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Outcomes after incidental durotomy during first-time lumbar discectomy

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Abstract

Introduction—Incidental durotomy is an infrequent but well-recognized complication during lumbar disc surgery. The effect of a durotomy on long-term outcomes is however, controversial. We sought to examine whether the occurrence of durotomy during surgery impacts long-term clinical outcome.

Methods—Spine Patient Outcomes Research Trial (SPORT) cohort participants with a confirmed diagnosis of intervertebral disc herniation (IDH) undergoing standard first-time open discectomy were followed from baseline at 6 weeks, 3, 6, and 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 (SD) follow-up among all analyzed IDH patients was 41.5 (14.5) months (No durotomy: 41.4 vs. Had durotomy: 40.2, p-value<0.68). The median (range) follow-up time among all analyzed IDH patients was 47 (1 to 95) months.

Results—799 patients underwent first-time lumbar discectomy. There was an incidental durotomy in 25 (3.1%) of these patients. There were no significant differences with or without durotomy in age, sex, race, body mass index, the prevalence of smoking, diabetes, hypertension, or herniation level or type. When outcome differences between the groups were analyzed, the durotomy group was found to have significantly increased operative duration, operative blood loss and inpatient stay. However, there were no differences in incidence of nerve root injury, post-op mortality, additional surgeries or SF-36 scores of bodily pain or physical function, or Oswestry Disability Index at 1, 2, 3 or 4 years.

Conclusions—Incidental durotomy during first time lumbar discectomy does not appear to impact long-term outcome in affected patients.

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Trial Registration:

Spine Patient Outcomes Research Trial (SPORT): Intervertebral Disc Herniation; 3 #NCT00000410; <http://www.clinicaltrials.gov/ct/show/NCT00000410?order=4>

Keywords

Durotomy; Clinical outcomes; Lumbar spine; Surgical complications

INTRODUCTION

Incidental durotomy is an infrequent, but well recognized complication from lumbar discectomy. Various series have estimated the incidence of an unintentional durotomy during lumbar spine surgery to be between 1 and 17%,^{1,2,4,9,12–19,21–27,30} with higher incidences associated with repeat surgery, increased patient age and reduced surgeon experience.^{4,7–9,13,25,27}

Various sequelae from dural tears in the lumbar spine have been reported, including spinal headaches, meningeal pseudocyst formation and dural-cutaneous cerebrospinal fluid fistulas.^{4,21} These consequences at least partly account for the finding that unintended durotomy accounts for a small but significant proportion of lawsuits pertaining to spine surgery.¹⁰

The risk of the aforementioned complications has led to the routine use of several intraoperative and postoperative measures once a dural tear is recognized. These include primary repair (with or without dural substitute and/or fibrin glue), lumbar drain placement, and post-operative bed rest.^{11–13,26,27} Even when such precautions are taken however, the effect of unintentional durotomy on long-term outcomes remains controversial.^{12,21}

The Spine Patient Outcomes Research Trial (SPORT),^{28,29} a multi-center trial including both randomized and observational cohorts initiated in March 2000, provides a valuable opportunity to examine long-term outcomes after incidental durotomy during discectomy given its large cohort size,^{28,29} standardized outcome measures and long-term follow-up. Furthermore, all discectomies were performed using the same approach (open) and all were performed in patients without a previous history of lumbar spine surgery.

This study was undertaken in order to investigate whether incidental durotomy during first-time lumbar discectomy across the 13 multidisciplinary spine clinics participating in the SPORT trial had any effects on long-term outcomes.

METHODS

Study Design

SPORT was conducted at 13 medical centers with multidisciplinary spine practices in 11 U.S. states. Institutional review board approval was obtained at each center. The trial was registered with ClinicalTrials.gov (NCT00000410). Additional background information is available in previous publications.^{28,29}

Patient Population

All patients had radicular leg pain with associated neurological signs, intervertebral disc herniation (IDH) seen on cross-sectional imaging, symptoms that had persisted for at least

six weeks, and physician confirmation that they were surgical candidates. Pre-enrollment non-operative care included physical therapy, epidural injections, chiropractic care, anti-inflammatory medications and opioid analgesics. Enrollment began in March 2000 and ended in February 2005.

Surgery Performed

The protocol surgery consisted of a standard open posterior lumbar discectomy at the affected level or levels. The use of a microscope was at the surgeon's discretion but was not recorded as part of SPORT data collection.

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; Sciatica Bothersomeness Index (SBI); and the American Academy of Orthopaedic Surgeons MODEMS (Musculoskeletal Outcomes Data Evaluation and Management System) version of the Oswestry Disability Index (ODI), 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 of the differences).

SF-36 scores range from 0 to 100 points, with higher scores indicating less severe symptoms; the ODI ranges from 0 to 100 points, with lower scores indicating less severe symptoms; the SBI ranges from 0 to 24 points, with lower scores indicating less severe symptoms.

Statistical Methods

The baseline characteristics 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 799 patients underwent standard open lumbar discectomy. Of these, durotomy occurred in 25, for an incidence of 3.1%.

Follow-up

As of May 2009, the mean (SD) follow-up among all analyzed IDH patients was 41.5 (14.5) months (No durotomy: 41.4 vs. Had durotomy: 40.2, p -value<0.68). The median (range) follow-up time among all analyzed IDH patients was 47 (1 to 95) months. The number of patients available for follow-up at various time intervals were as follows: 3 months - No Durotomy 684, Durotomy 22; 1 year - No Durotomy 636, Durotomy 20; 2 years - No Durotomy 639, Durotomy 20; 3 years - No Durotomy 565, Durotomy 16; 4 years - No Durotomy 510; Durotomy 13.

Baseline characteristics (Table 1)

Out of 799 patients that underwent surgery, 784 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 baseline clinical characteristics. These included age, sex, race, body mass index, the prevalence of smoking, diabetes and hypertension, pre-operative neurological symptoms or deficits, pre-operative lumbar epidural steroid injections, and pre-operative SF-36 and ODI scores. There were also no differences in the herniation level (L2 through S1) and type of herniation (protruding, extruded or sequestered), nor in the direction of herniation (posterolateral or other).

Operative events (Table 2)

A significantly increased operative duration was seen in the durotomy group (139 minutes versus 74.7 minutes, p <0.001). There was also a significant increase in operative blood loss (288.8ml versus 57.4ml, p <0.001), though not in the need for intra-operative or post-operative blood transfusion.

Short-term outcomes (Table 3)

There was a significantly increased length of hospital stay among the durotomy group (2.5 versus 0.9 days, p <0.001). There were no increases in the incidence of postoperative nerve root injury, wound infection, or wound hematoma. There were no occurrences of CSF fistula formation, wound dehiscence, bone graft complication, paralysis or cauda equina injury, or other complications attributable to surgery. There was no mortality within the first 6 weeks of surgery. One patient (in the no durotomy group) died after heart surgery within 3 months of lumbar discectomy. The death was judged unrelated to the spine surgery.

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

There were no significant differences between the durotomy and no-durotomy groups in the incidence of recurrent disc herniation. 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 ODI or SBI at 3 months, and 1, 2, 3 and 4 years (Table 4, Figure 1).

DISCUSSION

Lumbar discectomy is the most common surgical procedure performed in the United States for patients experiencing back and leg pain^{6,29} and incidental durotomy is among the most common complications arising from this surgery. One study found that durotomy after spine surgery accounted for a significant proportion of medical malpractice lawsuits against neurosurgeons,¹⁰ yet the effect of durotomy upon patient outcome is controversial. Our data indicate that incidental durotomies, while affecting intraoperative blood loss and hospital length of stay, do not increase the risk of other perioperative morbidities or adversely affect patient outcome at 6 weeks, 3 months and at 1, 2, 3 and 4 years.

Previous studies attempting to analyze effects on outcome after durotomy have yielded inconsistent results. Jones et al¹³ did not identify any difference in outcome between their 17 patients with incidental durotomies and appropriately matched controls. In agreement with these data, Wang et al²⁷ demonstrated that dural tears do not appear to have any deleterious effects on outcomes in the largest series of incidental durotomies (88 patients) presented to date. Cammisa et al⁴ reached similar conclusions in their study group of 66 incidental durotomies. These data support the observations of the current study. However, they are all based on retrospective studies and take into account all spinal procedures, including discectomies, surgeries for spondylolesthesis and spinal stenosis, as well as revision surgeries. These confounding variables have been eliminated in the current study, where prospectively collected data from patients with a single pathology and operation (open lumbar discectomy), that were part of a multi-institution study, are analyzed.

On the other hand, Saxler et al²¹ demonstrated that, in their retrospectively analyzed group of 41 patients followed for 10.2 years and compared with appropriately matched controls, incidental durotomy was associated with adverse long-term clinical sequelae. In fact, patients with incidental durotomy had a poorer outcome after surgery, with a decreased Tenger Score, more postoperative headaches, more re-operations, a longer inability to work, more back pain and functional limitations related to it. However, several methodological pitfalls limit the applicability of these results. Given the retrospective nature of the study and the fact that the authors do not report their patients' compliance to follow up, we are unable to assess the true impact of incidental durotomy. In fact, it is possible that patients with good postoperative results were lost to follow up, confounding the results. In addition, the value of the use of questionnaires, especially with questions dating back to the peri-operative period, is limited by recall bias mostly affecting the durotomy group. 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 3.2% and was comparable to the current literature.^{4,13,21,26,27} The incidence of dural tears has been reported to range from 1–17% and varies according to patient characteristics and the surgical procedures performed.

Deyo et al⁷ evaluated postoperative complications, including dural tears, in a large series of spinal procedures. The morbidity was lower for younger patients and for discectomies. By contrast, the rate was higher with age, spinal stenosis, and re-operations. Several other authors have confirmed these results.^{4,8,13,23,25,27} Our cohort was homogeneous since it included only discectomies and excluded patients with re-operations.

The complications attributed to dural tears in the literature are varied. The main risk identified is the formation of a pseudomeningocele and the development of postoperative headache. Other complications are nerve root entrapment with resultant neurological damage, a persistent leak of cerebrospinal fluid, meningitis, and arachnoiditis.^{9,10,13} In some series⁴ the incidence of deep wound infection has been reported to be as high as 8.1%. In addition, several extremely rare complications have been reported as a result of incidental durotomies, including symptomatic pneumorachis,²⁰ spinal subdural empyema,³¹ bilateral subdural hematomas,³ and cerebral vasospasm.⁵ Although in the present study, a significantly increased length of hospital stay among the durotomy group was observed, there were no increases 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 hospital stay among patients with dural tears may be attributed to the tendency for increased bed rest and slower mobilization of these patients. The increased operative time seen in patients with durotomy may be a result of various intraoperative measures for repair. Finally, increased blood loss seen in the durotomy group may reflect epidural venous bleeding exacerbated by cerebrospinal fluid loss. It is, however, important to bear in mind that these data are retrospective. Furthermore, potentially confounding factors not recorded in the SPORT database (e.g. surgeon experience) may contribute independently to both the likelihood of durotomy and the above outcomes. Hence, causal relationships, however intuitive, cannot be definitively established on the basis of these data.

Several outcome measures have been used in the literature to quantify long-term outcomes in patients with incidental durotomies. Saxler et al,²¹ have supported that patients with dural tears had a poorer outcome with a lower Tegner score, more re-operations, and functional limitations related to back-pain. In the current study, there were no significant differences between the durotomy and no-durotomy groups in the incidence of recurrent disc herniation 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 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 41 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. 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 treatments in 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 lumbar disc surgery. In the current study, the data of the SPORT trial were analyzed in an attempt to answer this question. The durotomy group was found to have significantly increased operative duration, operative blood loss and inpatient stay. There were, however, no differences in incidence of nerve root injury, wound complications, additional surgeries, SF-36 scores of body pain or physical function, or ODI at 3 months, and at 1, 2, 3 and 4 years. Therefore, incidental durotomy during first time lumbar discectomy does not appear to affect long-term outcome in affected patients.

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Abbreviations

IDH	intervertebral disc herniation
SF-36	Short form 36 questionnaire
ODI	Oswestry disability index
SCI	Sciatica bothersomeness index

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Figure 1.
Outcome results over time by status of durotomy with area under curve p-value that compares the No-durotomy group to Durotomy group.

Table 1

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

Characteristics	No durotomy (n=759)	Durotomy (n=25)	p-value
Mean Age (SD)	40.5 (10.8)	44 (10.8)	0.12
Female - no.(%)	329 (43%)	11 (44%)	0.89
Mean Body Mass Index (BMI), (SD) §	28.2 (5.7)	28.9 (5.9)	0.57
Smoker Comorbidities - no.(%)	192 (25%)	4 (16%)	0.41
Hypertension	94 (12%)	4 (16%)	0.82
Diabetes	27 (4%)	1 (4%)	0.67
Osteoporosis	9 (1%)	0 (0%)	0.68
Depression	87 (11%)	5 (20%)	0.32
Joint Problem	124 (16%)	3 (12%)	0.76
Other ¶	316 (42%)	10 (40%)	0.97
Pain Radiation	743 (98%)	25 (100%)	0.99
Any Neurological Deficit	593 (78%)	21 (84%)	0.65
Herniation Level			0.61
L2–L3 / L3–L4	41 (5%)	1 (4%)	
L4–L5	290 (38%)	12 (48%)	
L5–S1	428 (56%)	12 (48%)	
Herniation Type			0.46
Protruding	194 (26%)	9 (36%)	
Extruded	513 (68%)	14 (56%)	
Sequestered	52 (7%)	2 (8%)	
Posterolateral herniation	605 (80%)	16 (64%)	0.098
Baseline lumbar epidural steroid injection	384 (51%)	10 (40%)	0.40

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

¶Other indicates problems related to stroke, diabetes, osteoporosis, cancer, fibromyalgia, CFS, PTSD, alcohol, drug dependence, heart, lung, liver, kidney, blood vessel, nervous system, hypertension, migraine, anxiety, stomach or bowel.

Table 2

Comparison of operative events between the durotomy and no durotomy groups.

Outcome	No durotomy (n=774)	Durotomy (n=25)	p-value
Operation time (min)	74.7 (34.5)	139 (64.4)	<0.001
Blood loss (ml)	57.4 (64.1)	288.8 (399.1)	<0.001
Blood Replacement			
Intraoperative replacement	5 (1%)	1 (4%)	0.46
Post-operative transfusion	0 (0%)	0 (0%)	
Length of stay (days)	0.92 (0.9)	2.5 (2)	<0.001
Intraoperative complications §			
Nerve root injury	2 (0%)	0 (0%)	0.075
Other	2 (0%)	1 (4%)	0.18
None	770 (99%)	0 (0%)	<0.001

§None of the following were reported: aspiration, operation at wrong level, vascular injury.

Table 3

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

Outcome	No durotomy (n=774)	Durotomy (n=25)	p-value
Postoperative complications ¶			
Nerve root injury	1 (0%)	0 (0%)	0.007
Wound hematoma	4 (1%)	0 (0%)	0.28
Wound Infection	18 (2%)	0 (0%)	0.93
Other	27 (4%)	0 (0%)	0.70
None	723 (94%)	25 (100%)	0.40
Post-operative mortality (death within 6 weeks of surgery)	0 (0%)	0 (0%)	
Post-operative mortality (death within 3 months of surgery)	1 (0.1%) ‡	0 (0%)	
Additional surgeries (1-year rate)//	46 (6%)	0 (0%)	0.22
Additional surgeries (2-year rate)//	63 (8%)	1 (4%)	0.45
Additional surgeries (3-year rate)//	70 (9%)	1 (4%)	0.38
Additional surgeries (4-year rate)//	82 (11%)	1 (4%)	0.29
Recurrent disc herniation	49 (6%)	1 (4%)	
Complication or Other	21 (3%)	0	
New condition	9 (1%)	0	

* Surgical information was available for 774 No durotomy and 25 Durotomy patients.

‡ Patient died after heart surgery at another hospital, the death was judged unrelated to spine surgery

¶ Any reported complications up to 8 weeks post operation. None of the following were reported: bone graft complication, CSF leak, paralysis, cauda equina injury, wound dehiscence.

// One-, two-, three- and four-year post-surgical re-operation rates are Kaplan Meier estimates and p-values are based on 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 Sciatica bothersome index scores, according to status of durotomy.

	3-month			1-year			2-year			3-year			4-year			AUC p-value
	Difference [‡]	p-value		Difference [‡]	p-value		Difference [‡]	p-value		Difference [‡]	p-value		Difference [‡]	p-value		
SF-36 Bodily Pain (SE) [‡]	2.4 (-8.3, 13.1)	0.66		-3.6 (-14.3, 7.1)	0.51		-4.2 (-15.6, 7.2)	0.47		-0.9 (-12.5, 10.7)	0.88		-7 (-19.3, 5.4)	0.27		0.39
SF-36 Physical Function (SE) [‡]	-5.7 (-15.5, 4.2)	0.26		-6.3 (-16.2, 3.5)	0.21		-9.4 (-19.9, 1.1)	0.08		-7.4 (-18.1, 3.3)	0.17		-6.5 (-17.8, 4.8)	0.26		0.089
SF-36 Mental Component Summary (SE) [‡]	0.1 (-4.5, 4.7)	0.97		-0.3 (-4.9, 4.3)	0.90		-0.7 (-5.5, 4.2)	0.79		0 (-5, 4.9)	0.99		1.6 (-3.7, 6.8)	0.56		0.89
Oswestry Disability Index (SE) [§]	-2.2 (-10.4, 6.1)	0.61		3.8 (-4.5, 12)	0.37		1.8 (-6.9, 10.6)	0.68		-0.9 (-9.8, 8)	0.84		3.4 (-5.9, 12.7)	0.47		0.65
Sciatica Bothersome Index (SE) [¶]	-0.5 (-3.3, 2.4)	0.74		1.4 (-1.1, 3.9)	0.26		0.6 (-2, 3.2)	0.65		0.3 (-2.4, 3)	0.82		0.2 (-2.7, 3.1)	0.90		0.63
Number of patients available for follow-up	No Durotomy 684; Durotomy 22			No Durotomy 636; Durotomy 20			No Durotomy 639; Durotomy 20			No Durotomy 565; Durotomy 16			No Durotomy 510; Durotomy 13			

* 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 Sciatica Bothersomeness Index ranges from 0 to 24, with lower scores indicating less severe symptoms