than non-operative treatment⁵⁻⁷.
9 Surgical options include decompression alone, decompression with (instrumented) fusion, and
10 decompression with posterior dynamic stabilization. The relative efficacy of each of these
11 interventions in terms of the reduction in pain/disability and improvement in walking capacity remains
12 uncertain⁸. Moreover, patients with dominant back pain as opposed to dominant leg pain appear to
13 respond differently to surgical decompression. Kleinstuck et al. and later Pearson et al. reported
14 significantly less favorable outcome after decompression in patients with dominant back pain^{9, 10}.
15 Beyond treatment and patient characteristics, there is still a limited understanding of other factors that
16 may potentially be associated with treatment efficiency, such as hospital characteristics, standard
17 clinical procedures and healthcare systems. To date, the association of the latter with treatment
18 outcome in LSS has not been studied. Patient characteristics have been scrutinized frequently,
19 although they account for only a proportion of the variance in poor outcome. There is growing interest
20 in hospital benchmarking and quality assurance, which requires good understanding of the variation in
21 treatment outcomes.

22
23 Much of the published literature on LSS has focused on analyzing factors thought to be associated
24 with an increased likelihood of achieving the most favorable treatment outcome^{1, 11}, or on finding a
25 balance between benefits and harms to the patient¹². However, in view of the ethical principle of non-
26 maleficence, it is equally important to analyze cases of failed therapy.

27

1 The aim of this study was to determine potential risk factors for negative global treatment outcomes
2 (GTO) as self-assessed by patients who had undergone a surgical treatment for degenerative LSS. We
3 hypothesized that risk factors associated with negative outcome are apparent at both the patient and
4 hospital-level. Based on the evidence of different prognoses for patients with dominant back pain
5 rather than dominant leg pain⁹, the analyses were stratified for these two groups.

7 **Materials and Methods**

8 *Study design*

9 We conducted a case-control study using data from the international spine registry Spine Tango,
10 hosted at the University of Bern¹³. The data were collected in a prospective observational multi-center
11 manner. Physician-based forms are used to document demographic and diagnostic data, previous
12 treatments and surgical details. The registry also collects data from the Core Outcome Measures Index
13 (COMI) completed by the patients themselves either at the treating center or independently at home.
14 The last three iterations of the Spine Tango surgery data collection form (versions 2005, 2006, and
15 2011) were used in the analysis. These form versions covered the period from 2004-2017 and included
16 patient data from 114 hospitals in 17 countries.

18 *Patient population*

19 The inclusion criteria included: diagnosis of degenerative LSS¹⁴, aged between 18 and 100 years,
20 documented American Society of Anesthesiologists (ASA) classification, any surgical decompression
21 procedure before 01.2017. The diagnosis of degenerative LSS as primary pathology¹⁴ precluded the
22 concomitant degenerative pathologies spondylolisthesis, deformity and instability, and additional main
23 pathologies such as tumor, inflammation etc.; it also required that laminotomy, hemi-laminectomy,
24 laminectomy, partial facet joint resection or the use of an interspinous spacer be one of the surgical
25 measures used. Patients also had to have completed both a pre-operative patient self-assessment form
26 and at least one post-operative form, 3-30 months after the index surgery. Exclusion criteria included:

1 anterior dynamic stabilization, any previous spine surgery, and hospitals from countries with a lacking
2 validated version of the COMI available in the patient's language (validated ten languages).
3 If multiple surgeries were documented for a patient, only the first surgery for LSS was considered,
4 with the follow-up COMI being the latest one prior to any subsequent surgery. If multiple follow-up
5 forms were available for a patient, the latest dated form (before any subsequent surgery if the patient
6 was re-operated) was used for analysis.

7

8 *Outcome*

9 Patients completed the Spine Tango patient self-assessment form that includes the COMI. The COMI
10 is a self-administered questionnaire¹⁵ consisting of seven questions evaluating five dimensions: pain
11 (back and leg), back-related function, symptom-specific well-being, general quality of life and
12 disability (social and work)¹⁶. Two pain graphic rating scales (GRS 0-10 points) capture back and leg
13 pain, and all other items use a 5-point scale. For the summary score the average of the scores for all
14 five dimensions (each transformed to 0–10) is calculated¹⁶. At follow-up, the patient self-assessment
15 form includes an additional question on the patient's assessment of the GTO ("Overall, how much did
16 the operation that you received help your back problem?") with five response options ("helped a lot",
17 "helped", "helped only little", "did not help", or "made things worse"). For the purposes of this
18 analysis, a "negative" global treatment outcome (poor and very poor outcome) was defined as one
19 where the patient reported that surgery either "didn't help" or "made things worse". Patients who
20 reported that surgery "helped" or "helped a lot" were defined as having a "positive" global treatment
21 outcome (good and very good outcome). We excluded patients who reported that surgery "helped only
22 little" (middling cases), to have distinct cases and controls.

23

24 *Statistical analysis*

25 Patients were analyzed separately according to whether they reported predominant leg pain (leg
26 pain > back pain; "LP") or back pain equal to or greater than leg pain (back pain \geq leg pain; "BP").

1 The difference between pre- and post-operative COMI scores was calculated to assess whether the
2 observed change in COMI score was consistent with the reported global treatment outcome.

3 Bivariate comparisons of pre-operative patient and treatment characteristics between the groups were
4 performed using Chi-square test for categorical data and Wilcoxon rank-sum test for continuous data.

5

6 Considering the hierarchical structure of the data, 2-level (1-patient, 2-hospital department)
7 multivariate logistic regression models were used to analyze factors associated with a negative
8 outcome. The treating department was assessed as the second level, and the department specific
9 intercepts were used to describe the department specific deviations from the overall average.

10 Covariates included in the model as fixed effects were: age and sex; the continuous variables for back
11 pain, leg pain, and COMI scores at baseline, follow-up rate, and time between index surgery and
12 follow-up (months); binary (yes/no) variables for the additional diagnoses of disc degeneration and of
13 disc herniation, surgical measures of partial facet joint resection, full facet joint resection, laminotomy,
14 hemilaminectomy, laminectomy, foraminotomy, discectomy, sequestrectomy, fusion, rigid
15 stabilization, posterior dynamic stabilization; and categorical variables for ASA classification (1, 2,
16 ≥ 3), extent of lesion (1, 2-3, >3 segments), most severely affected segment (L1/2, L2/3, L3/4, L4/5,
17 L5/S1), duration of previous conservative treatment (none, <6 months, 6-12 months, >12 months), and
18 surgeon credentials (specialist, in training, other).

19 The GLIMMIX procedure was used for the multilevel modelling. To examine the effect of hospital,
20 the residual pseudo-likelihoods were compared in the models with and without the random effect
21 using the COVTEST command to assess whether the models with random effect of the departments
22 fitted the data better.

23 The percentage of reduction in variance achieved in the 2-level model in comparison with the simpler
24 1-level (department only) model indicated the degree to which individual patient and department level
25 characteristics accounted for the observed outcome variation. A comparison of patient and treatment
26 characteristics between departments with greater odds for a negative outcome versus all others was
27 performed using multivariate logistic regression, in which all baseline factors were included and the

1 likelihood of being a department with negative outcome was modelled separately for LP and BP
2 patients.

3 The level of significance was 0.05. All statistical analyses were conducted using SAS9.4 (SAS
4 Institute Inc., Cary, NC, USA).

5

6 **Results**

7 *Patient, surgeon, and department characteristics*

8 The database contained data on 103,164 spine surgeries between 01.2004-05.2017. Of 10,675 patients
9 meeting the medical inclusion criteria, 4,836 (45.3%) had completed a patient assessment form both
10 preoperatively and postoperatively, with their last available follow-up being between 3 and 30 months
11 postoperatively. Of these, 4,504 were available for inclusion in the analysis, after patients reporting
12 that surgery “helped only little” were excluded (Fig. 1). The study population of 4,504 patients had
13 received surgery for LSS between 10.2004-12.2016, in one of 39 departments (from 38 centers) in ten
14 countries (Australia, Austria, Belgium, Germany, Italy, Poland, Portugal, Switzerland, UK, and USA).
15 Of the patients analyzed, 2,312 (51.3%) reported back pain equal to or greater than leg pain,
16 preoperatively.

17 Overall, at the time of the latest available follow-up, 648 patients (14.4%) reported that their surgery
18 did not help their back problem or made things worse. A negative outcome was reported by 251
19 (11.4%) of the patients with predominant leg pain, and 397 (17.2%) of the patients with predominant
20 back pain, both at a mean follow-up time of 1.3 years after the index surgery (overall inter-quartile
21 range 0.9–2.0 years). A comparison of patient and treatment characteristics for both analysis groups is
22 presented in Table 1.

23

24 In the *LP* group, compared with patients with a positive outcome, patients with a negative outcome
25 were younger, more often had L5/S1 rather than L4/5 as the affected level, more often had surgery
26 performed by a surgeon in training or with other surgeon credentials, and more often were
27 decompressed using laminectomy; a lower proportion of them had received laminotomy, fusion, and

1 rigid and dynamic stabilization, and they had higher leg pain, back pain and COMI scores at baseline
2 (Table 1). In the *LP* group, the mean reductions in leg pain were 0.8 ± 2.6 (from 7.9 points at baseline)
3 and 5.2 ± 3.0 points (from 7.6 points at baseline) for those reporting a negative outcome and a positive
4 outcome, respectively ($p < 0.001$); the mean changes in back pain were an increase of 1.2 ± 3.8 (from
5 4.7 points at baseline) and a reduction of 1.5 ± 3.0 points (from 3.9 points at baseline), respectively
6 ($p < 0.001$). Finally, the reductions in mean COMI score in the groups were 0.0 ± 1.7 (from 7.8 points
7 at baseline) and 4.5 ± 2.7 points (from 7.4 points at baseline), respectively ($p < 0.001$).

8
9 In the *BP* group, compared with patients with a positive outcome patients with a negative outcome
10 were younger, more often had received either no preoperative conservative treatment or treatment for
11 6-12 months' duration, more often had L5/S1 rather than L4/5 as the affected level, more often had
12 surgery performed by a surgeon in training, and more often were decompressed using laminectomy; a
13 lower proportion of them had received partial facet joint resection, fusion, and rigid and dynamic
14 stabilizations, and they had higher leg pain, back pain and COMI scores at baseline (Table 1). In the
15 *BP* group, the mean reductions in leg pain were 0.0 ± 3.2 (from 6.6 points at baseline) and 3.6 ± 3.5
16 points (from 6.3 points at baseline), for those reporting a negative outcome and a positive outcome,
17 respectively ($p < 0.001$); the mean changes in back pain were 0.6 ± 2.4 (from 7.7 points at baseline) and
18 4.1 ± 3.0 (from 7.2 points at baseline) points, respectively ($p < 0.001$). Finally, the reductions in mean
19 COMI score in the groups were 0.2 ± 1.7 (from 8.2 points at baseline) and 4.0 ± 2.7 points (from 7.6
20 points at baseline), respectively ($p < 0.001$).

21 22 *Multi-level analysis*

23 Variance of LP and BP model was reduced by 16% and 17%, respectively, when individual patient
24 and department level data were included, with a strong effect of department. Of the remaining
25 variation in both random intercept models, 14% of the variance across departments could be explained
26 by patient factors and 86% of the variance remained unexplained.

27

1 One factor was associated with negative global outcome in patients with predominant leg pain and six
2 factors in patients with predominant back pain (Table 2). Back pain score prior to surgery was a risk
3 factor for both groups, with the odds of a negative outcome increasing 9% and 14% for each point
4 increase in the pain scale for those with predominant leg pain and predominant back pain,
5 respectively. In *BP* patients, the odds of a negative outcome also increased with $ASA \geq 3$ in
6 comparison to *ASA* 1. The corresponding odds decreased by 2% per year of age, by a factor 0.22 if
7 rigid stabilization was performed, and by a factor of 0.60 if L3/4 was the most affected segment
8 compared with L5/S1, and by a factor of 0.65 if the patient also had disc herniation documented
9 (Table 2).

10

11 The likelihood ratio test comparing the covariance structures of the data with and without the random
12 effect of the department was significant ($p < 0.001$) in both models, implying that the model including a
13 random effect of the treating department fitted the data better.

14 Of the 35 departments with *LP* patients, the *LP*-model revealed two departments, from the same
15 country, with a significantly higher odds of a negative outcome after adjusting for patient and
16 treatment characteristics (Fig. 2): in one, the odds of a negative outcome were 2.30-times (95%CI
17 1.29–4.12; $p = 0.005$), and in the other, 2.78-times (95%CI 1.18–6.53; $p = 0.019$) the overall average.
18 For the other departments, there was no significant difference in the odds of a negative outcome
19 compared with average (p all ≥ 0.05) (Fig. 2).

20

21 Of the 36 departments with *BP* patients, the *BP*-model revealed two departments from two different
22 countries with significantly greater odds of a negative outcome (one department of which was the
23 same outlier as for the previous analysis with *LP*), and another department from a third country with a
24 significantly lower odds of a negative outcome compared with the average (Fig. 3): in the first case,
25 the odds of a negative outcome were 2.48-times (95%CI 1.44–4.25; $p = 0.001$), in the second, 2.55-
26 times (95%CI 1.20–5.42; $p = 0.015$), and in the third 0.48-times (95%CI 0.23–0.99; $p = 0.046$) the
27 overall average. For the other departments, there was no significant difference in the odds of negative
28 outcome compared with average (p all ≥ 0.06) (Fig. 3).

1
2 Comparison of patient and treatment characteristics in the departments with greater odds of a negative
3 outcome, the department with lower odds of a negative outcome and other departments are shown in
4 Table 3.

5 **Discussion**

6 *Summary of the results*

7 Overall, 11.4% of the patients with predominant leg pain and 17.2% of the patients with predominant
8 back pain in the cohort reported at the last available follow-up that surgery did not help or made things
9 worse. The mean leg pain relief in the *LP* group and back pain relief in the *BP* group was in each case
10 close to zero. Multi-level analysis revealed one risk factor (higher back pain at baseline) associated
11 with negative global outcome in *LP* patients, and two risk factors (higher back pain at baseline and
12 $ASA \geq 3$) and four protective factors (higher age, rigid stabilization, concomitant disc herniation,
13 affected level being L3/4) associated with negative outcome in *BP* patients. Moreover, the effect of the
14 treating department was significant. In patients with predominant leg pain, two departments, from the
15 same country, had greater odds of negative outcome compared with average. In patients with
16 predominant back pain, there were two departments with greater odds (one of which was the same
17 outlying department as for *LP*, described above) and one department with lower odds of negative
18 outcome. Hence, three out of the five significant effects observed for "department" involved
19 departments from the same country.

20

21 *Clinical implications*

22 Many open questions exist in the diagnosis and treatment of LSS today, and the pressure for
23 comparative effectiveness research and benchmarking is constantly growing. Under these
24 circumstances, understanding the factors associated with a negative treatment outcome is essential to
25 help with patient selection procedures.

26 Based on the studies of Kleinstuck et al.⁹, Pearson et al.¹⁰, and Atlas et al.¹⁷ there is no doubt that
27 patients with predominant back pain have a higher likelihood of an unfavorable treatment outcome

1 than do other LSS patients (patients exhibiting predominant leg pain or no pain predominance). Based
2 on this consideration, we stratified the LSS patients in the present study into two groups. The differing
3 numbers of predictors (one in the *LP*- and six in the *BP*-model) in these patient groups supports the
4 assumption that the two patient groups do indeed differ. In both groups, back pain at baseline was
5 revealed as a risk factor for a negative treatment outcome, which both confirms the results of the
6 previous studies mentioned above and also highlights the importance of an accurate indication for
7 surgical treatment of LSS (see later).

8 We also identified factors associated with a decreased likelihood of a negative outcome in the *BP*
9 group. Increasing age was associated with fewer negative outcomes after adjusting for other
10 confounding factors, although patients with a high ASA grade (≥ 3 ; severe or life-threatening systemic
11 disease) were more likely to have a negative outcome. The explanation for age as an independent
12 predictor, once the effect of ASA was taken into account, is not obvious. It is possible that age is
13 serving as a proxy for a non-observed true predictor. One may speculate that in younger patients, the
14 causes of back and leg pain are more likely to be something other than (or in addition to) degenerative
15 disease, and may confuse the indication, while in the elderly degeneration is clearly in the foreground
16 and responds better to surgery. Another possible explanation is that younger patients have higher
17 expectations, and require a greater improvement in symptoms before judging the operation to be
18 satisfactory in its outcome.

19
20 Undergoing decompression surgery at L3/4, as compared with L5/S1, was found to reduce the
21 likelihood of a negative outcome in *BP* patients. L5/S1 is known to be the biomechanically most
22 problematic spine segment carrying the greatest loading in the spine¹⁸. This segment was affected in
23 about every sixth patient in our study population, while L3/4 was affected in about every fifth case. A
24 trend for higher rates of complications and revisions in L5/S1 and L4/5 is known¹⁹. The majority of
25 our patients had an affected L4/5 segment (>55%), but this segment was not significantly different to
26 L5/S1 in term of the odds of a negative outcome in *BP* patients.

27

1 Good quality studies have reported better surgical outcomes after LSS surgery in patients with
2 predominant leg pain at baseline^{9, 10, 20}. However, according to the SPORT trial, patients with
3 predominant back pain still improved significantly more with surgery than when treated non-
4 operatively¹⁰. Nevertheless, in consideration of the fact that decompression alone did not seem to
5 alleviate low back pain sufficiently, Kleinstuck et al. recommended detailed analysis of the underlying
6 back pain before undertaking LSS surgery⁹. The etiology of back pain cannot always be distinctly
7 attributed to an anatomical region or structure. Leg and back pain in the same patient may also have
8 different etiologies such as muscular and degenerative changes, referred pain and neuropathic pain. In
9 the present study, in patients with predominant back pain at baseline decompression alone (as opposed
10 to with additional rigid stabilization) increased the odds of a negative outcome by a factor of 4.55
11 (=1/0.22 the odds ratio for rigid stabilization), although relatively wide confidence intervals were seen
12 implying that the estimate is less certain. Primary or iatrogenic instability or significant foraminal
13 stenosis that may not be sufficiently addressed by decompression alone may partly explain the greater
14 likelihood of a negative outcome in these patients. Rigid stabilization eliminates the painful motion
15 whatever the cause of pain. A more focused analysis would be required to accurately explain why
16 rigid stabilization was associated with better treatment outcome after LSS in patients with
17 predominant back pain. Caution is, however, required in recommending the addition of stabilization,
18 in view of the typically increased surgical and general complications associated with it¹². Moreover,
19 hardware failure, screw loosening, and adjacent segment degeneration are further potentially
20 problematic long-term complications associated with rigid stabilization. As such, the simple
21 observation of an association between negative mid-term global treatment outcome and the lack of use
22 of rigid stabilization in patients with predominant back pain at baseline does not support a
23 recommendation for the application of stabilization across the board. The recent Swedish randomized
24 clinical trial (RCT) that included a heterogeneous patient population with and without
25 spondylolisthesis did not observe better clinical outcomes when adding a fusion to a decompression
26 alone²¹, although these findings were not supported by another RCT²².

27

28 In relation to the *BP* model, the diagnosis of herniated disc in addition to stenosis in the LSS patients

1 reduced the likelihood of a negative outcome. Patients with a disc herniation are probably a different
2 patient population. The simplest explanation for this result may be the clear, and relatively easily
3 removable morphological correlate of stenosis (herniated disc) with relatively good prognosis,
4 contrasted with the likely more profusely narrowed spinal canal in LSS cases without herniated disc.
5 It is possible that some patients with preexisting lumbar spinal stenosis are not symptomatic until
6 some notable change occurs. If disc herniation further reduces the space available for the rootlets,
7 patients may suddenly become symptomatic. They may therefore have a shorter duration of symptoms
8 and hence potentially be in better physical condition (shorter time lived with disability before surgery)
9 and thus recover more quickly and to a greater extent after surgery.

10 The influence of the treating department on the proportion of patients with a negative outcome is a
11 further important finding of this study. We were anticipating departments with both higher and lower
12 likelihoods of negative outcomes. Obviously, the vast majority of departments fell into the wide
13 average bandwidth, and "negative" outliers were more common than "positive" ones.

14 The reasons why some departments had inferior results are not obvious. Other influential factors like
15 patient selection may be hidden behind this variable, such as the manner/context in which the
16 questionnaires are administered in the given hospital and the patients' perception of the likely
17 anonymity of the answers they provide. Although the results of the study were adjusted for patient age,
18 sex, comorbidity, and baseline pain levels, other factors such as smoking status and body mass index
19 were not included in the models and may have influenced the treatment results in the departments. We
20 are in dialog with the involved departments to discuss other possible reasons for their outlying results.

21 Further, more detailed data collection and analyses may be required to help understand this finding.

22 Interestingly, three out of four of the statistically significant negative effects of "department" were
23 from a single country out of the ten countries whose data were used in the analyses. One of the outlier
24 departments was among the higher caseload centers. This finding may highlight the influence of
25 national regulation, reimbursement models, and clinical guidelines rather than specific characteristics
26 of individual treating departments alone. Moreover, language issues, different levels of "gratitude" and
27 "optimism/positivity" in the inhabitants of the outlier country may have played an important role in
28 explaining this effect. However, the patients' rating of either positive or negative outcome was

1 commensurate with similar changes (or lack thereof) of pain levels and COMI scores. This can be seen
2 from the almost parallel lines for the change in pain in different departments within a given outcome
3 group, shown in Figure 4. This observation would tend to support a “non-language/cultural” effect on
4 global outcome ratings but doesn't exclude the possibility that simply everything is rated more
5 negatively in the outlier country.

6

7 *Limitations*

8 The study evaluated a patient-based perspective of negative treatment outcome, which may differ from
9 that of the surgeon²³. The question “Overall, how much did the operation that you received help your
10 back problem?” might not reflect all parts of the problem for which surgery was indicated. The
11 patient's perspective is considered to be of greatest importance in elective surgery, but patient-centered
12 outcomes can also be influenced by factors such as information and expectations^{24, 25}, as well as by
13 cultural differences²⁶. Soroceanu et al. showed that greater fulfilment of preoperative expectations
14 leads to higher postoperative satisfaction and better functional outcomes²⁷. Taking into account
15 department-level and potentially country-level factors, future studies should focus also on
16 clinical/surgical outcomes. Our analysis accounted for a number of patient and treatment
17 characteristics; however, further, non-documented factors outside of the data collected in Spine Tango
18 may have influenced the likelihood of a negative outcome. Among others, preoperative depression has
19 been identified as having a negative predictive role in LSS surgery²⁸. Similarly, other ongoing diseases
20 that were not identified and treated at the time of the index surgery may be responsible for the negative
21 outcome. The models also did not include information regarding the technical success of the surgery
22 (such as the extent of decompression or the correctness of screw positioning), postoperative
23 complications, the amount of segmental deformity, the presence of foraminal stenosis, or the duration
24 of symptoms, which all may have influenced the study results.

25 The study population had an overall follow-up rate of just 45.3%, although the follow-up rate of the
26 department had no effect on the outcome (Table 2). Irrespective of the multi-national registry setting
27 and large number of participating centers, this rate should still be considered a limitation of the study.

1 Furthermore, the study was based on observational data from a voluntary registry, which is offered to
2 surgeons for their own quality assurance. Different levels of documentation coverage within the
3 hospitals are possible and may have influenced the study results. Finally, we observed evidence for
4 large variation in treatment outcome across 39 departments, yet were unable to completely explain its
5 causes. A further tightly focused analysis is required for a better understanding of this variation.

6

7 *Conclusions*

8 The study shows that LSS surgery fails to help every tenth patient or more. High back pain at baseline
9 is the most important risk factor associated with a negative treatment outcome. Patients should be
10 advised that decompression will not necessarily relieve their back pain; decompression may also
11 relieve back pain, but it is not the goal of the treatment.

12 Department-level and potentially country-level factors of unknown origin explain a non-negligible
13 variation in treatment results. Further evaluation of such factors using the appropriate methodology to
14 assess causality might allow for the development of measures to promote more standardized spinal
15 care across borders.

16

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20

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26 in St. Andrew's Hospital in Adelaide (Australia); Dept. of Orthopaedic Surgery in University Hospital
27 Graz (Austria); Dept. of Orthopaedic Surgery in Grand Hôpital de Charleroi (Belgium); Dept. of

1 Orthopaedic Surgery in Edith Cavell Clinic of Brussels (Belgium); Dept. of Orthopaedic Surgery in
2 University Hospital of St. Luc (Belgium); Dept. of Orthopaedic Surgery in Saint Pierre Clinic of
3 Ottignies (Belgium); Dept. of Neurosurgery in Köpenick Hospital DRK Kliniken Berlin (Germany);
4 Dept. of Neurosurgery in University Hospital of Cologne (Germany); Dept. of Orthopaedic Surgery
5 and Traumatology in University Hospital of Cologne (Germany); Dept. of Neurosurgery in Hospital
6 Cologne-Merheim (Germany); Dept. of Spine Surgery in Hospital Dortmund (Germany); Group
7 Practice of Orthopaedics and Neurosurgery in Hof (Germany); Dept. of Spine Surgery in Krankenhaus
8 der Barmherzigen Brüder of Trier (Germany); Dept. of Special Spine Surgery in Leopoldina Hospital
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11 Orthopedic Surgery in Orthopedic and Traumatological Clinic Poznan (Poland); Dept. of
12 Neurosurgery in Specialized Medical Center S.A. Polanica (Poland); Dept. of Neurosurgery in
13 Bethesda Hospital of Basel (Switzerland); Dept. of Spine Surgery in Sonnenhof Hospital of Bern
14 (Switzerland); Dept. of Orthopaedic Surgery in Cantonal Hospital of Fribourg (Switzerland); Dept. of
15 Neurosurgery in General Hospital of Fribourg (Switzerland); Dept. of Orthopaedic Surgery in Hospital
16 Schwyz (Switzerland); Dept. of Orthopaedic Surgery and Traumatology in Cantonal Hospital of St.
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25

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28 improvement in quality of life and pain relief in lumbar spinal stenosis relative to patient age:

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41

42 **Figure legends**

43 Figure 1. Study flow chart.

44 Figure 2. Deviations from the overall average for the odds of having a negative outcome in 35 treating
45 departments, from the multivariate mixed effect model in the *LP* sample.

- 1 Note: the significantly deviating centers are in red.
- 2 Figure 3. Deviations from the overall average of having of negative outcome in 36 treating
- 3 departments, from the multivariate mixed effect model in the *BP* sample.
- 4 Note: the significantly deviating centers are in red.
- 5 Figure 4. The pain relief and COMI score improvement in the hospital departments with greater odds
- 6 of negative outcome versus other hospital departments by group.
- 7 Note: depts. – departments.

Table 1. Patient and treatment characteristics of patients with negative versus positive outcomes by predominant type of pain.

Patient and treatment characteristics	Categories/values	LP		Comparison [p-value]	BP		Comparison [p-value]
		Negative outcome	Positive outcome		Negative outcome	Positive outcome	
N [row %]	-	251 (11.4)	1941 (88.6)	-	397 (17.2)	1915 (82.8)	-
Age [years]	Mean \pm SD	65.4 \pm 12.6	67.1 \pm 12.1	0.031	65.1 \pm 13.4	67.7 \pm 11.6	0.002
	Range	37.4 - 91.0	18.7 - 97.1	-	21.8 - 90.6	18.8 - 94.4	-
Sex [%]	Female	45.4	45.8	0.92	46.1	47.8	0.53
Disc degeneration [%]	Yes	15.4	18.3	0.23	14.4	16.7	0.26
Disc herniation [%]	Yes	29.1	28.9	0.94	21.2	24.2	0.20
ASA [%]	1	17.5	19.9	0.65	16.4	15.9	0.12
	2	61.4	58.8		56.9	61.9	
	\geq 3	21.1	21.3		26.7	22.3	
Extent of lesion [%]	1 segment	50.6	48.5	0.72	45.3	44.7	0.70
	2-3 segments	44.2	46.8		49.1	48.6	
	>3 segments	5.2	4.6		5.5	6.7	
Previous conservative treatment [%]	None	18.5	15.2	0.41	19.0	15.7	0.021
	<6 months	26.1	29.9		23.1	29.4	
	6-12 months	24.5	22.9		26.0	21.5	
	>12 months	30.9	32.0		31.9	33.5	
Segment [%]	L1/2	0.4	0.5	0.048	1.8	0.8	0.006
	L2/3	3.2	4.6		6.8	5.8	
	L3/4	20.7	20.5		20.4	25.2	
	L4/5	51.0	57.3		51.6	54.5	
	L5/S1	24.7	17.2		19.4	13.8	
Surgeon credentials [%]	Specialist surgeon	83.7	89.6	0.001	80.9	88.4	<0.001
	Surgeon in training	12.4	9.1		17.1	10.3	
	Other	4.0	1.3		1.3	2.0	
Type of decompression [%]	Discectomy	24.7	25.0	0.92	79.1	74.6	0.06
	Sequestrectomy	8.0	10.7	0.18	6.6	8.0	0.33
	Facet joint resection partial	57.4	63.1	0.08	49.1	61.8	<0.001
	Facet joint resection full	1.2	2.2	0.31	3.3	3.2	0.97
	Laminotomy	48.2	56.3	0.016	46.9	47.7	0.75
	Laminectomy	27.1	17.7	<0.001	30.7	22.8	<0.001
	Hemilaminectomy	14.3	13.0	0.55	15.1	12.4	0.15
	Foraminotomy	49.0	45.4	0.28	42.3	40.3	0.46
Fusion [%]	Yes	5.6	12.2	0.002	10.3	18.6	<0.001
Rigid stabilization [%]	Yes	5.2	12.1	0.001	9.1	18.3	0.002
Post. dynamic stabilization [%]	Yes	1.6	5.2	0.012	2.5	7.6	<0.001
Leg pain at baseline [points]	Mean \pm SD	7.9 \pm 1.8	7.6 \pm 1.8	0.002	6.6 \pm 2.8	6.3 \pm 2.8	0.008
Back pain at baseline [points]	Mean \pm SD	4.7 \pm 2.7	3.9 \pm 2.7	<0.001	7.7 \pm 2.1	7.2 \pm 2.2	<0.001
COMI score at baseline [points]	Mean \pm SD	7.8 \pm 1.6	7.4 \pm 1.7	<0.001	8.2 \pm 1.6	7.6 \pm 1.8	<0.001
Follow-up interval [months]	Mean \pm SD	16.1 \pm 8.5	16.1 \pm 8.4	0.75	16.3 \pm 8.2	15.5 \pm 8.5	0.10

Note: SD – standard deviation. The significantly different p-values are highlighted in bold.

Table 4. The summary of all fixed effects.

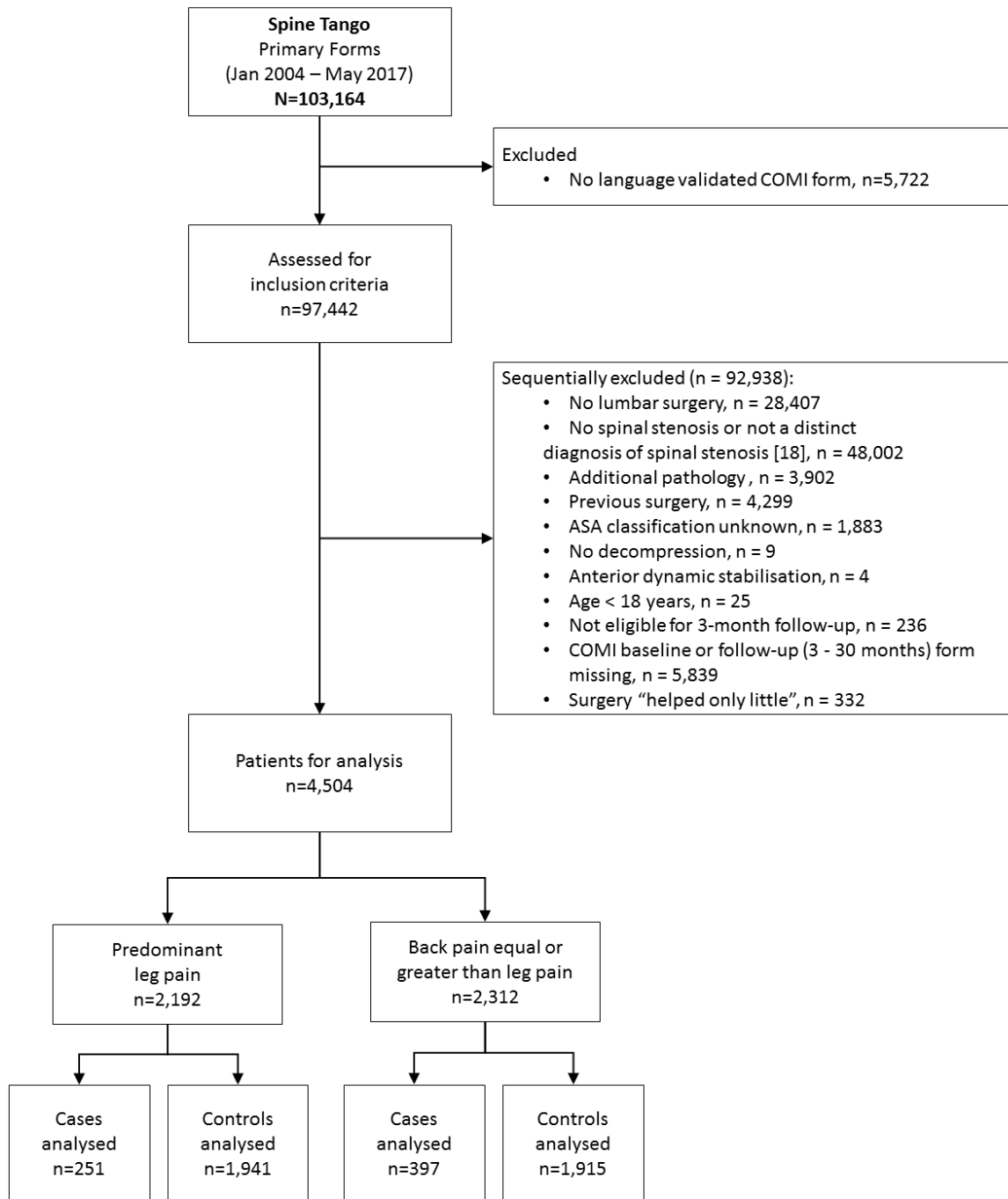
Patient or treatment characteristic	Categories/values	LP		BP	
		p-value	Odds ratio	p-value	Odds ratio
Back pain at baseline	Per point	0.007	1.09 (1.02 - 1.15)	0.002	1.14 (1.05 - 1.23)
Time between surgery and follow-up	Per months	0.05	0.98 (0.97 - 1.00)	0.76	1.02 (0.99 - 1.02)
Degenerative disc disease	Yes vs. no	0.10	1.42 (0.94 - 2.15)	0.97	0.99 (0.69 - 1.44)
Age	Per year	0.11	0.99 (0.98 - 1.00)	<0.001	0.98 (0.97 - 0.99)
ASA	2 vs. 1	0.20	1.36 (0.91 - 2.05)	0.005	1.07 (0.75 - 1.53)
	≥3 vs. 1		1.58 (0.94 - 2.65)		1.76 (1.15 - 2.70)
Surgeon credentials	In training vs. specialist	0.21	0.91 (0.56 - 1.50)	0.67	1.16 (0.80 - 1.67)
	Other vs. specialist		2.16 (0.84 - 5.59)		0.92 (0.35 - 2.93)
Rigid stabilization	Yes vs. no	0.23	0.31 (0.04 - 2.25)	0.015	0.22 (0.07 - 0.72)
Laminotomy	Yes vs. no	0.27	0.78 (0.50 - 1.23)	0.51	1.15 (0.75 - 1.75)
Segment	L1/2 vs. L5/S1	0.39	0.59 (0.07 - 5.30)	0.019	2.57 (0.92 - 7.20)
	L2/3 vs. L5/S1		0.55 (0.24 - 1.26)		0.82 (0.47 - 1.44)
	L3/4 vs. L5/S1		0.78 (0.49 - 1.25)		0.60 (0.40 - 0.91)
	L4/5 vs. L5/S1		0.72 (0.50 - 1.03)		0.75 (0.54 - 1.04)
Facet joint resection partial	Yes vs. no	0.42	1.15 (0.81 - 1.65)	0.96	1.01 (0.74 - 1.37)
Laminectomy	Yes vs. no	0.43	1.25 (0.70 - 2.20)	0.40	1.23 (0.75 - 2.03)
Disc herniation	Yes vs. no	0.44	0.85 (0.55 - 1.31)	0.028	0.65 (0.44 - 0.95)
Discectomy	Yes vs. no	0.45	1.18 (0.76 - 1.85)	0.34	1.21 (0.81 - 1.79)
Foraminotomy	Yes vs. no	0.50	1.11 (0.81 - 1.52)	0.20	0.84 (0.65 - 1.10)
Motion preserving stabilization	Yes vs. no	0.52	0.65 (0.14 - 3.01)	0.59	0.80 (0.32 - 2.00)
Extent of lesion	2-3 vs. 1	0.64	1.10 (0.79 - 1.55)	0.25	1.25 (0.95 - 1.65)
	>3 vs. 1		1.40 (0.67 - 2.94)		1.03 (0.57 - 1.87)
Leg pain at baseline	Per point	0.72	1.02 (0.93 - 1.12)	0.12	0.95 (0.90 - 1.01)
Sex	Female vs. male	0.75	0.95 (0.71 - 1.28)	0.89	0.98 (0.77 - 1.26)
Hemi-laminectomy	Yes vs. no	0.79	1.08 (0.61 - 1.89)	0.42	1.23 (0.74 - 2.04)
Follow-up rate	per 10%	0.86	1.00 (0.98 - 1.01)	0.77	1.00 (0.98 - 1.01)
Fusion	Yes vs. no	0.87	1.16 (0.17 - 7.71)	0.18	2.12 (0.70 - 6.42)
Facet joint resection full	Yes vs. no	0.91	1.08 (0.25 - 4.69)	0.20	1.66 (0.72 - 3.83)
Previous conservative treatment	<6 months vs. none	0.95	0.94 (0.61 - 1.47)	0.20	0.84 (0.57 - 1.22)
	6-12 months vs. none		0.95 (0.60 - 1.50)		1.20 (0.83 - 1.74)
	>12 months vs. none		1.04 (0.68 - 1.61)		1.08 (0.75 - 1.55)
Sequestrectomy	Yes vs. no	0.99	1.00 (0.55 - 1.80)	0.92	0.98 (0.58 - 1.65)

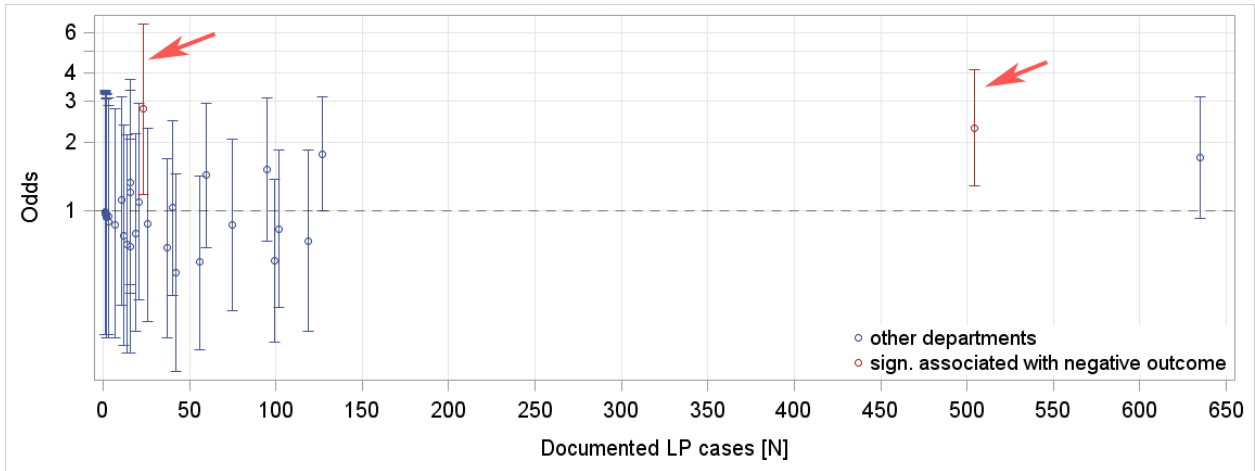
Note: significant fixed effects are in bold.

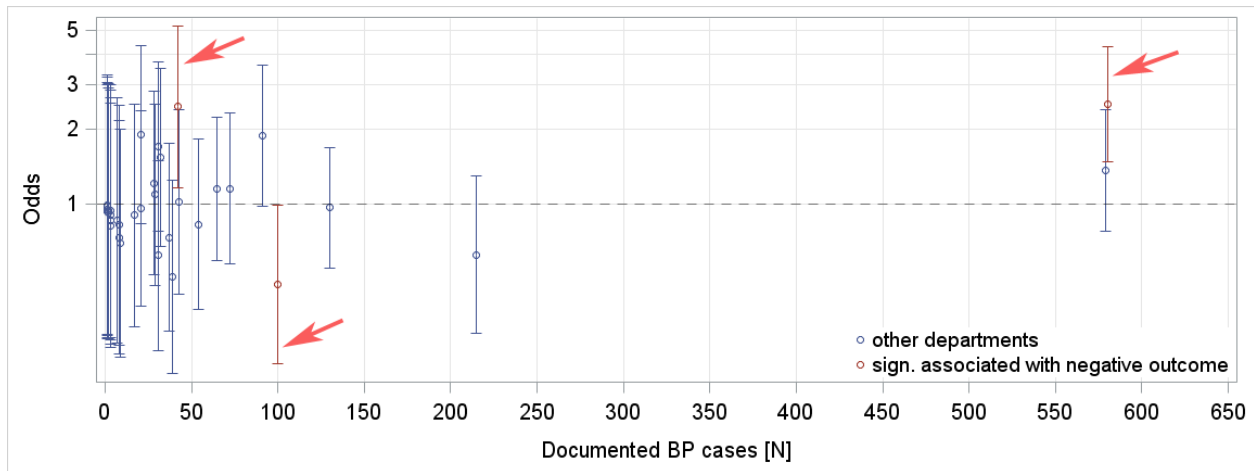
Table 3. Comparison of patient and treatment characteristics in the departments with greater odds of a negative outcome, the department with lower odds of a negative outcome and other departments.

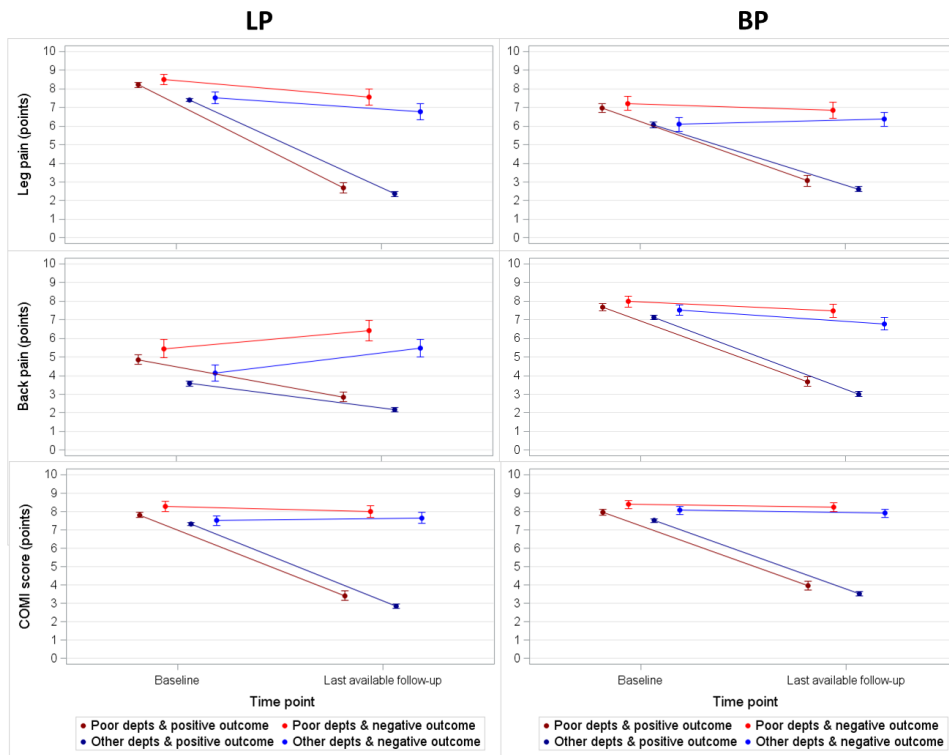
Patient characteristics	Categories/values	LP			BP			
		2 departments with greater odds of poor outcome	Other departments	Comparison[p-value]	2 departments with greater odds of poor outcome	1 department with lower odds of poor outcome	Other departments	Comparison[p-value]
N	-	527	1665	-	622	100	1590	-
Age ± SD [years]	Mean	63.6 ± 12.8	68.0 ± 11.8	<0.001	64.9 ± 13.0	68.5 ± 12.6	68.1 ± 11.4	<0.001
	Range	29.2 - 92.5	18.7 - 97.1	-	18.8 - 94.4	28.9 - 89.0	21.8 - 91.3	-
Sex [%]	Female	43.8	46.3	0.32	45.7	47.0	48.3	0.53
Degenerative disc disease (%)	Yes	13.5	16.5	0.10	9.0	31.0	18.2	<0.001
Disc herniation (%)	Yes	29.8	28.6	0.59	23.8	36.0	22.8	0.011
ASA [%]	1	24.7	18.1	<0.001	20.9	10.0	14.4	<0.001
	2	63.0	57.8		63.2	54.0	60.6	
	>2	12.3	24.1		15.9	36.0	25.0	
Extent of lesion [%]	1 segment	72.5	41.3	<0.001	65.1	32.0	37.7	<0.001
	2-3 segments	26.9	52.7		34.4	65.0	53.3	
	>3 segments	0.6	6.0		0.5	3.0	9.1	
Previous treatment [%]	None	23.0	13.3	<0.001	23.3	-	14.6	<0.001
	<6 months	28.1	30.0		26.0	26.0	29.3	
	6-12 months	28.7	20.8		28.9	30.0	19.1	
	>12 months	20.3	35.6		21.8	44.0	37.0	
Segment [%]	L1/2	0.4	0.5	<0.001	0.5	1.0	1.1	<0.001
	L2/3	2.9	4.9		4.5	7.0	6.5	
	L3/4	15.8	22.0		21.4	22.0	25.7	
	L4/5	54.3	57.4		52.4	61.0	54.2	
	L5/S1	26.8	15.3		21.2	9.0	12.6	
Surgeon credentials [%]	Specialist surgeon	70.2	94.9	<0.001	71.2	99.0	92.5	<0.001
	Surgeon in training	24.1	4.8		24.8	-	7.1	
	Other surgeon credentials	5.7	0.3		4.0	1.0	0.4	
Type of decompression [%]	Discectomy	23.9	25.3	0.52	18.5	46.0	25.7	<0.001

	Sequestrectomy	3.0	12.7	<0.001	3.7	15.0	8.9	<0.001
	FJ resection partial	34.4	71.3	<0.001	30.7	82.0	69.6	<0.001
	FJ resection full	1.1	2.3	0.09	1.1	15.0	3.3	<0.001
	Laminotomy	39.7	60.3	<0.001	31.7	75.0	52.1	<0.001
	Laminectomy	41.0	11.8	<0.001	48.2	10.0	15.6	<0.001
	Hemi-laminectomy	13.9	12.9	0.58	13.7	11.0	12.7	0.70
	Foraminotomy	51.2	44.1	0.004	44.7	37.0	39.3	0.05
Fusion [%]	Yes	1.5	14.6	<0.001	2.1	48.0	21.3	<0.001
Rigid stabilisation [%]	Yes	1.3	14.4	<0.001	1.6	45.0	20.9	<0.001
Dynamic stabilisation [%]	Yes	-	6.3	<0.001	0.3	16.0	8.7	<0.001
Leg pain at baseline \pm SD [points]	Mean	8.3 \pm 1.5	7.4 \pm 1.9	<0.001	7.0 \pm 2.6	5.8 \pm 2.7	6.1 \pm 2.8	<0.001
Back pain at baseline \pm SD [points]	Mean	5.0 \pm 2.7	3.6 \pm 2.6	<0.001	7.8 \pm 2.1	6.9 \pm 2.2	7.2 \pm 2.2	<0.001
COMI score at baseline \pm SD [points]	Mean	7.9 \pm 1.5	7.3 \pm 1.8	<0.001	8.1 \pm 1.6	7.1 \pm 1.8	7.6 \pm 1.8	<0.001
Follow-up interval \pm SD [months]	Mean	18 \pm 8	16 \pm 9	0.78	17 \pm 8	14 \pm 8	15 \pm 9	0.31









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Abbreviations

ASA American Society of Anesthesiologists

BP back pain model

CI confidence intervals

COMI Core Outcome Measures Index

GRS graphic rating scales

GTO global treatment outcomes

LP leg pain model

LSS lumbar spinal stenosis

RCT randomized clinical trial

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