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Surgery for lumbar degenerative spondylolisthesis in SPORT: Does incidental durotomy affect outcome?

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Abstract

Study Design—Retrospective review of a prospectively collected multi-institutional database.

Objective—In the present analysis we investigate the impact of incidental durotomy on outcome in patients undergoing surgery for lumbar degenerative spondylolisthesis.

Summary of Background Data—Surgery for lumbar degenerative spondylolisthesis has several potential complications, one of the most common of which is incidental durotomy. The effect of incidental durotomy on outcome, however, remains uncertain.

Methods—Spine Patient Outcomes Research Trial cohort participants with a confirmed diagnosis of lumbar degenerative spondylolisthesis (DS) undergoing standard first-time open decompressive laminectomy, with or without fusion, were followed from baseline at 6 weeks, and 3, 6, 12 months and yearly thereafter, at 13 spine clinics in 11 US states. Patient data from this prospectively gathered database was reviewed. As of May 2009, the mean (Standard Deviation) follow-up among all analyzed DS patients was 46.6 (13.1) months (No durotomy: 46.7 vs. Had durotomy: 45.2, p-value=0.49). The median (range) follow-up time among all analyzed DS patients was 47.6 (2.5, 84) months.

Results—A 10.5% incidence of durotomy was detected among the 389 patients undergoing surgery. No significant differences were observed with or without durotomy in age, race, the prevalence of smoking, diabetes and hypertension, decompression level, number of levels, or whether a fusion was performed. There were no differences in incidence of nerve root injury, post-op mortality, additional surgeries, SF-36 scores of body pain or physical function, or Oswestry disability index at 1, 2, 3 and 4 years.

Conclusions—Incidental durotomy during first time surgery for lumbar degenerative spondylolisthesis does not appear to impact outcome in affected patients.

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Trial Registration: Spine Patient Outcomes Research Trial (SPORT): Degenerative Spondylolisthesis; 3 #NCT00000410; http://www.clinicaltrials.gov/ct/show/NCT00000410?order=4

Keywords

Durotomy; Clinical outcomes; Lumbar spine surgery; Degenerative spondylolisthesis; Surgical complications

INTRODUCTION

Spinal surgery for lumbar spondylolisthesis, with any combination of laminectomy and fusion, is generally a safe procedure. However, it is can be complicated by incidental durotomy. The estimated incidence of durotomy during lumbar spine surgery, in the literature, is between 1 and 17%[1–20], with higher incidences associated with repeat surgery, reduced surgeon experience and increased patient age[1, 3, 7, 8, 20–22].

Dural tears have been associated with significant morbidity. Frequent symptoms commonly attributed to durotomies are spinal headaches, meningeal pseudocyst formation and dural-cutaneous cerebrospinal fluid fistulas[8, 10]. Several interventions have been proposed once a dural tear is recognized. These include primary repair, lumbar drain placement and post-operative bed rest[1, 4, 6, 7, 23]. Despite the use of these measures, there has been no well designed study to investigate the effect of incidental durotomy on short and long-term outcomes[6, 10]. In addition, the incidence of dural tears specific to spinal surgery for spondylolisthesis and the outcomes for these subgroups has not been investigated.

The Spine Patient Outcomes Research Trial[24, 25], a multi-center trial (13 multidisciplinary spine clinics) including both randomized and observational cohorts initiated in March 2000, allows to examine long-term outcomes after incidental durotomy during surgery for spondylolisthesis given its large cohort size[24, 25], standardized outcome measures and long-term follow-up. Furthermore, all procedures were performed in patients without previous history of lumbar spine surgery.

METHODS

Study Design

The SPORT was conducted at 13 medical centers with multidisciplinary spine practices in 11 states in the United States. Institutionalreview board approval was obtained at each center. The trial was registered with ClinicalTrials.gov (NCT00000411). Additional background information is available in previous publications[24, 25].

Patient Population

All patients had lumbar spondylolisthesis seen on cross-sectional imaging. Reported symptoms were neurogenic claudication or radicular leg pain with associated neurological signs, that had persisted for at least six weeks, and physician confirmation that they were surgical candidates. Pre-enrollment nonoperative care included physical therapy, anti-inflammatory medications, opioid analgesics, epidural injections, and chiropractic care. Enrollment began in March 2000 and ended in February 2005. 'Instability' was defined as a change of more than 10 degrees of angulation or more than 4 mm of translation of the vertebrae between flexion and extension of the spine. The severity of stenosis was classified as mild, moderate or severe based on subjective assessment by the clinician.

Surgery Performed

The protocol surgery consisted of a standard open laminectomy at the affected level or levels, with or without, instrumented or non-instrumented, fusion. The use of a microscope was not recorded as part of the SPORT database, since it was at the surgeon's discretion.

Study Measures

The short-term outcome measures were operative duration, operative blood loss, inpatient length of stay, perioperative nerve root injury, requirement for blood transfusion, wound complications (e.g. infection) and post-operative mortality up to 3 months.

The long-term outcome measures were the need for repeat surgery at 3 months, and 1, 2, 3 and 4 years, the Short Form-36 (SF-36) bodily pain, physical function and mental component scores, Stenosis bothersomeness index (SBI) and the American Academy of Orthopaedic Surgeons MODEMS (Musculoskeletal Outcomes Data Evaluation and Management System) version of the Oswestry Disability Index, measured at 3 months, and yearly up to 4 years. The effect of the incidental durotomy on long-term outcome was defined as the difference in the mean changes, as compared with baseline, between the durotomy and no-durotomy groups (the difference in the difference).

SF-36 scores range from 0 to 100 points, with higher scores indicating less severe symptoms. The Stenosis Bothersomeness Index ranges from 0 to 24 points, with lower scores indicating less severe symptoms. SF-36 scores range from 0 to 100 points, with higher scores indicating less severe symptoms; the Oswestry Disability Index ranges from 0 to 100 points, with lower scores indicating less severe symptoms.

Statistical Methods

The baseline characteristics and short and long-term outcome measures were compared between the patients in the durotomy cohort and those in the no-durotomy cohort. The analyses consisted of comparisons of both groups. The baseline characteristics were only analyzed for patients in both groups that had at least one year of follow-up. Computations were performed with the use of the PROC MIXED procedure for continuous data and the PROC GENMOD procedure for binary and non-normal secondary outcomes from the SAS software package (version 9.1; SAS Institute, Cary, North Carolina). Significance was defined as $p < 0.05$ on the basis of a two-sided hypothesis test with no adjustments made for multiple comparisons. The data for these analyses were collected through May 1, 2009.

RESULTS

Incidence of dural tears

A total of 389 patients underwent surgery for degenerative spondylolisthesis, from which specific procedure information was available for 382 patients. Surgery comprised of laminectomy alone in 24 patients, noninstrumented fusion in 81 patients, and instrumented fusion in 277 patients. Overall, durotomy occurred in 41 patients, for an incidence of 10.5%.

Follow-up

As of May 2009, the mean (SD) follow-up among all analyzed DS patients was 46.6 (13.1) months (No durotomy: 46.7 vs. Had durotomy: 45.2, p-value=0.49). The median (range) follow-up time among all analyzed DS patients was 47.6 (2.5, 84) months. The number of patients available for follow-up at various time intervals were as follows: 3 months - No Durotomy , Durotomy ; 1 year - No Durotomy , Durotomy ; 2 years - No Durotomy , Durotomy ; 3 years - No Durotomy , Durotomy ; 4 years - No Durotomy ; Durotomy .

Baseline characteristics (Table 1)

Out of 389 patients that underwent surgery, 385 patients had greater than one-year follow-up and their baseline characteristics were reviewed. No significant differences were seen between the durotomy and no-durotomy groups in age, race, the prevalence of smoking, diabetes and hypertension, pre-operative neurological symptoms or deficits, and pre-operative SF-36 and Oswestry disability index scores. Female patients and patients with a higher body mass index demonstrated a higher incidence of durotomy. There were no associations found between durotomy status and listhesis level, stenosis level or number of levels, or stenosis severity (mild, moderate, severe).

Operative events (Table 2)

There were no differences between the two groups in decompression levels, number of levels. There was a significantly increased operative blood loss (571.9ml versus 668.2ml, $p<0.001$) in the durotomy group. However, these patients did not have increased needs for intra-operative or post-operative blood transfusion.

Short-term outcomes (Table 3)

There was no difference in the hospital stay between the two groups. There were no increases in the incidence of wound hematoma or infection and post-operative nerve root injury. No occurrences of CSF fistula formation, wound dehiscence, bone graft complication, paralysis or cauda equina injury, pseudoarthrosis, or other complications attributable to surgery were observed. One patient (in the no durotomy group) died within 6 weeks of surgery.

Long-term outcomes (Table 3, 4, Figure 1)

There were no significant differences between the durotomy and no-durotomy groups in the incidence of recurrent stenosis or the development of progressive listhesis. One-, two-, three- and four-year post-surgical re-operation rates were calculated from Kaplan-Meier plots. When the durotomy and no-durotomy groups were compared there were no significant differences in re-operation rates (Table 3).

There were no differences between the durotomy and no-durotomy groups in mean difference from baseline for SF-36 bodily pain, physical function and mental component summary scores, at 3 months, 1 year, 2 years, 3 years and 4 years. Similarly there were no difference in Oswestry disability index and Stenosis bothersomeness index scores at 3 months, and 1, 2, 3 and 4 years (Table 4, Figure1).

DISCUSSION

The effects of incidental durotomies on long-term outcome measures are unknown. Despite this however, a significant portion of medical malpractice lawsuits against neurosurgeons involve durotomy after spine surgery[26]. In addition, there is a lack of data on the incidence of dural tears and their outcomes in patients undergoing surgical procedures for specific spinal pathology.

Previous studies attempting to analyze the effects of durotomy on outcomes have tended to arrive at mixed conclusions. In the present study we have demonstrated that in patients undergoing laminectomy with or without fusion for lumbar degenerative spondylolisthesis, incidental durotomy does not appear to be associated with worsened perioperative morbidity or patient outcome at 6 weeks, 3 months and at 1, 2, 3 and 4 years. In agreement with our data, Jones et al[1] did not demonstrate any difference in outcome between their 17 patients with incidental durotomies and appropriately matched controls. Wang et al[7], in one of the

largest series of incidental durotomies involving 88 patients, supported that dural tears have no adverse effects on long-term outcomes. The findings of Cammisa et al[8], support these results. However, the design of most of these previous studies has been biased. All the previous studies were retrospective in nature and took into account all spinal procedures, including discectomies, surgeries for spondylolisthesis, as well as revisions. These confounding variables have been addressed in the current study, where prospectively collected data from patients with a single pathology (spondylolisthesis) and operation (open lumbar laminectomy with or without fusion), that were part of a multi-institution study, are analyzed.

In contrast, Saxler et al[10], in their retrospectively analyzed group that included 41 discectomy patients with durotomies, demonstrated that patients with incidental durotomies had worst outcomes after surgery. In fact, they were characterized by a decreased Tenger Score, more re-operations, more postoperative headaches, a longer time of inability to work, more back pain and functional limitations related to it. Although these data disagree with most of the previously mentioned authors, they are not in conflict with the present study on laminectomy for spondlylolisthesis patients, since they are specific to discectomy patients. However, several methodological pitfalls of this study raise valuable concerns. Recall bias can hinder the validity of these results, while the retrospective nature of the study makes it possible that patients with good postoperative results were lost at follow up further confounding the outcomes. On the contrary, the current study overcomes several of these limitations by describing standardized outcomes in a multi-center cohort of prospectively collected data of patients undergoing first time surgery.

The rate of incidental durotomy in the present study was 10.5%, similar to several other studies[1, 4, 7, 8, 10]. The reported incidence of dural tears ranges from 1–17% and varies based on the patient characteristics and the surgical procedures performed. The relative complexity of the procedures performed for spondylolisthesis that usually involve instrumented fusion could justify the fact that the incidence of incidental durotomies observed is at the high end of the reported spectrum. Deyo et al[21] evaluated postoperative complications, including dural tears in a large series of spinal procedures. The morbidity was lower for younger patients and for discectomies, while worst outcomes were associated with increased age, spinal stenosis, and re-operations. Several other authors have confirmed these results[1, 3, 7, 8, 11, 22].

The sequelae of dural tears include nerve root entrapment with resultant neurological damage, a persistent leak of cerebrospinal fluid, postoperative headache, pseudomeningocele, meningitis, and arachnoiditis[1, 20, 26]. In addition, several extremely rare complications have been reported as a result of incidental durotomies, including symptomatic pneumorachis[27], spinal subdural empyema[28], bilateral subdural hematomas[29], and cerebral vasospasm[30]. We did not observe an increase in the incidence of post-operative nerve root injury, wound infection or hematoma. There were no occurrences of CSF fistula formation, wound dehiscence, neurological complications, or other complications attributable to surgery. The observed increased length of stay among patients with dural tears may be attributed to the tendency for increased bed rest and slower mobilization of these patients.

Several outcome measures have been used in the literature to quantify long-term outcomes in patients with incidental durotomies[10]. In the present study, there were no significant differences between the durotomy and no-durotomy groups in the incidence of recurrent stenosis, development of listhesis, or re-operations (Table 3). There were no differences between the durotomy and no-durotomy groups in mean difference from baseline for SF-36 bodily pain, physical function and mental component summary scores, and in in Oswestry

disability index and sciatica bothersome index in several time points during follow up (Table 4).

The current study has several limitations. Although our data were collected prospectively in the setting of a multicenter study, they were retrospectively analyzed. While the median follow-up was 47.6 months, patients were lost to follow-up at increasing time intervals (Table 4), and a relatively small number of durotomies resulted in relatively large confidence intervals for some measures. The power of the present study in evaluating differences in outcome should also be considered. While the sample size is relatively large in comparison to previously reported series, the 95% confidence intervals for the differences in the long-term outcome measures (SF-36, Oswestry Disability Index, Stenosis Bothersomeness Index) between the durotomy and nodurotomy groups in this study are relatively broad and this can reflect the limited power of the study to confirm equivalence in outcomes (Table 4). We did not have access to the precise methods of treatment followed in the different centers for the incidental durotomies and therefore their homogeneity cannot be assessed, and a comparison with the treatments of the literature cannot be attempted. In the present study, data on the use of microscope were not collected and therefore we cannot provide an answer as to whether the incidence of durotomy can be altered by its use.

Conclusions

Incidental durotomy is a relatively common complication during surgery for lumbar degenerative spondylolisthesis. In the current study, the data of the SPORT trial were analyzed in an attempt to investigate whether the occurrence of durotomy affected outcomes. No significant differences were found between durotomy and no-durotomy patients in operative duration, blood loss, inpatient stay, nerve root injury, wound complications, additional surgeries, SF-36 scores of body pain or physical function, or Oswestry disability index at 3 months and 1, 2, 3 and 4 years. Therefore, incidental durotomy during first time surgery for lumbar degenerative spondylolisthesis does not appear to affect outcomes in affected patients.

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Abbreviations

DS	Degenerative spondylolisthesis
SF-36	Short form 36 questionnaire
ODI	Oswestry disability index
SBI	Stenosis bothersomeness index

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Key Points

1. Incidental durotomy is a well recognized complication during surgery for lumbar degenerative spondylolisthesis
2. Patients in the SPORT study undergoing surgery for lumbar degenerative spondylolisthesis in whom a durotomy occurred did not have any significant difference in outcomes including nerve root injury, post-operative mortality, additional surgeries, SF-36 scores, or Oswestry disability index at 1, 2, 3 and 4 years.
3. Incidental durotomy during first time surgery for lumbar spondylolisthesis does not appear to impact long-term outcome in affected patients.

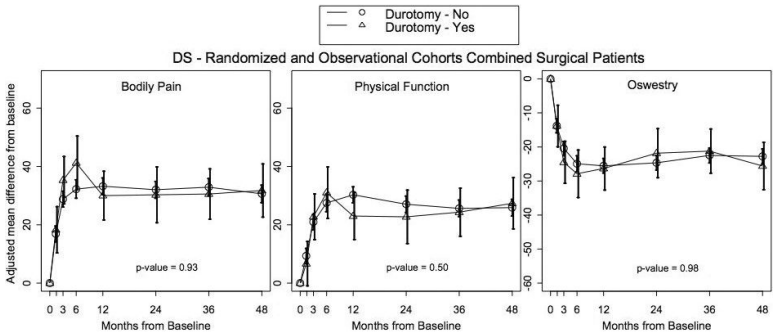

figure 1.

Table 1

Comparison of baseline characteristics between the durotomy and no durotomy groups.

Characteristics	No durotomy (n=345)	Durotomy (n=40)	p-value
Mean Age (SD)	64.4 (10)	66.6 (10.9)	0.21
Female - no.(%)	244 (71%)	20 (50%)	0.013
Mean Body Mass Index (BMI), (SD)	29.6 (6.5)	27.1 (5.2)	0.021
Smoker	30 (9%)	5 (12%)	0.62
Comorbidities - no.(%)			
Hypertension	157 (46%)	15 (38%)	0.43
Diabetes	46 (13%)	3 (8%)	0.43
Osteoporosis	36 (10%)	4 (10%)	0.85
Depression	63 (18%)	5 (12%)	0.49
Joint Problem	194 (56%)	21 (52%)	0.78
SF-36 scores, mean (SD)			
Bodily Pain (BP)	31.2 (18.8)	28.3 (18.2)	0.37
Mental Component Summary (MCS)	49.4 (11.7)	50.3 (11.8)	0.92
Oswestry Disability Index (ODI)(SD)[‡‡]	45 (16.7)	42.6 (15.7)	0.40
Stenosis Bothersome Index (0–24)(SD)[§§]	15.5 (5.4)	15.7 (6.3)	0.75
Pseudoclaudication	296 (86%)	35 (88%)	0.96
SLR or femoral tension	44 (13%)	6 (15%)	0.88%
Pain Radiation	268 (78%)	32 (80%)	0.89
Any Neurological Deficit	184 (53%)	25 (62%)	0.35
Reflexes- Asymmetric Depressed	83 (24%)	17 (42%)	0.02
Sensory- Asymmetric Decrease	101 (29%)	8 (20%)	0.29
Motor- Asymmetric Weakness	80 (23%)	9 (22%)	0.92
Listhesis Level			0.94
L3-L4	31 (9%)	4 (10%)	
L4-L5	314 (91%)	36 (90%)	
Stenosis Level			
L2-L3	30 (9%)	4 (10%)	0.98
L3-L4	130 (38%)	24 (60%)	0.011
L4-L5	336 (97%)	37 (92%)	0.23
L5-S1	27 (8%)	5 (12%)	0.48
Number of Moderate/ Severe Stenotic Levels			
None	11 (3%)	0 (0%)	
One	218 (63%)	23 (57%)	
Two	94 (27%)	14 (35%)	
Three +	22 (6%)	3 (8%)	
Stenosis Locations			

Characteristics	No durotomy (n=345)	Durotomy (n=40)	p-value
Central	375 (92%)	37 (92%)	0.86
Lateral Recess	318 (92%)	34 (85%)	0.22
Neuroforamen	152 (44%)	9 (22%)	0.014
Stenosis Severity			0.36
Mild	11 (3%)	0 (0%)	
Moderate	123 (36%)	12 (30%)	
Severe	211 (61%)	28 (70%)	
Instability	30 (9%)	4 (10%)	

* Patients received surgery were classified according to whether they received surgical treatment during the first 4 years of enrollment.

§ The body-mass index is the weight in kilograms divided by the square of the height in meters.

¶ Other indicates problems related to stroke, cancer, lung, fibromyalgia, chronic fatigue syndrome, post traumatic stress disorder, alcohol, drug dependency, liver, kidney, blood vessel, nervous system, migraine,

†† The SF-36 scores range from 0 to 100, with higher score indicating less severe symptoms.

‡‡ The Oswestry Disability Index ranges from 0 to 100, with lower scores indicating less severe symptoms.

§§ The Stenosis Bothersomeness index range from 0 to 24, with lower scores indicating less severe symptoms.

¶¶ The Low Back Pain Bothersomness Scale ranges from 0 to 6, with lower scores indicating less severe symptoms.

Table 2

Comparison of operative events between the durotomy and no durotomy groups

Outcome	No durotomy (n=348)	Durotomy (n=41)	p-value
Specific Procedures†			0.046
Decompression Only	18 (5%)	6 (15%)	
Non instrumented Fusion	74 (22%)	7 (18%)	
Instrumented Fusion	251 (73%)	26 (67%)	
Multi-level Fusion	78 (22%)	13 (32%)	0.26
Levels Decompressed			0.055
None	4 (1%)	0 (0%)	
1	147 (42%)	12 (29%)	
2	125 (36%)	13 (32%)	
3+	72 (21%)	16 (39%)	
Operation time (min)	205.9 (84)	211.2 (80.7)	0.70
Blood loss (ml)	571.9 (464.4)	668.2 (505.6)	0.22
Blood Replacement			
Intraoperative replacement	117 (34%)	15 (37%)	0.87
Post-operative transfusion	70 (20%)	11 (28%)	0.40
Length of stay (days)	5.7 (20)	5.6 (4.4)	0.98
Intraoperative complications§			
Vascular injury	1 (0%)	0 (0%)	0.20
Other	8 (2%)	1 (2%)	0.62
None	340 (98%)	0 (0%)	< 0.001

*Surgical information was available for 371 non-durotomy and 38 durotomy patients.

†Specific procedure data was available for 363 non-durotomy and 37 durotomy patients.

§No cases were reported of aspiration into the respiratory tract or operation at wrong level.

Table 3

Comparison of post-operative outcomes between the durotomy and no durotomy groups.

Outcome	No durotomy (n=774)	Durotomy (n=25)	p-value
Nerve root injury	0 (0%)	1 (2%)	0.19
Wound dehiscence	1 (0%)	0 (0%)	0.19
Wound hematoma	1 (0%)	0 (0%)	0.19
Wound Infection	10 (3%)	1 (2%)	0.72
Other	27 (8%)	10 (25%)	0.001
None	244 (71%)	23 (57%)	0.12
Post-operative mortality (6 wks of surgery)	1 (0.3%)	0 (0%)	
Post-operative mortality (3 mo of surgery)	2 (0.5%)	0 (0%)	
Additional surgeries (1-year rate)	23 (7%)	1 (2%)	0.30
Additional surgeries (2-year rate)	44 (13%)	3 (7%)	0.32
Additional surgeries (3-year rate)	50 (14%)	4 (10%)	0.41
Additional surgeries (4-year rate)	82 (11%)	1 (4%)	0.29
Recurrent stenosis / progressive listhesis	18 (5%)	2 (5%)	
Pseudarthrosis / fusion /exploration	4 (1.2%)	0	

* Surgical information was available for 348 non-durotomy and 41 durotomy patients.

† Specific procedure data was available for 343 non-durotomy and 39 durotomy patients.

§ No cases were reported of aspiration into the respiratory tract or operation at wrong level.

¶ Complications or events occurring up to 8 weeks after surgery are listed. There were no reported cases of bone-graft complication, cerebrospinal fluid leak, paralysis, cauda equina injury or pseudarthrosis.

// Rates of repeated surgery at 1, 2,3,and 4 years are Kaplan-Meier estimates. P values were calculated with the use of the log-rank test. Numbers and percentages are based on the first additional surgery if more than one additional surgery

Table 4

Change scores and their differences ("No durotomy" minus "durotomy") for long-term SF-36 scores, Oswestry disability index scores and Stenosis bothersome index scores, according to status of durotomy.

	3-month		1-year		2-year		3-year		4-year		
	Difference†	**p-value**	**Difference†**	**p-value**	**Difference†**	**p-value**	**Difference†**	**p-value**	**Difference†**	**p-value**	**AUC p-value**
SF-36 Bodily Pain (SE)‡	−6.5 (−15.1, 2.1)	0.14	3.2 (−5.6, 12.1)	0.48	1.7 (−8.3, 11.7)	0.74	2.3 (−6.8, 11.5)	0.62	−1.2 (−10.8, 8.4)	0.81	0.93
SF-36 Physical Function (SE)‡	−1.8 (−10, 6.4)	0.67	7.2 (−1.3, 15.8)	0.10	4.3 (−5.3, 13.9)	0.38	1.3 (−7.4, 10.1)	0.77	−1.5 (−10.8, 7.8)	0.75	0.50
SF-36 Mental Component Summary (SE) ‡	1.5 (−2.2, 5.1)	0.43	−3.1 (−6.9, 0.7)	0.11	−0.8 (5.1, 3.4)	0.70	0.6 (−3.3, 4.5)	0.77	0.4 (−4, 4.8)	0.85	0.79
Oswestry Disability Index (SE)§	4.1 (−2.5, 10.6)	0.22	0.8 (−5.9, 7.5)	0.81	−2.8 (−10.3, 4.7)	0.46	−1.3 (−8.2, 5.6)	0.71	2.8 (−4.5, 10.1)	0.45	0.98
Stenosis Bothersome Index (SE)¶	−0.1 (−3, 2.8)	0.93	1.7 (−4, 0.7)	0.16	−0.4 (−3.1, 2.3)	0.78	0.1 (−2.4, 2.6)	0.94	0.3 (−2.5, 3)	0.85	0.68

*Adjusted for age, gender, BMI and baseline score.

†Difference is the difference between no durotomy group mean change from baseline and had durotomy group mean change from baseline.

‡The SF-36 scores range from 0 to 100, with higher score indicating less severe symptoms.

§The Oswestry Disability Index ranges from 0 to 100, with lower scores indicating less severe symptoms

¶The Stenosis Bothersomeness Index ranges from 0 to 24, with lower scores indicating less severe symptoms

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