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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PII: S1878-8750(19)33179-1

DOI: https://doi.org/10.1016/j.wneu.2019.12.147

Reference: WNEU 13994

To appear in: World Neurosurgery

Received Date: 23 July 2019

Revised Date: 22 December 2019

Accepted Date: 23 December 2019

Please cite this article as: Aghayev E, Mannion AF, Fekete T, Janssen S, Goodwin K, Zwahlen M, Berlemann U, Lorenz T, Spine Tango Registry Group, Risk factors for negative global treatment outcomes in lumbar spinal stenosis surgery: a mixed effects model analysis of data from an international spine registry, *World Neurosurgery* (2020), doi: https://doi.org/10.1016/j.wneu.2019.12.147.

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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 \geq 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).

Four departments had significantly higher odds of a negative outcome, while one department had significantly lower odds. Three out of the four negative effects were related to two departments from 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

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

the central canal and/or the intervertebral foramen due to degenerative changes, and possibly also genetic factors, leading to compression of neural and vascular elements in the lumbar spine². According to the Framingham population-based study, between 19-47% of people aged over 60 years have radiological evidence of spinal stenosis on computed tomography, depending on the criteria 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, surgery is advocated and has been shown to result in better outcomes than non-operative treatment⁵⁻⁷. 8 9 Surgical options include decompression alone, decompression with (instrumented) fusion, and decompression with posterior dynamic stabilization. The relative efficacy of each of these 10 11 interventions in terms of the reduction in pain/disability and improvement in walking capacity remains uncertain⁸. Moreover, patients with dominant back pain as opposed to dominant leg pain appear to 12 respond differently to surgical decompression. Kleinstuck et al. and later Pearson et al. reported 13 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 may potentially be associated with treatment efficiency, such as hospital characteristics, standard 16 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 in hospital benchmarking and quality assurance, which requires good understanding of the variation in 20 21 treatment outcomes.

22

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

27

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

6

7 Materials and Methods

8 Study design

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

17

18 *Patient population*

The inclusion criteria included: diagnosis of degenerative LSS¹⁴, aged between 18 and 100 years, 19 20 documented American Society of Anesthesiologists (ASA) classification, any surgical decompression procedure before 01.2017. The diagnosis of degenerative LSS as primary pathology¹⁴ precluded the 21 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 measures used. Patients also had to have completed both a pre-operative patient self-assessment form 25 and at least one post-operative form, 3-30 months after the index surgery. Exclusion criteria included: 26

anterior dynamic stabilization, any previous spine surgery, and hospitals from countries with a lacking
 validated version of the COMI available in the patient's language (validated ten languages).

If multiple surgeries were documented for a patient, only the first surgery for LSS was considered, with the follow-up COMI being the latest one prior to any subsequent surgery. If multiple follow-up forms were available for a patient, the latest dated form (before any subsequent surgery if the patient was re-operated) was used for analysis.

8 Outcome

9 Patients completed the Spine Tango patient self-assessment form that includes the COMI. The COMI is a self-administered questionnaire¹⁵ consisting of seven questions evaluating five dimensions: pain 10 11 (back and leg), back-related function, symptom-specific well-being, general quality of life and disability (social and work)¹⁶. Two pain graphic rating scales (GRS 0-10 points) capture back and leg 12 13 pain, and all other items use a 5-point scale. For the summary score the average of the scores for all five dimensions (each transformed to 0-10) is calculated¹⁶. At follow-up, the patient self-assessment 14 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 analysis, a "negative" global treatment outcome (poor and very poor outcome) was defined as one 18 where the patient reported that surgery either "didn't help" or "made things worse". Patients who 19 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

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

⁷

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, \geq 3), extent of lesion (1, 2–3, >3 segments), most severely affected segment (L1/2, L2/3, L3/4, L4/5, 16 17 L5/S1), duration of previous conservative treatment (none, <6 months, 6-12 months, >12 months), and 18 surgeon credentials (specialist, in training, other).

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

The percentage of reduction in variance achieved in the 2-level model in comparison with the simpler 1-level (department only) model indicated the degree to which individual patient and department level characteristics accounted for the observed outcome variation. A comparison of patient and treatment characteristics between departments with greater odds for a negative outcome versus all others was performed using multivariate logistic regression, in which all baseline factors were included and the likelihood of being a department with negative outcome was modelled separately for LP and BP
 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 that surgery "helped only little" were excluded (Fig. 1). The study population of 4,504 patients had 12 received surgery for LSS between 10.2004-12.2016, in one of 39 departments (from 38 centers) in ten 13 14 countries (Australia, Austria, Belgium, Germany, Italy, Poland, Portugal, Switzerland, UK, and USA). Of the patients analyzed, 2,312 (51.3%) reported back pain equal to or greater than leg pain, 15 16 preoperatively.

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

23

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

rigid and dynamic stabilization, and they had higher leg pain, back pain and COMI scores at baseline (Table 1). In the *LP* group, the mean reductions in leg pain were 0.8 ± 2.6 (from 7.9 points at baseline) and 5.2 ± 3.0 points (from 7.6 points at baseline) for those reporting a negative outcome and a positive outcome, respectively (p<0.001); the mean changes in back pain were an increase of 1.2 ± 3.8 (from 4.7 points at baseline) and a reduction of 1.5 ± 3.0 points (from 3.9 points at baseline), respectively (p<0.001). Finally, the reductions in mean COMI score in the groups were 0.0 ± 1.7 (from 7.8 points 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 points (from 6.3 points at baseline), for those reporting a negative outcome and a positive outcome, 16 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

Variance of LP and BP model was reduced by 16% and 17%, respectively, when individual patient and department level data were included, with a strong effect of department. Of the remaining variation in both random intercept models, 14% of the variance across departments could be explained 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 ≥ 3 in 6 comparison to ASA 1. The corresponding odds decreased by 2% per year of age, by a factor 0.22 if rigid stabilization was performed, and by a factor of 0.60 if L3/4 was the most affected segment 7 compared with L5/S1, and by a factor of 0.65 if the patient also had disc herniation documented 8 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.

Of the 35 departments with *LP* patients, the *LP*-model revealed two departments, from the same country, with a significantly higher odds of a negative outcome after adjusting for patient and treatment characteristics (Fig. 2): in one, the odds of a negative outcome were 2.30-times (95%CI 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. For the other departments, there was no significant difference in the odds of a negative outcome compared with average (p all \geq 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

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 are shown in
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 outlying department as for LP, described above) and one department with lower odds of negative 17 18 outcome. Hence, three out of the five significant effects observed for "department" involved 19 departments from the same country.

20

21 *Clinical implications*

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

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

than do other LSS patients (patients exhibiting predominant leg pain or no pain predominance). Based on this consideration, we stratified the LSS patients in the present study into two groups. The differing numbers of predictors (one in the *LP*- and six in the *BP*-model) in these patient groups supports the assumption that the two patient groups do indeed differ. In both groups, back pain at baseline was revealed as a risk factor for a negative treatment outcome, which both confirms the results of the previous studies mentioned above and also highlights the importance of an accurate indication for 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 (\geq 3; severe or life-threatening systemic 11 disease) were more likely to have a negative outcome. The explanation for age as an independent predictor, once the effect of ASA was taken into account, is not obvious. It is possible that age is 12 serving as a proxy for a non-observed true predictor. One may speculate that in younger patients, the 13 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 and responds better to surgery. Another possible explanation is that younger patients have higher 16 17 expectations, and require a greater improvement in symptoms before judging the operation to be 18 satisfactory in its outcome.

19

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

27

12

Good quality studies have reported better surgical outcomes after LSS surgery in patients with 1 predominant leg pain at baseline^{9, 10, 20}. However, according to the SPORT trial, patients with 2 3 predominant back pain still improved significantly more with surgery than when treated nonoperatively¹⁰. Nevertheless, in consideration of the fact that decompression alone did not seem to 4 5 alleviate low back pain sufficiently, Kleinstuck et al. recommended detailed analysis of the underlying back pain before undertaking LSS surgery⁹. The etiology of back pain cannot always be distinctly 6 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 stenosis that may not be sufficiently addressed by decompression alone may partly explain the greater 13 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 rigid stabilization was associated with better treatment outcome after LSS in patients with 16 17 predominant back pain. Caution is, however, required in recommending the addition of stabilization, in view of the typically increased surgical and general complications associated with it¹². Moreover, 18 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 alone²¹, although these findings were not supported by another RCT²². 26

- 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.

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

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

6

7 Limitations

The study evaluated a patient-based perspective of negative treatment outcome, which may differ from 8 that of the surgeon²³. The question "Overall, how much did the operation that you received help your 9 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 outcomes can also be influenced by factors such as information and expectations^{24, 25}, as well as by 12 cultural differences²⁶. Soroceanu et al. showed that greater fulfilment of preoperative expectations 13 leads to higher postoperative satisfaction and better functional outcomes²⁷. Taking into account 14 department-level and potentially country-level factors, future studies should focus also on 15 clinical/surgical outcomes. Our analysis accounted for a number of patient and treatment 16 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 been identified as having a negative predictive role in LSS surgery²⁸. Similarly, other ongoing diseases 19 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.

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

Furthermore, the study was based on observational data from a voluntary registry, which is offered to surgeons for their own quality assurance. Different levels of documentation coverage within the hospitals are possible and may have influenced the study results. Finally, we observed evidence for large variation in treatment outcome across 39 departments, yet were unable to completely explain its 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

17 Funding sources

This research did not receive any specific grant from funding agencies in the public, commercial, ornot-for-profit sectors.

20

21 Acknowledgment

All the participants of the Spine Tango Register are acknowledged for their continuous contribution that makes it possible for us to conduct such studies reflecting the daily practice of spine surgeons. The data of the following centers were used (in alphabetic order of country, city, hospital and department): Dept. of Spinal Surgery in Royal Adelaide Hospital (Australia); Dept. of Spinal Surgery in St. Andrew's Hospital in Adelaide (Australia); Dept. of Orthopaedic Surgery in University Hospital Graz (Austria); Dept. of Orthopaedic Surgery in Grand Hôpital de Charleroi (Belgium); Dept. of

Orthopaedic Surgery in Edith Cavell Clinic of Brussels (Belgium); Dept. of Orthopaedic Surgery in University Hospital of St. Luc (Belgium); Dept. of Orthopaedic Surgery in Saint Pierre Clinic of Ottignies (Belgium); Dept. of Neurosurgery in Köpenick Hospital DRK Kliniken Berlin (Germany); Dept. of Neurosurgery in University Hospital of Cologne (Germany); Dept. of Orthopaedic Surgery and Traumatology in University Hospital of Cologne (Germany); Dept. of Neurosurgery in Hospital Cologne-Merheim (Germany); Dept. of Spine Surgery in Hospital Dortmund (Germany); Group Practice of Orthopaedics and Neurosurgery in Hof (Germany); Dept. of Spine Surgery in Krankenhaus der Barmherzigen Brüder of Trier (Germany); Dept. of Special Spine Surgery in Leopoldina Hospital of Schweinfurt (Germany); Department of Spine Surgery in Clinica Cellini in Torino (Italy); Department of Neurosurgery in Sant'Andrea Hospital of the Sapienza University (Italy); Dept. of Orthopedic Surgery in Orthopedic and Traumatological Clinic Poznan (Poland); Dept. of Neurosurgery in Specialized Medical Center S.A. Polanica (Poland); Dept. of Neurosurgery in Bethesda Hospital of Basel (Switzerland); Dept. of Spine Surgery in Sonnenhof Hospital of Bern (Switzerland); Dept. of Orthopaedic Surgery in Cantonal Hospital of Fribourg (Switzerland); Dept. of Neurosurgery in General Hospital of Fribourg (Switzerland); Dept. of Orthopaedic Surgery in Hospital Schwyz (Switzerland); Dept. of Orthopaedic Surgery and Traumatology in Cantonal Hospital of St.

16 17 Gallen (Switzerland); Dept. of Spine Surgery in The Spine Center Thun (Switzerland); Dept. of 18 Orthopedic Surgery in Zollikerberg Hospital (Switzerland); Dept. of Spine Surgery in University 19 Hospital Balgrist of Zurich (Switzerland); Spine Center Division in Schulthess Clinic of Zurich 20 (Switzerland); Spine Unit of Nuffield Oxford Centre (UK); Dept. of Neurosurgery in Salford Royal 21 NHS Foundation Trust (UK); Dept. of Spine Surgery in Salford Royal NHS Foundation Trust (UK); 22 Dept. of Neurosurgery in The Walton Centre (UK); Dept. of Spine Surgery of Christiana Care 23 Hospital in Newark, Delaware (USA); Division of Spine Surgery in NYU Hospital of New York 24 (USA).

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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.

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- 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.

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

		L	P	Compari	B	Compari	
Patient and treatment characteristics	Categories/values	Negative outcome	Positive outcome	son [p-value]	Negative outcome	Positive outcome	son [p- value]
N [row %]	-	251 (11.4)	1941 (88.6)	-	397 (17.2)	1915 (82.8)	-
	Mean ± SD	65.4 ± 12.6	67.1 ± 12.1	0.031	65.1 ± 13.4	67.7 ± 11.6	0.002
Age [years]	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
	1	17.5	19.9		16.4	15.9	
ASA [%]	2	61.4	58.8	0.65	56.9	61.9	0.12
	≥3	21.1	21.3		26.7	22.3	
	1 segment	50.6	48.5		45.3	44.7	
Extent of lesion [%]	2-3 segments	44.2	46.8	0.72	49.1	48.6	0.70
	>3 segments	5.2	4.6		5.5	6.7	
	None	18.5	15.2		19.0	15.7	0.021
Previous conservative	<6 months	26.1	29.9	0.41	23.1	29.4	
treatment [%]	6-12 months	24.5	22.9	0.41	26.0	21.5	
	>12 months	30.9	32.0		31.9	33.5	
	L1/2	0.4	0.5	X	1.8	0.8	0.006
	L2/3	3.2	4.6		6.8	5.8	
Segment [%]	L3/4	20.7	20.5	0.048	20.4	25.2	
	L4/5	51.0	57.3		51.6	54.5	
	L5/S1	24.7	17.2		19.4	13.8	
	Specialist surgeon	83.7	89.6		80.9	88.4	<0.001
Surgeon credentials [%]	Surgeon in training	12.4	9.1	0.001	17.1	10.3	
	Other	4.0	1.3		1.3	2.0	
	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
Type of decompression [%]	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 ± SD	7.9 ± 1.8	7.6 ± 1.8	0.002	6.6 ± 2.8	6.3 ± 2.8	0.008
Back pain at baseline [points]	Mean ± SD	4.7 ± 2.7	3.9 ± 2.7	<0.001	7.7 ± 2.1	7.2 ± 2.2	<0.001
COMI score at baseline [points]	Mean ± SD	7.8 ± 1.6	7.4 ± 1.7	<0.001	8.2 ± 1.6	7.6 ± 1.8	<0.001
Follow-up interval [months]	Mean ± SD	16.1 ± 8.5	16.1 ± 8.4	0.75	16.3 ± 8.2	15.5 ± 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. Journal Pre-proof

Patient or treatment characteristic	Catagorias /values		LP	BP		
Fatient of treatment characteristic	categories/values	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)	
	2 vs. 1	0.20	1.36 (0.91 - 2.05)	0.005	1.07 (0.75 - 1.53)	
ASA	≥3 vs. 1	0.20	1.58 (0.94 - 2.65)	0.005	1.76 (1.15 - 2.70)	
Curren en dentiele	In training vs. specialist	0.21	0.91 (0.56 - 1.50)	0.07	1.16 (0.80 - 1.67)	
Surgeon credentials	Other vs. specialist	0.21	2.16 (0.84 - 5.59)	0.67	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	
	L1/2 vs. L5/S1		0.59 (0.07 - 5.30)		2.57 (0.92 - 7.20)	
Segment	L2/3 vs. L5/S1	0.30	0.55 (0.24 - 1.26)	0.019	0.82 (0.47 - 1.44)	
Segment	L3/4 vs. L5/S1	0.39	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 locion	2-3 vs. 1	0.64	1.10 (0.79 - 1.55)	0.25	1.25 (0.95 - 1.65)	
	>3 vs. 1	0.04	1.40 (0.67 - 2.94)	0.25	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)	
	<6 months vs. none		0.94 (0.61 - 1.47)		0.84 (0.57 - 1.22)	
Previous conservative treatment	6-12 months vs. none	0.95	0.95 (0.60 - 1.50)	0.20	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.

	Categories/values		LP		ВР			
Patient characteristics		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]
Ν	-	527	1665	-	622	100	1590	-
Age + SD [vears]	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
1.80 - 00 [[[00:0]]	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
	1	24.7	18.1	2	20.9	10.0	14.4	<0.001
ASA [%]	2	63.0	57.8	<0.001	63.2	54.0	60.6	
	>2	12.3	24.1		15.9	36.0	25.0	
	1 segment	72.5	41.3	<0.001	65.1	32.0	37.7	<0.001
Extent of lesion [%]	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	
	None	23.0	13.3	<0.001	23.3	-	14.6	<0.001
Previous treatment [%]	<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	
	L1/2	0.4	0.5		0.5	1.0	1.1	<0.001
	L2/3	2.9	4.9	<0.001	4.5	7.0	6.5	
Segment [%]	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	
	Specialist surgeon	70.2	94.9	<0.001	71.2	99.0	92.5	<0.001
Surgeon credentials [%]	Surgeon in training	24.1	4.8		24.8	-	7.1	
	Other surgeon credentials	5.7	0.3	1	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 ± SD [points]	Mean	8.3 ± 1.5	7.4 ± 1.9	<0.001	7.0 ± 2.6	5.8 ± 2.7	6.1 ± 2.8	<0.001
Back pain at baseline ± SD [points]	Mean	5.0 ± 2.7	3.6 ± 2.6	<0.001	7.8 ± 2.1	6.9 ± 2.2	7.2 ± 2.2	<0.001
COMI score at baseline ± SD [points]	Mean	7.9 ± 1.5	7.3 ± 1.8	<0.001	8.1 ± 1.6	7.1 ± 1.8	7.6 ± 1.8	<0.001
Follow-up interval ± SD [months]	Mean	18 ± 8	16 ± 9	0.78	17 ± 8	14 ± 8	15 ± 9	0.31





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Abbreviations

- ASA American Society of Anesthesiologists
- ΒP back pain model
- CI confidence intervals
- Core Outcome Measures Index COMI
- GRS graphic rating scales
- GTO global treatment outcomes
- LP leg pain model
- LSS lumbar spinal stenosis
- RCT randomized clinical trial

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