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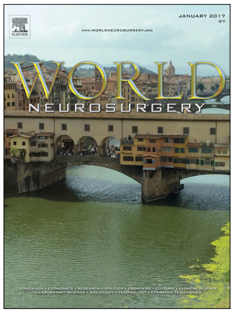

Risk factors for negative global treatment outcomes in lumbar spinal stenosis surgery: a mixed effects model analysis of data from an international spine registry

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

Abstract

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

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

Results: 4,504 patients from 39 departments in ten countries were include. Overall, 14.4% of patients reported a negative GTO after an average follow-up of 1.3 years. In patients with dominant leg pain, negative outcome was associated with higher baseline back pain; in those with dominant back pain, it was associated with higher baseline back pain, ASA≥3, lower age, not having rigid stabilization, not 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.

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

Keywords

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

Introduction

Degenerative lumbar spinal stenosis (LSS) is one the underlying indications for 42% of all spine surgeries recorded in the international Spine Tango registry[1]. 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 spine[2]. 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 used[3]. With increasing life expectancy, the overall prevalence of LSS will continue to increase[4].

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 treatment[5-7]. Surgical options include decompression alone, decompression with (instrumented) fusion, and decompression with posterior dynamic stabilization. The relative efficacy of each of these interventions in terms of the reduction in pain/disability and improvement in walking capacity remains uncertain[8]. Moreover, patients with dominant back pain as opposed to dominant leg pain appear to respond differently to surgical decompression. Kleinstuck et al. and later Pearson et al. reported significantly less favorable outcome after decompression in patients with dominant back pain[9, 10]. 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 clinical procedures and healthcare systems. To date, the association of the latter with treatment outcome in LSS has not been studied. Patient characteristics have been scrutinized frequently, 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 treatment outcomes.

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 patient[12]. However, in view of the ethical principle of non-maleficence, it is equally important to analyze cases of failed therapy.

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 pain[9], the analyses were stratified for these two groups.

Materials and Methods

Study design

We conducted a case-control study using data from the international spine registry Spine Tango, hosted at the University of Bern[13]. The data were collected in a prospective observational multi-center 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 (COMI) completed by the patients themselves either at the treating center or independently at home. 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 patient data from 114 hospitals in 17 countries.

Patient population

The inclusion criteria included: diagnosis of degenerative LSS[14], aged between 18 and 100 years, documented American Society of Anesthesiologists (ASA) classification, any surgical decompression procedure before 01.2017. The diagnosis of degenerative LSS as primary pathology[14] precluded the concomitant degenerative pathologies spondylolisthesis, deformity and instability, and additional main pathologies such as tumor, inflammation etc.; it also required that laminotomy, hemi-laminectomy, 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 and at least one post-operative form, 3-30 months after the index surgery. Exclusion criteria included:

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.

Outcome

Patients completed the Spine Tango patient self-assessment form that includes the COMI. The COMI is a self-administered questionnaire[15] consisting of seven questions evaluating five dimensions: pain (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 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 calculated[16]. At follow-up, the patient self-assessment form includes an additional question on the patient’s assessment of the GTO (“Overall, how much did the operation that you received help your back problem?”) with five response options (“helped a lot”, “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 where the patient reported that surgery either “didn’t help” or “made things worse”. Patients who reported that surgery “helped” or “helped a lot” were defined as having a “positive” global treatment outcome (good and very good outcome). We excluded patients who reported that surgery “helped only little” (middling cases), to have distinct cases and controls.

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≥leg pain; “*BP*”).

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

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

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

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

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

Results

Patient, surgeon, and department characteristics

The database contained data on 103,164 spine surgeries between 01.2004-05.2017. Of 10,675 patients meeting the medical inclusion criteria, 4,836 (45.3%) had completed a patient assessment form both preoperatively and postoperatively, with their last available follow-up being between 3 and 30 months 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 received surgery for LSS between 10.2004-12.2016, in one of 39 departments (from 38 centers) in ten 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, 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.

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 ($p<0.001$).

In the *BP* group, compared with patients with a positive outcome patients with a negative outcome were younger, more often had received either no preoperative conservative treatment or treatment for 6-12 months' duration, more often had L5/S1 rather than L4/5 as the affected level, more often had surgery performed by a surgeon in training, and more often were decompressed using laminectomy; a lower proportion of them had received partial facet joint resection, fusion, and rigid and dynamic stabilizations, and they had higher leg pain, back pain and COMI scores at baseline (Table 1). In the *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, respectively ($p<0.001$); the mean changes in back pain were 0.6±2.4 (from 7.7 points at baseline) and 4.1±3.0 (from 7.2 points at baseline) points, respectively ($p<0.001$). Finally, the reductions in mean 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 points at baseline), respectively ($p<0.001$).

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.

One factor was associated with negative global outcome in patients with predominant leg pain and six factors in patients with predominant back pain (Table 2). Back pain score prior to surgery was a risk factor for both groups, with the odds of a negative outcome increasing 9% and 14% for each point increase in the pain scale for those with predominant leg pain and predominant back pain, respectively. In *BP* patients, the odds of a negative outcome also increased with ASA ≥3 in 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 compared with L5/S1, and by a factor of 0.65 if the patient also had disc herniation documented (Table 2).

The likelihood ratio test comparing the covariance structures of the data with and without the random effect of the department was significant (p<0.001) in both models, implying that the model including a 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 ≥0.05) (Fig. 2).

Of the 36 departments with *BP* patients, the *BP*-model revealed two departments from two different countries with significantly greater odds of a negative outcome (one department of which was the same outlier as for the previous analysis with *LP*), and another department from a third country with a significantly lower odds of a negative outcome compared with the average (Fig. 3): in the first case, the odds of a negative outcome were 2.48-times (95%CI 1.44–4.25; p=0.001), in the second, 2.55-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 overall average. For the other departments, there was no significant difference in the odds of negative outcome compared with average (p all ≥0.06) (Fig. 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 are shown in Table 3.

Discussion

Summary of the results

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

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).

We also identified factors associated with a decreased likelihood of a negative outcome in the *BP* group. Increasing age was associated with fewer negative outcomes after adjusting for other confounding factors, although patients with a high ASA grade (≥3; severe or life-threatening systemic 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 serving as a proxy for a non-observed true predictor. One may speculate that in younger patients, the causes of back and leg pain are more likely to be something other than (or in addition to) degenerative 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 expectations, and require a greater improvement in symptoms before judging the operation to be satisfactory in its outcome.

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 spine[18]. 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 known[19]. 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.

Good quality studies have reported better surgical outcomes after LSS surgery in patients with predominant leg pain at baseline[9, 10, 20]. However, according to the SPORT trial, patients with predominant back pain still improved significantly more with surgery than when treated non-operatively[10]. Nevertheless, in consideration of the fact that decompression alone did not seem to alleviate low back pain sufficiently, Kleinstuck et al. recommended detailed analysis of the underlying back pain before undertaking LSS surgery[9]. The etiology of back pain cannot always be distinctly attributed to an anatomical region or structure. Leg and back pain in the same patient may also have different etiologies such as muscular and degenerative changes, referred pain and neuropathic pain. In the present study, in patients with predominant back pain at baseline decompression alone (as opposed to with additional rigid stabilization) increased the odds of a negative outcome by a factor of 4.55 (=1/0.22 the odds ratio for rigid stabilization), although relatively wide confidence intervals were seen 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 likelihood of a negative outcome in these patients. Rigid stabilization eliminates the painful motion 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 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 it[12]. Moreover, hardware failure, screw loosening, and adjacent segment degeneration are further potentially problematic long-term complications associated with rigid stabilization. As such, the simple observation of an association between negative mid-term global treatment outcome and the lack of use of rigid stabilization in patients with predominant back pain at baseline does not support a recommendation for the application of stabilization across the board. The recent Swedish randomized clinical trial (RCT) that included a heterogeneous patient population with and without spondylolisthesis did not observe better clinical outcomes when adding a fusion to a decompression alone[21], although these findings were not supported by another RCT[22].

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

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

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

Limitations

The study evaluated a patient-based perspective of negative treatment outcome, which may differ from that of the surgeon[23]. The question “Overall, how much did the operation that you received help your back problem?” might not reflect all parts of the problem for which surgery was indicated. The 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 cultural differences[26]. Soroceanu et al. showed that greater fulfilment of preoperative expectations leads to higher postoperative satisfaction and better functional outcomes[27]. Taking into account department-level and potentially country-level factors, future studies should focus also on clinical/surgical outcomes. Our analysis accounted for a number of patient and treatment characteristics; however, further, non-documented factors outside of the data collected in Spine Tango may have influenced the likelihood of a negative outcome. Among others, preoperative depression has been identified as having a negative predictive role in LSS surgery[28]. Similarly, other ongoing diseases that were not identified and treated at the time of the index surgery may be responsible for the negative outcome. The models also did not include information regarding the technical success of the surgery (such as the extent of decompression or the correctness of screw positioning), postoperative complications, the amount of segmental deformity, the presence of foraminal stenosis, or the duration 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.

Conclusions

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

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

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Figure legends

Figure 1. Study flow chart.

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

Note: the significantly deviating centers are in red.

Figure 3. Deviations from the overall average of having of negative outcome in 36 treating departments, from the multivariate mixed effect model in the *BP* sample.

Note: the significantly deviating centers are in red.

Figure 4. The pain relief and COMI score improvement in the hospital departments with greater odds of negative outcome versus other hospital departments by group.

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* Negative outcome	*LP* Positive outcome	Comparison [p-value]	*BP* Negative outcome	*BP* Positive outcome	Comparison [p-value]
N [row %]	-	251 (11.4)	1941 (88.6)	-	397 (17.2)	1915 (82.8)	-
Age [years]	Mean ± SD	65.4 ± 12.6	67.1 ± 12.1	**0.031**	65.1 ± 13.4	67.7 ± 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	
	≥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 ± 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.

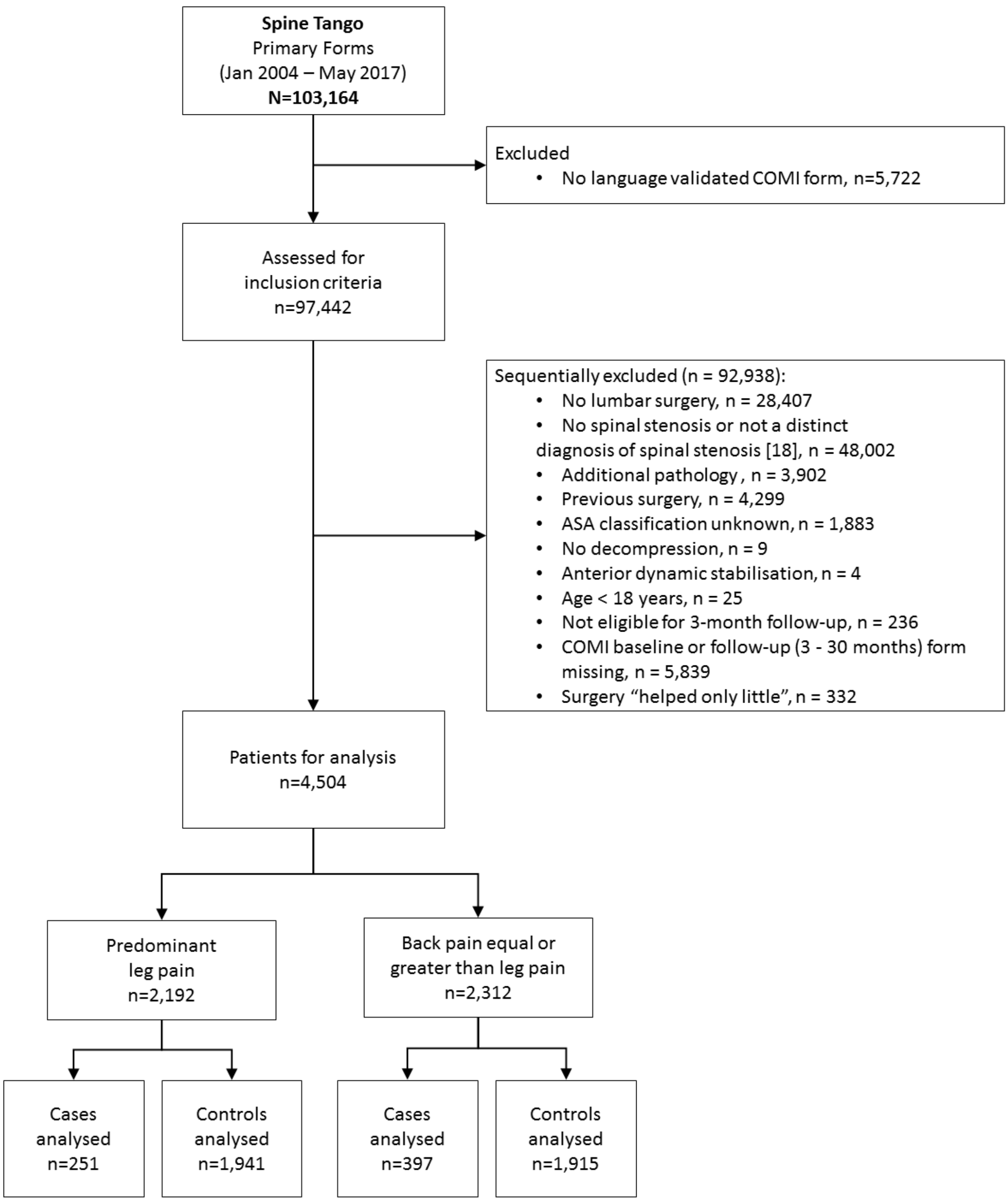
Patient or treatment characteristic	Categories/values	LP		BP	
		p-value	Odds ratio	p-value	Odds ratio
Back pain at baseline	Per point	**0.007**	**1.09 (1.02 - 1.15)**	**0.002**	**1.14 (1.05 - 1.23)**
Time between surgery and follow-up	Per months	0.05	0.98 (0.97 - 1.00)	0.76	1.02 (0.99 - 1.02)
Degenerative 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)

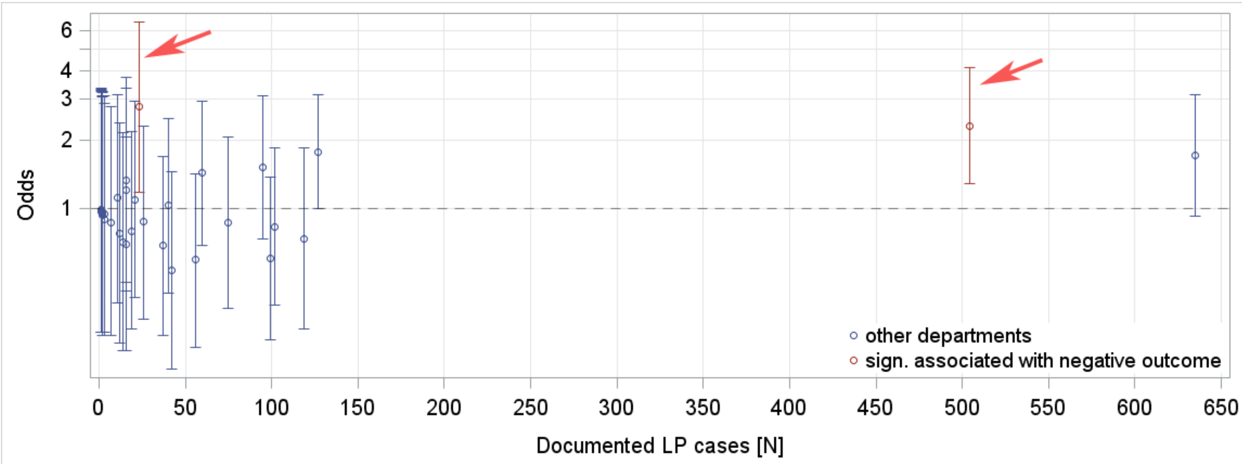
Note: significant fixed effects are in bold.

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 ± 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


Spine Tango
Primary Forms
(Jan 2004 – May 2017)
N=103,164
Excluded
• No language validated COMI form, n=5,722
Assessed for
inclusion criteria
n=97,442
Sequentially excluded (n = 92,938):
• No lumbar surgery, n = 28,407
• No spinal stenosis or not a distinct
diagnosis of spinal stenosis [18], n = 48,002
• Additional pathology , n = 3,902
• Previous surgery, n = 4,299
• ASA classification unknown, n = 1,883
• No decompression, n = 9
• Anterior dynamic stabilisation, n = 4
• Age < 18 years, n = 25
• Not eligible for 3-month follow-up, n = 236
• COMI baseline or follow-up (3 - 30 months) form missing, n = 5,839
• Surgery "helped only little", n = 332
Patients for analysis
n=4,504
Predominant
leg pain
n=2,192
Back pain equal or
greater than leg pain
n=2,312
Cases
analysed
n=251
Controls
analysed
n=1,941
Cases
analysed
n=397
Controls
analysed
n=1,915



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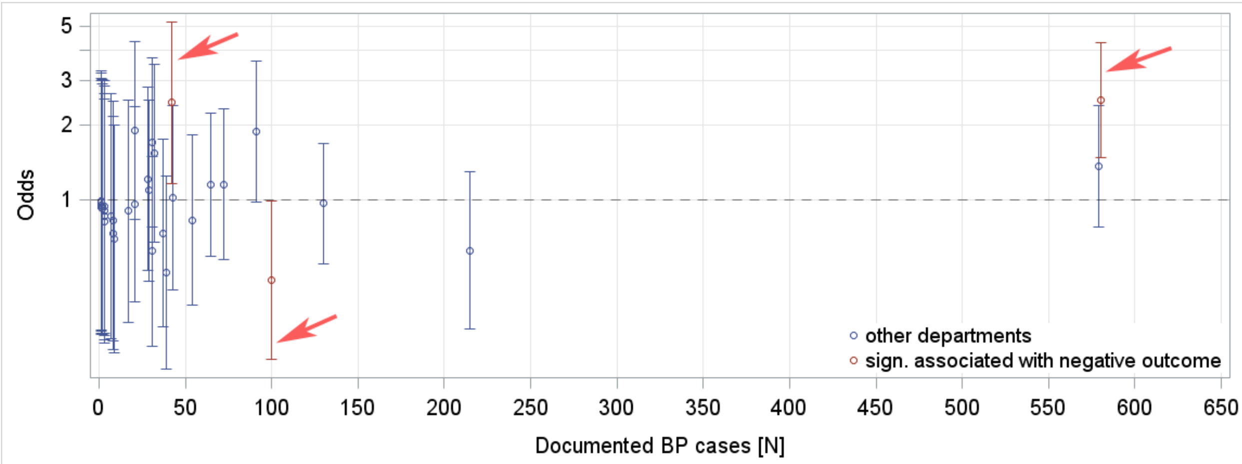
other departments
sign. associated with negative outcome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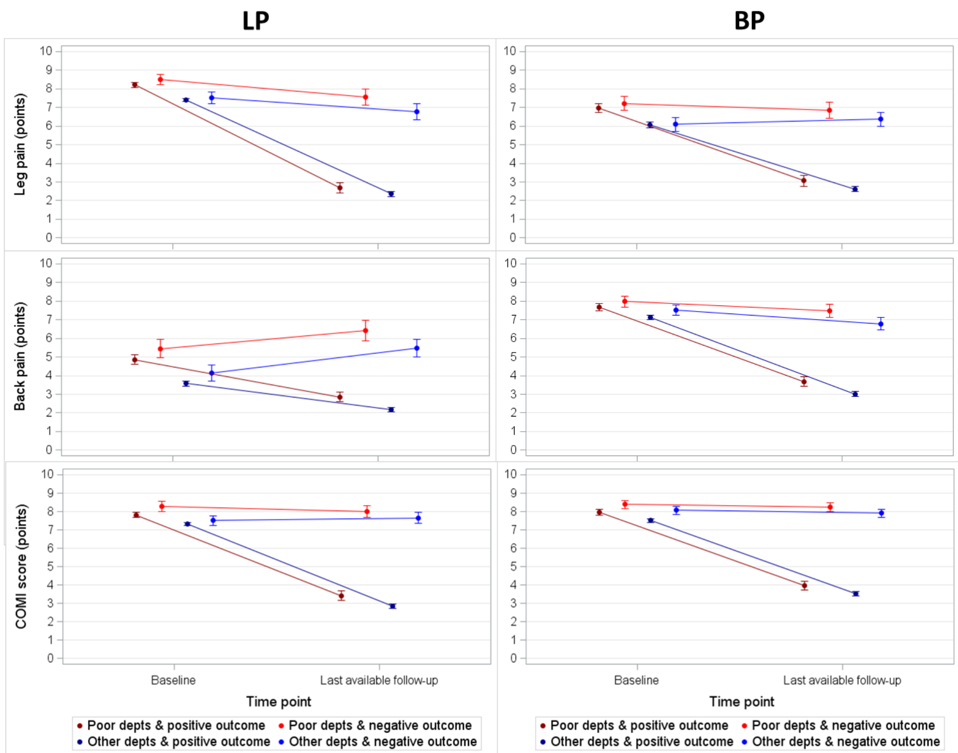
LP
BP
Leg pain (points)
Back pain (points)
COMI score (points)
10
9
8
7
6
5
4
3
2
1
0
Baseline
Last available follow-up
Time point
Poor depts & positive outcome
Poor depts & negative outcome
Other depts & positive outcome
Other depts & negative outcome

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