


Incidental durotomy in decompression for lumbar spinal stenosis: incidence, risk factors and effect on outcomes in the Spine Tango registry

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Abstract

Purpose The three aims of this Spine Tango registry study of patients undergoing decompression for spinal stenosis were to: report the rate of dural tear (DT) stratified by treatment centre; find factors associated with an increased likelihood of incurring a DT; and compare treatment outcomes in relation to DT (none vs. repaired vs. unrepaired DT).

Methods Multivariate logistic regression was used to assess the association between DT and patient and treatment characteristics. Patient-rated and surgical outcomes

were compared in patients with no DT, repaired DT, and unrepaired DT, while adjusting for case-mix.

Results DT occurred in 328/3254 (10.1%) of included patients. The rate for all 29 contributing hospitals was within 95% confidence intervals of the average. The likelihood of DT increased by 2% per year of age, 1.78 times with previous spine surgery, 1.67 for a minimally/less invasive surgery, 1.58 times with laminectomy, and 1.40, and 2.12 times for BMI 31–35, and >35 in comparison with BMI 26–30, respectively. The majority of DTs (272/328; 82.9%) were repaired. Repairing the DT was associated with a longer duration of surgery ($p < 0.001$). More patients with repaired than with unrepaired DTs were satisfied with treatment, but the difference was not statistically significant. There was no association between DT and patient-reported outcomes.

Conclusion The unadjusted rate of incidental DT during decompression for LSS was homogeneous across the participating centres and was associated with age, BMI, previous surgery at the same spinal level, minimally/less invasive surgery, and laminectomy. Non-repair of DTs had no negative association with treatment outcome; however, the unrepaired DTs may have been those that were smaller in size.

Keywords Spine Tango registry · Lumbar spinal stenosis · Decompression · Durotomy · Outcome

Introduction

More than 40% of spine surgeries in the international spine registry, Spine Tango, are for lumbar spinal stenosis (LSS) [1], with the established surgical procedure being open posterior decompression with or without fusion.

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Incidental tearing of the dural sac is one of the most common complications associated with the procedure. Depending on the precise intervention, incidental durotomy (DT) rates as high as 17% have been reported [2–5]. DT rates in the studies from the Spine Patient Outcome Research Trial (SPORT), Spine Tango, and the Swespine registry range between 7.4 and 9.0% [5–7]. Risk factors for DT are well known: patient age, previous surgery, obesity, number of treated levels, and degree of surgical invasiveness [7–10].

The intraoperative management of DT is the subject of debate. Intraoperative suturing of a lesion with or without additional fibrin glue seems to be the preferred procedure [11, 12], though other alternatives to suturing exist, including fascia patches, fat or muscle grafts with or without fibrin glue, and other closure options such as direct coverage with artificial sleeves [13–15]. However, the literature provides no clear consensus or recommendations on DT management, and it may depend on the accessibility, location, and size of the lesion. Each surgeon generally uses his/her own repair procedure based on his/her own experience. The consequences of a DT include headache, nausea, vomiting, vertigo, persistent cerebrospinal fluid (CSF) leak, fistula or pseudomeningocele, wound healing disorders, infection, meningitis, or intracerebral bleeding, and, in the worst case, cerebellar tonsil herniation as a lethal complication [3, 4, 16–18].

At least two studies have demonstrated no effect of incidental DT on surgical and patient-reported outcomes. A study of the SPORT data reported no effect of incidental DT on wound complications, early mortality, or long-term patient-rated outcome, though the overall length of stay, duration of surgery, and intraoperative blood loss were all higher for patients with a DT [19]. Analysis of Swespine registry data similarly demonstrated no effect of DT on 1-year patient-rated outcomes [7]. These studies were limited geographically to one country only and accounted for only few potential confounders.

The aim of the present study was to use data from the international Spine Tango registry to: (1) examine the rate of incidental DT in open decompression for spinal stenosis, stratified by treatment centre, (2) analyse factors associated with DT and (3) compare outcomes amongst patients with no DT, repaired DT, and unrepaired DT, while adjusting for case-mix.

Materials and methods

The study was carried out using the Spine Tango data pool and written in accordance with the STROBE guidelines [20].

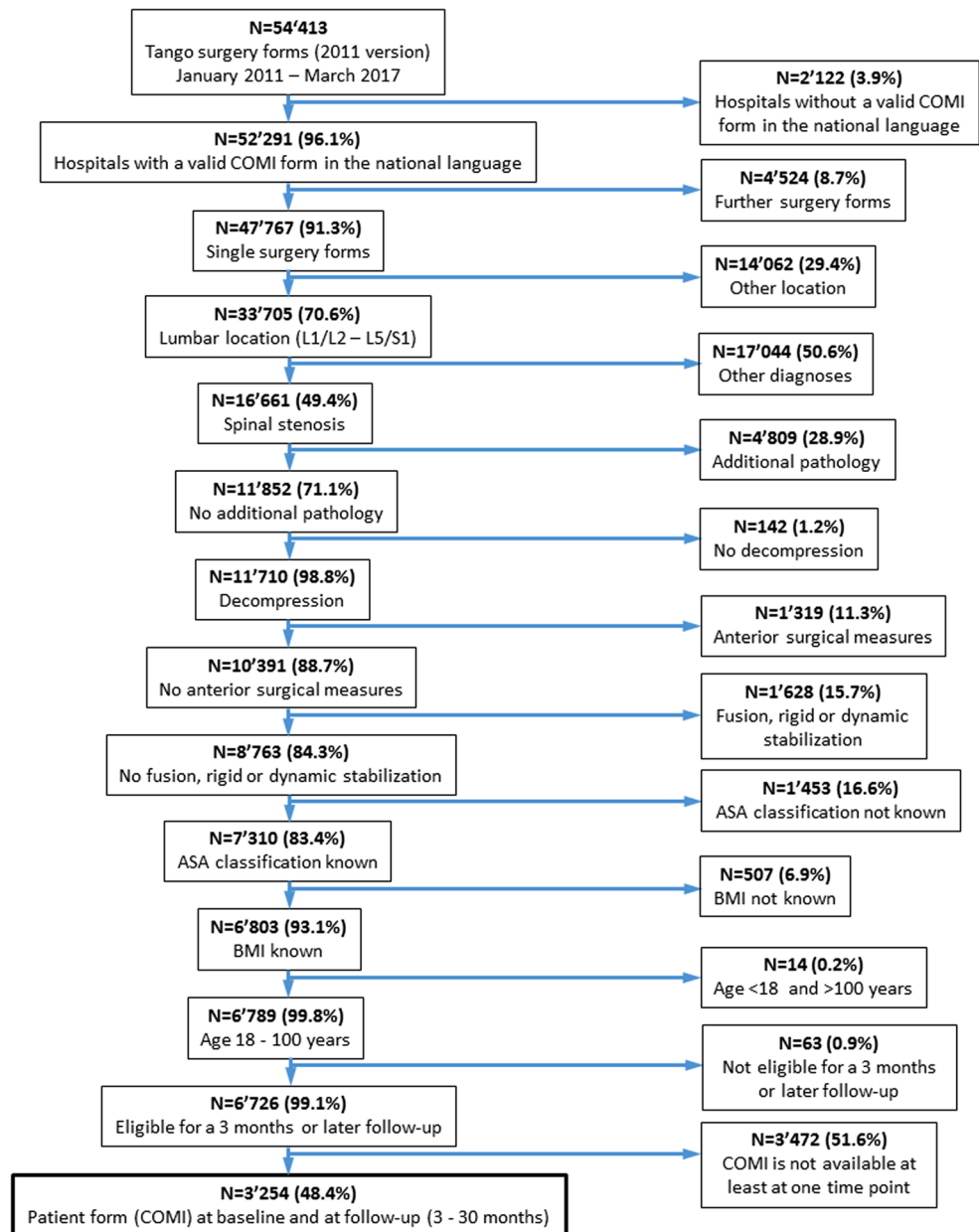
Spine Tango

Spine Tango is the international spine registry of Eurospine, the Spine Society of Europe, in which patient and physician-based data are collected on a prospective basis [21]. We used the current Spine Tango surgery form (version 2011; <http://www.eurospine.org/forms.htm>), which records data on patient demographics, pathology, indication for treatment, previous treatments, and surgical details. Patient-rated outcome data were collected using the Spine Tango “Patient self-assessment form” (<http://www.eurospine.org/forms.htm>) which includes the Core Outcome Measures Index (COMI) questionnaire [22] (completed pre and postoperatively) and single item outcome questions (completed postoperatively only) enquiring about the following: the global treatment outcome (“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, made things worse); further spine surgery (none, different level, same level); and patient satisfaction with treatment in the hospital (very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied, very dissatisfied). In the analyses, global treatment outcome was dichotomized into “good” (helped a lot + helped) and “poor” (helped only little + did not help + made things worse); further surgery, into “reoperation at the same level” and “no reoperation at the same level”; and patient satisfaction, into “satisfied” (very satisfied + satisfied) and “not satisfied” (very dissatisfied + dissatisfied + neither satisfied nor dissatisfied).

Inclusion criteria

Between January 2011 and March 2017, 54,413 patients were documented in Spine Tango from 15 countries. Patients in Finland, India, Moldova, Netherlands, Singapore, Slovenia, Taiwan, and Turkey were not considered in the present study due to the lack of a validated language version of the COMI. For the remaining 52,291 patients in Australia, Belgium, Germany, Poland, Switzerland, UK, and USA, further inclusion criteria were applied to identify patients undergoing posterior decompression only for spinal stenosis, with additional conditions regarding the availability of accompanying data such as BMI, comorbidity, patient-questionnaires, as listed in Fig. 1. If multiple surgeries were available for a patient, only the first dated surgery was considered. If multiple follow-up forms were available for a patient within the given follow-up period, the most recent data form was selected for analysis. Application of these selection criteria resulted in 3254 LSS patients who were eligible for inclusion in the study.

Fig. 1 Selection algorithm and proportions of excluded patients by selection criterion



Statistical analyses

Unadjusted rates of DT

The unadjusted DT rate was calculated for each treatment centre and plotted against the number of documented surgeries in a funnel plot. The 95% confidence intervals (95% CI) were included around the overall average DT rate.

Risk factors for DT

Comparisons of patient and treatment characteristics between those patients with and without incidental DT

were performed using the Chi-square test for nominal data and the Wilcoxon rank-sum test for continuous data.

The analysis of statistical predictors for incurring a DT was carried out using multivariate logistic regression analysis. The following covariates were included in the model: patient age (continuous) and sex (male, female), BMI category (<20, 20–25, 26–30, 31–35, >35), smoking status (smoker, nonsmoker, unknown), previous treatment (none, surgical, <6 months conservative, 6–12 months conservative, >12 months conservative), ASA status (1, 2, >2), segment (L1/2–L2/3, L3/4, L4/5, L5/S1), extent of lesion (1 segment, 2–3 segments, >3 segments), number of previous spine surgeries (continuous), previous spine surgery on the same level (yes, no), surgeon experience (board

certified, in training), minimally/less invasive surgical approach (yes/no), discectomy (yes, no), laminotomy (yes, no), hemilaminectomy (yes, no), laminectomy (yes, no), facet joint resection partial or full (yes, no), flavectomy (yes, no), foraminotomy (yes, no), and other decompression (yes, no). A stepwise selection algorithm was used and second-order interactions were assessed.

No DT, repaired and unrepaired DT

The study sample of 3254 patients was subdivided into three groups: 2926 (89.9%) patients without DT; 272 (8.4%) patients with DT, repaired using fibrin glue and/or suture ($n = 268$), fat graft ($n = 3$), fascia patch ($n = 2$), Duragen ($n = 1$), clip ($n = 1$), or Spongostan ($n = 1$); and 56 (1.7%) patients whose DT was not repaired.

Eleven outcome measures were assessed in these groups: duration of surgery, postoperative cranial complication, CSF leak, superficial or deep infection, back pain relief, leg pain relief, COMI score improvement, patient-reported reoperations at the same vertebral level, patient satisfaction with treatment in the hospital, patient assessment of the global treatment outcome, and length of postoperative hospital stay (LOS) (days between operation date and discharge date).

The inverse probability of treatment weighting (IPTW) using the propensity score was applied to balance the three patient groups for their patient and treatment characteristics. This method uses weights based on the propensity score to create a synthetic sample in which the distribution of measured baseline and treatment covariates is independent of the group assignment. In this way the patient groups are made similar to each other and outcome measures can be compared between similar patients. The propensity score was estimated without regard to outcome variables using multiple logistic regression analysis. The above-mentioned covariates and, additionally, back pain, leg pain, and COMI score at baseline and follow-up (all continuous) were included in the propensity score. Bivariate comparison of patient characteristics in the patient groups before and after weighting adjustment was performed using general linear modelling or the Chi square test as appropriate. The level of significance was set to 0.05 throughout the study. All statistical analyses were conducted using SAS 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

Unadjusted rates of DT

In total, there were 328/3254 (10.1%) intraoperative DTs (Table 1). DT rates varied between treatment centres with

different numbers of documented operative procedures. Overall, 21 out of 29 centres reported a DT. None of the centres had a DT rate beyond the 95% CI for the average (Fig. 2).

Seven out of the twenty-one centres documented an unrepaired DT with the average rate of unrepaired vs. all DTs in those seven centres being 24.2% (range 7.1–41.9%). The remaining 21 centres had five or fewer DTs each, which all were repaired. Seven out of twenty-one centres documented an unrepaired DT with the average rate of unrepaired vs. all DTs in those seven centres being 24.2% (range 7.1–41.9%). The remaining 21 centres had five or fewer DTs each, which all were repaired.

Risk factors for DT

Demographic and clinical characteristics of the patients with and without DT are summarized in Table 1. Bivariate, unadjusted analyses revealed that, compared with patients with no DT, patients with DT were on average 2.5 years older; more often had an ASA >2; more often had a BMI >30 and less often 26–30; had previously undergone a greater number of spine surgeries overall; had previously undergone a greater number of spine surgeries at the same level; more often had two or more involved segments; more often had been operated on with a minimally/less invasive surgical approach; and had more often undergone laminectomy and less often, discectomy. Other characteristics did not differ significantly between the groups.

The multivariate analysis demonstrated that age, BMI, previous surgery at the same level, minimally/less invasive surgery, and laminectomy were significantly associated with the occurrence of DT. According to the model, the likelihood of a DT increased by 2% per year of age, by a factor of 1.78 with prior surgery at the same level, by a factor of 1.67 with minimally/less invasive surgery, by a factor of 1.58 with laminectomy, and by factors of 1.40, and 2.12 for BMI 31–35, and >35 each in comparison with BMI 26–30 (Table 2).

IPTW adjustment for no DT, repaired DT and unrepaired DT

The three groups (no DT, repaired DT and unrepaired DT) were successfully balanced for their patient and treatment characteristics ($p \geq 0.26$; Table 3). Patients with repaired DT had a longer duration of surgery than patients with unrepaired DT or those without DT (Table 4). Furthermore, patients with repaired DT had a higher rate of cerebral complications and a longer hospital stay than patients without DT. Finally, patients without DT had a lower rate of CSF leak than each of the groups with DT (Table 4).

Table 1 Demographic and treatment characteristics of patients with and without dural tear (DT)

Patient characteristics	DT, <i>n</i> = 328 (10.1%)	No DT, <i>n</i> = 2926 (89.9%)	Comparison (<i>p</i> value)
Mean age ± SD (years)	67.1 ± 12.4	64.6 ± 13.1	<0.001
Female (%)	45.7	45.2	0.84
BMI <20 (%)	3.7	2.5	<0.001
BMI 20–25 (%)	25.0	26.2	
BMI 26–30 (%)	34.8	43.1	
BMI 31–35 (%)	24.1	21.0	
BMI >35 (%)	12.5	7.3	
Current smoker (%)	9.8	12.5	0.36
Not-smoker (%)	67.1	65.0	
Smoking status unknown (%)	23.2	22.5	
No previous treatment (%)	19.2	20.9	0.76
Previous surgical treatment (%)	2.4	3.5	
<6 months conservative treatment (%)	28.4	28.3	
6–12 months conservative treatment (%)	23.2	22.5	
>12 months conservative treatment (%)	26.8	24.8	
ASA 1 (%)	17.1	22.1	0.017
ASA 2 (%)	61.3	61.4	
ASA >2 (%)	21.7	16.5	
L1/2–L2/3 (%)	6.4	7.1	0.33
L3/4 (%)	23.5	21.6	
L4/5 (%)	53.4	50.6	
L5/S1 (%)	16.8	20.8	
1 segment involved (%)	49.7	55.2	0.011
2–3 segments involved (%)	43.0	40.4	
>3 segments involved (%)	7.3	4.4	
Number of previous spine surgeries ± SD (<i>n</i>)	1.3 ± 0.6	1.2 ± 0.6	0.020
Previous spine surgery on the same level (%)	15.1	10.0	0.028
Board-certified surgeon (%)	86.0	84.2	0.40
Surgeon in training (%)	14.0	15.8	
Minimally/less invasive surgical approach (%)	14.3	10.5	0.033
Discectomy (%)	16.2	24.3	0.001
Laminotomy (%)	39.3	44.1	0.10
Hemilaminectomy (%)	14.0	11.7	0.21
Laminectomy (%)	34.8	25.2	<0.001
Facet joint resection partial or full (%)	45.7	45.2	0.84
Flavectomy (%)	63.7	64.2	0.87
Foraminotomy (%)	40.6	40.9	0.89
Other decompression (%)	18.6	18.8	0.93

Significant differences are highlighted in bold

Both before and after IPTW adjustment, the differences in pain relief and in COMI score improvement (Fig. 3) among the groups were not statistically significant ($p > 0.41$). Other outcomes, including the proportion of patients that were satisfied with the treatment and the global treatment outcome, were not significantly different ($p \geq 0.10$; Table 4), although the proportions of “not satisfied” patients and patients reporting a “poor” global outcome, respectively, were 9 and 8% higher in the

unrepaired DT group than in either of the other two groups (Table 4).

Discussion

The major findings of this study were: (1) the overall incidence of DT during decompression surgery for LSS was 10.1%; (2) all centres within the registry were within

Fig. 2 Unadjusted rates of DT for the individual treatment centres by number of documented surgeries

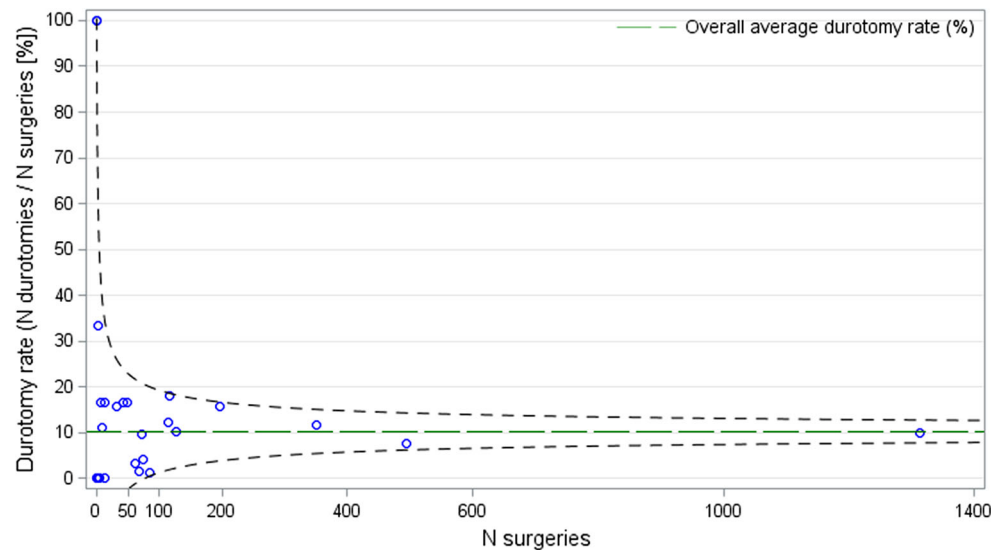


Table 2 Summary of the multivariate logistic regression analysis of predictors for DT

Patient or treatment characteristics	Effect	Odds ratio with 95% CI	<i>p</i> value
Previous surgery at the same spinal level	Yes vs. no	1.78 (1.28–2.49)	<0.001
Laminectomy	Yes vs. no	1.58 (1.23–2.05)	<0.001
BMI	<20 vs. 26–30 kg m ⁻²	1.79 (0.93–3.42)	0.002
	21–25 vs. 26–30 kg m ⁻²	1.17 (0.86–1.58)	
	31–35 vs. 26–30 kg m ⁻²	1.40 (1.03–1.89)	
	>35 vs. 26–30 kg m ⁻²	2.12 (1.44–3.13)	
Age	Per year	1.02 (1.01–1.03)	0.002
Minimal/less invasive surgical approach	Yes vs. no	1.67 (1.18–2.36)	0.004

95% CI 95% confidence intervals

the 95% CI for the average value; (3) independent predictors for incidental DT were greater age, BMI >30, previous surgery at the same level, a minimally/less invasive surgical approach, and laminectomy; (4) DTs that were not repaired were associated only with a shorter duration of surgery than the repaired ones; (5) the groups did not differ significantly in relation to patient-reported outcomes, although potentially clinically important group differences were observed in the proportion of patients reporting that they were satisfied with the treatment and had a “good” global treatment outcome (with fewer in the DT-unrepaired group).

Clinical implications

Voluntary, non-monitored medical registries are criticised for a risk of selection bias favouring successful cases and underreporting complications. However, the 10.1% incidence of DT in our study was higher than that reported for a similar patient population in the Swespine registry (7.4%) [7], the data quality of which is generally well regarded. Our rate was also slightly higher than those of other good quality studies, including the SPORT [3, 19]. This suggests

that systematic underreporting of durotomies in Spine Tango is unlikely. An underreporting of complications in any individual treatment centre in our study sample is also unlikely because none demonstrated a DT rate below the overall mean within the 95% CI. Also, no outlier above the 95% CI was found, indicating a fairly homogeneous reporting of DTs across the individual treatment centres. The greater variation in DT rates in low throughput centres can be attributed to a greater variation in patient and treatment characteristics. Their larger confidence intervals also suggest a higher degree of uncertainty. However, only raw (not adjusted) rates were calculated for the individual treatment centres. A more accurate presentation of the variation in adjusted DT rates between the individual centres would require evaluation in a separate study using a hierarchical modelling approach. The multinational character of the data further reinforces the generalizability of the rate of 10.1% for DTs in decompression for lumbar spinal stenosis. Good registry data capture real-life clinical practice with high external validity [23].

In a large cohort study of patients undergoing surgery for LSS, age was shown to be associated with the incidence of DT [8, 10, 24]. However, a recent retrospective analysis

Table 3 Patient and treatment characteristics before and after the IPTW adjustment in patient groups

Patient and treatment characteristics	Before weighting adjustment				After weighting adjustment			
	DT			Comparison (<i>p</i> value)	DT			Comparison (<i>p</i> value)
	Repaired, <i>n</i> = 272 (8.4%)	Unrepaired, <i>n</i> = 56 (1.7%)	None, <i>n</i> = 2926 (89.9%)		Repaired, <i>n</i> = 167 (8.0%)	Unrepaired, <i>n</i> = 32 (1.5%)	None, <i>n</i> = 1882 (90.4%)	
Mean age (years ± SD)	67.4 ± 12.3	66.0 ± 12.6	64.6 ± 13.1	0.003	64.1 ± 13.6	65.4 ± 11.1	64.9 ± 13.0	0.58
Female (%)	45.6	46.4	45.2	0.97	43.2	36.3	45.2	0.38
BMI <20 (%)	2.9	7.1	2.5	0.002	2.2	3.6	2.6	0.99
BMI 20–25 (%)	23.9	30.4	26.2		26.0	23.1	26.1	
BMI 26–30 (%)	35.3	32.1	43.1		43.2	37.9	42.2	
BMI 31–35 (%)	25.7	16.1	21.0		20.6	27.1	21.3	
BMI >35 (%)	12.1	14.3	7.3		8.0	8.3	7.8	
Current smoker (%)	9.2	12.5	12.5	0.59	12.0	7.1	12.2	0.80
Not-smoker (%)	66.9	67.9	65.0		63.7	68.5	65.2	
Smoking status unknown (%)	23.9	19.6	22.5		24.3	24.4	22.6	
No previous treatment (%)	15.8	35.7	20.9	0.043	21.8	26.2	20.8	0.96
Previous surgical treatment (%)	1.8	5.4	3.5		3.7	1.5	3.4	
<6 months conservative treatment (%)	29.4	23.2	28.3		27.6	21.6	28.3	
6–12 months conservative treatment (%)	24.6	16.1	22.5		22.8	26.7	22.6	
>12 months conservative treatment (%)	28.3	19.6	24.8		24.2	24.0	25.0	
ASA 1 (%)	16.2	21.4	22.1	0.041	22.6	18.2	21.6	0.91
ASA 2 (%)	61.0	62.5	61.4		61.5	61.0	61.5	
ASA >2 (%)	22.8	16.1	16.5		16.0	20.8	17.0	
L1/2–L2/3 (%)	6.6	5.4	7.1	0.23	6.9	4.3	7.0	0.83
L3/4 (%)	24.3	19.6	21.6		20.2	18.4	21.8	
L4/5 (%)	50.7	66.1	50.6		52.1	61.6	50.8	
L5/S1 (%)	18.4	8.9	20.8		20.8	15.8	20.3	
1 segment involved (%)	49.3	51.8	55.2	0.11	53.2	64.1	54.7	0.68
2–3 segments involved (%)	43.4	41.1	40.4		42.5	31.4	40.6	
>3 segments involved (%)	7.4	7.1	4.4		4.4	4.5	4.7	
Number of previous spine surgeries (<i>n</i> ± SD)	1.3 ± 0.6	1.3 ± 0.7	1.2 ± 0.6	0.040	1.2 ± 0.5	1.2 ± 0.5	1.2 ± 0.6	0.89
Previous spine surgery on the same level (%)	15.8	10.7	9.3	0.003	10.3	11.8	9.8	0.88
Board-certified surgeon (%)	84.6	92.9	84.2	0.21	84.3	89.1	84.3	0.67
Surgeon in training (%)	15.4	7.1	15.8		15.7	11.0	15.7	

Table 3 continued

Patient and treatment characteristics	Before weighting adjustment				After weighting adjustment			
	DT			Comparison (<i>p</i> value)	DT			Comparison (<i>p</i> value)
	Repaired, <i>n</i> = 272 (8.4%)	Unrepaired, <i>n</i> = 56 (1.7%)	None, <i>n</i> = 2926 (89.9%)		Repaired, <i>n</i> = 167 (8.0%)	Unrepaired, <i>n</i> = 32 (1.5%)	None, <i>n</i> = 1882 (90.4%)	
Discectomy (%)	16.9	12.5	24.3	0.003	22.9	17.7	23.5	0.62
Laminotomy (%)	37.1	50.0	44.1	0.053	42.0	40.8	43.6	0.81
Hemilaminectomy (%)	15.1	8.9	11.7	0.20	11.9	11.1	11.9	0.99
Laminectomy (%)	35.7	30.4	25.2	<0.001	25.7	31.3	26.2	0.70
Facet joint resection partial or full (%)	46.3	42.9	45.2	0.88	42.7	34.8	45.2	0.26
Flavectomy (%)	63.6	64.3	64.2	0.98	64.8	66.9	64.1	0.91
Foraminotomy (%)	41.5	35.7	40.9	0.71	42.1	43.7	40.9	0.86
Other decompression (%)	20.2	10.7	18.8	0.25	17.3	12.7	18.7	0.47
Back pain baseline ± SD (points)	5.8 ± 2.9	6.5 ± 2.4	5.9 ± 2.9	0.26	5.9 ± 2.9	6.3 ± 2.3	5.9 ± 2.9	0.61
Leg pain baseline ± SD (points)	7.2 ± 2.4	7.4 ± 2.2	7.2 ± 2.4	0.93	7.2 ± 2.4	7.3 ± 1.9	7.2 ± 2.4	0.96
COMI score baseline ± SD (points)	7.6 ± 1.6	7.8 ± 1.7	7.7 ± 1.7	0.80	7.7 ± 1.6	7.8 ± 1.6	7.7 ± 1.7	0.80
COMI interval ± SD (months)	14.9 ± 8.3	16.9 ± 8.2	15.4 ± 8.3	0.25	15.2 ± 8.5	15.0 ± 7.5	15.4 ± 8.3	0.89

DT durotomy, SD standard deviation

Significant differences are written in bold

of 563 patients did not confirm this [25]. Obesity, too, has been associated with a higher incidence of DT in lumbar spine surgery [9]. Our results showed that, compared with BMI 26–30, higher (>30) BMI scores had a significant association with the incidence of intraoperative DT. Higher BMI (>30) is a widely accepted risk factor for complications during spinal surgery [9, 26]. The explanation for this association resides in the difficulty of surgical exposure due to the greater volume of soft tissue and the depth of the incision.

In our study, the likelihood for a DT increased by 67% if a minimally/less invasive surgical approach was used. Teli et al. found in a randomized trial clearly higher DT rate in micro-endoscopic surgeries than in surgeries using microscope only or in an open discectomy (8.7, 2.7 and 3.0%, respectively) [27]. However, this difference was not statistically significant. Similar to the association with obesity, the explanation for this finding may also lie in the difficulty of access with a minimally or less invasive approach, and poor perception of depth [27]. The fact that the 95% CI for this finding were rather narrow (1.18–2.36) suggests that this is a reliable estimate. We also found a

significant association of laminectomy with DT, which appears reasonable for this invasive decompression close to the dura. Deyo et al. also found laminectomy to be associated with a higher incidence of DT [10].

Several studies have demonstrated that previous surgery at the same level is an important risk factor for incidental DT [8, 28]. Scar tissue that adheres to the dura and complicates the surgical differentiation between the two may explain this association. Odds ratios of 2.21 and 4.78, respectively, have been reported by others for the occurrence of DT in patients undergoing revision surgery [8, 28]. Our odds ratio was 1.78. The origin of the differences in the precise association between revision surgery and occurrence of DT may lie in different patient populations or reporting accuracy.

The rate of patient-reported reoperations at the same vertebral level was not different between the groups. There is little evidence in the recent literature on reoperation rates after incidental DT. A relatively small study by Grannum et al. showed no reoperations in 14 unrepaired DT cases and concluded that DT in LSS surgery can be managed without repair with no negative effect on surgical outcome [29].

Table 4 IPTW adjusted outcomes in the patient groups

Patient and treatment characteristics	Dura lesion			Repaired vs. unrepaired DT (<i>p</i> value)	Repaired vs. no DT (<i>p</i> value)	Unrepaired vs. no DT (<i>p</i> value)
	Repaired DT, <i>n</i> = 272 (8.02%)	Unrepaired DT, <i>n</i> = 56 (1.54%)	No DT, <i>n</i> = 2926 (90.44%)			
Surgery time: unknown (%)	0.6	–	0.6	<0.001	<0.001	0.53
Surgery time: <1 h (%)	17.6	47.6	34.2			
Surgery time: 1–2 h (%)	54.7	44.5	56.8			
Surgery time: 2–3 h (%)	20.9	4.8	7.2			
Surgery time: >3 h (%)	6.2	3.2	1.2			
Cerebral complication (%)	0.8	–	0.1	1.0	0.003	1.0
CSF leak (%)	3.2	9.2	0.1	0.15	<0.001	<0.001
Superficial infection (%)	–	–	0.3	–	1.0	1.0
Deep infection (%)	–	–	0.2	–	1.0	1.0
Back pain postop ± SD (points)	4.2 ± 3.1	3.7 ± 2.8	3.8 ± 3.1	0.87	0.26	1.0
Back pain relief ± SD (points)	1.7 ± 3.0	2.6 ± 2.8	2.1 ± 3.3	0.23	0.21	0.80
Leg pain postop ± SD (points)	4.0 ± 3.3	4.1 ± 3.2	3.8 ± 3.3	1.0	1.0	0.62
Leg pain relief ± SD (points)	3.2 ± 3.7	3.2 ± 3.2	3.5 ± 3.6	1.0	1.0	0.54
COMI score postop ± SD (points)	4.7 ± 2.8	4.8 ± 2.9	4.5 ± 3.0	1.0	1.0	0.46
COMI score change ± SD (points)	2.9 ± 2.9	3.0 ± 2.7	3.2 ± 3.0	1.0	1.0	0.41
Patient-reported reoperations on the same level (%)	2.9	2.0	2.4	1.0	1.0	1.0
Satisfied (%)	88.7	79.7	89.2	0.23	1.0	0.10
Not satisfied (%)	11.3	20.3	10.8			
Helped (%)	70.6	62.7	71.1	0.78	1.0	0.58
Did not help (%)	29.4	37.3	28.9			
Length of hospital stay ± SD (days)	4.9 ± 4.6	4.2 ± 4.7	3.6 ± 3.7	0.76	<0.001	0.69

Only weighted proportions and values are shown for raw proportions and values. Appendix 1

DT durotomy, SD standard deviation

Significant differences are written in bold

In relation to the experience of the surgeon, Sin et al. demonstrated that there was a higher risk of DT in surgeons in training [26]. In our study, however, surgeon experience did not influence DT rates.

Duration of surgery was significantly longer in patients with repaired DT compared with patients without DT. More than 27% of the patients with repaired DT had a duration of surgery >2 h, whereas only around 8% the patients in the other two groups had a duration of surgery that long. Desai et al. also found incidental DT to be associated with significantly longer surgery times regardless of repaired or not [19]. Patients with a DT in our study had inpatient stays that were on average 1 day longer than

those without DT. Similar increases in the length of stay by 1.2 and 1.8 days on average were also reported by Desai et al. and Nandyala [19, 30]. It has been argued that this makes the treatment of DT uneconomic [30].

Influence of incidental durotomies on patient-rated outcome

Patient satisfaction with treatment in the hospital and the global treatment outcome ratings did not differ significantly among the patient groups. However, the proportions of patients who were “not satisfied” and who reported a “poor global treatment outcome” were, respectively, 9 and

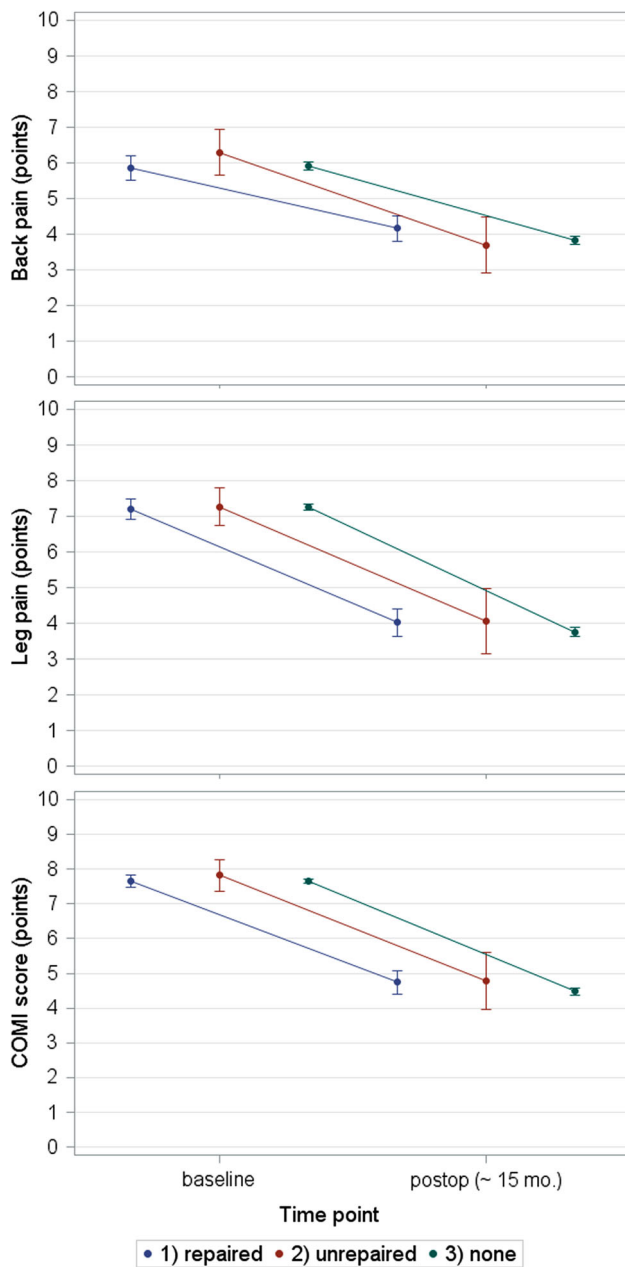


Fig. 3 Pain relief and improvement in COMI score in patients with no DT, repaired DT, and unrepaired DT, adjusted for case-mix

8% higher in the unrepaired DT group than in either of the other groups. This results in numbers needed to treat (NNT) of 11 (95% CI 6–97) and 13 (95% CI 5–20), respectively. These NNTs may potentially be clinically relevant, as $NNT = 10$ is usually regarded as a cut-off for clinical relevance [23]. However, they should be confirmed in future studies with larger sample sizes, to obtain tighter confidence intervals. The reason why fewer patients with unrepaired DT were satisfied with their care is not obvious, considering the otherwise similar outcomes. The only observed significant difference between patients with

repaired and those with unrepaired DT was in the duration of surgery. In almost 50% of the patients with unrepaired DT the duration of surgery was <1 h; in those with a repaired DT, surgery lasted <1 h in just 18%. In addition, a higher proportion of CSF leaks was seen in patients with unrepaired DT in comparison with repaired DT, although the difference was not statistically significant. It can be speculated that these two factors might have contributed to lower levels of satisfaction in those patients, perhaps due to the patients' perception that the operation did not proceed as well as expected.

The association between DT and patient outcome in LSS treatment is still debated. A matched study ($n = 82$) by Saxler et al. reported that patients with incidental DT had a tendency to report more back pain, were more likely to have further surgery, and had a longer return-to-work time after surgery [4]. Williams et al. reported a DT rate of 1.6% in 108,478 cases, and found an association between incidental DT and development of a new neurological deficit [24]. In a more recent study on 880 patients, Kothe et al. reported an association between incidental DT and an increase of patients' LOS, higher risk of re-intervention due to CSF leak and an inferior outcome in terms of leg pain after a 12 months follow-up [31]. However, Desai et al. reported no significant difference between DT and non-DT groups over a mean follow-up of 47.6 months in the SPORT data [19]. In a recent prospective multicenter study, Ulrich et al. also reported no effect of incidental DT on patient-rated outcomes after a follow-up of 24 months in a cohort of 167 patients [32]. In our international cohort, an incidental DT was not associated with the postoperative outcome in terms of leg and back pain relief and reduction in COMI score at the average follow-up of 15.4 months.

Management of incidental durotomies

Since there is ongoing discussion as to how to best manage incidental DTs, each surgeon tends to just use her/his own protocol, including choosing not to repair. A methodologically correct approach to evaluating the best management practice would involve randomization of DTs into repaired and unrepaired groups, but setting up such a study protocol is not feasible because it would be considered unethical to refuse a DT repair, since there are known, potentially dangerous complications of durotomies such as CSF leakage. However, observational registry data have the known limitation of hidden cause–effect relationships. We do not know why surgeons chose to repair DTs or close the wounds without repair. Thus can we only report on the association between DTs and outcomes using robust statistical methods.

We used the IPTW method to balance patient characteristics between patient groups to enable us to assess

outcomes in a more unbiased way. This method mirrors some characteristics of randomized clinical trials and removes systematic differences between groups to a degree comparable to propensity score based matching (which is preferred when there are two groups only) [33]. As matching between more than two groups is not normal or simple, the IPTW was used. An important limitation of post hoc adjustment methods is that they cannot adjust for unobserved factors. In our analysis this means, for example, that we were not able to adjust for factors such as lesion size, location, and accessibility that might have led to the decision to repair the DT or not. Indeed, there are dural lesions that cannot be repaired in a watertight fashion. Nonetheless, twice as many potential confounders were considered in the present study in comparison with previous studies [7, 19].

In the Spine Tango data, the majority of DTs were repaired. Only 17% of all DTs were not, and these were documented in just seven out of the 21 centres. From this, it might be assumed that the management of DT is preference-based rather than being homogeneously distributed between the participating centres. However, the total number of DTs occurring in each of the other 21 hospitals was only between 1 and 5, making any such conclusions difficult. By far the leading approach to DT repair, in 98.5% of cases across all the centres, was suture and/or the use of a fibrin glue (this characterization cannot be made more specific). Despite the multinational nature of this study and a putative lack of consensus about surgical management, these findings suggest surprisingly homogeneous management of incidental DTs.

Postoperative CSF leakage is a possible consequence of incidental DT. Therefore, a higher CSF leak rate in patients with DTs than in those without is not unexpected, although we saw early postoperative CSF leakage in two patients (0.1%) with no record of DT. This was almost certainly related in each case to an unrecognised DT.

Patients with unrepaired DT differed from those with repaired DT in that they had a shorter duration of surgery. Additionally, a lower proportion of satisfied patients and patients with a good global treatment outcome, and a higher proportion of patients with CFS leaks were seen in this group, although the differences were not statistically significant and need to be evaluated in larger series of patients. Beyond these findings, no significant inter-group differences were found, including, in particular, no difference in patient-rated outcomes measured as pain relief and improvement in COMI score. This agrees with previous research [7, 19]. Limitations in this context were the study's overall follow-up rate of 48.4% and potentially also the small size of the group with unrepaired DT. However, one of the centres with a follow-up rate >95% has already reported no significant association between DT and patient-

reported outcome [34]. Another limitation of the study is that we did not control for centres when we compared treatment outcomes in relation to DT (none vs. repaired vs. unrepaired DT), and outcome may have been confounded by centre.

Conclusions

The unadjusted rates of incidental DT during decompression for lumbar spinal stenosis are reasonably comparable across the treatment centres represented in the international Spine Tango registry. Higher patient age, obesity, previous surgery at the same spinal level, minimally/less invasive surgery, and laminectomy were associated with an increased likelihood of DT. Non-repair of DTs had no negative association with treatment outcome; however, the unrepaired DTs may have been those that were smaller in size. No significant associations between incidental DT and patient-reported outcomes were found.

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Compliance with ethical standards

Conflict of interest The authors have nothing to disclose.

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