The effect of epidural steroid injection on postoperative outcome in patients from the lumbar spinal stenosis outcome study

Fekete, Tamas; Woernle, Christoph; Mannion, Anne F; Held, Ulrike; Min, Kan; Kleinstück, Frank; Ulrich, Nils; Haschtmann, Daniel; Becker, Hans-Juergen; Porchet, Francois; Theiler, Robert; Steurer, Johann

Abstract: STUDY DESIGN: Retrospective analysis of data from patients participating in the Lumbar Spinal Stenosis Outcome Study (LSOS). OBJECTIVE: The aim of LSOS was to assess clinical outcomes after surgical or nonoperative treatment in patients with and without prior epidural steroid injections. SUMMARY OF BACKGROUND DATA: Epidural steroid injections (ESI), a common treatment modality, reduce symptoms in the short-term, but according to a subgroup analysis from the Spine Patient Outcomes Research Trial (SPORT) they reduce the amount of improvement after subsequent surgical or nonoperative treatment. METHODS: The data of 281 patients with lumbar spinal stenosis who had completed baseline and 6-month follow-up assessments were analyzed. Patients completed the Spinal Stenosis Measure (SSM). Changes in the SSM scores from baseline to follow-up were compared between patients with and without prior ESI, for the surgical and nonsurgical treatment groups. RESULTS: The mean (SD) age of the patients was 75 (8.7) years. 229 patients underwent surgery and 111 of these had received an ESI in the 12 months before surgery. Of the 52 patients treated nonoperatively, 29 had received a prior ESI. The unadjusted changes (improvement) in the SSM-symptom scores between baseline and 6 months' follow up were: surgery and prior ESI 0.95, surgery and no prior ESI 0.78 ($P = 0.15$); no surgery and prior ESI 0.28, no surgery and no prior ESI 0.29 ($P = 0.85$). When adjusted for confounding factors, the reduction in SSM-symptom score was greater for surgery than for nonoperative treatment by 0.41 points ($P < 0.001$); the effect of having had an ESI prior to study entry was -0.08 ($P = 0.40$). CONCLUSION: The analysis of outcomes in the LSOS cohort provided no evidence that ESIs have a negative effect on the short-term outcome of surgery or nonoperative treatment in patients with lumbar spinal stenosis. LEVEL OF EVIDENCE: 3.

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OUTCOMES

The Effect of Epidural Steroid Injection on Postoperative Outcome in Patients From the Lumbar Spinal Stenosis Outcome Study

Tamas Fekete, MD,* Christoph Woernle, MD,† Anne F. Mannion, PhD,‡ Ulrike Held, PhD,§ Kan Min, MD,† Frank Kleinstück, MD,* Nils Ulrich, MD,† Daniel Haschtmann, MD,* Hans-Juergen Becker, MD,* Francois Porchet, MD* Robert Theiler, MD,¶ J. Steurer, MD,§ and on behalf of the LSOS Working Group

Study Design. Retrospective analysis of data from patients participating in the Lumbar Spinal Stenosis Outcome Study (LSOS).

Objective. The aim of LSOS was to assess clinical outcomes after surgical or nonoperative treatment in patients with and without prior epidural steroid injections.

Summary of Background Data. Epidural steroid injections (ESI), a common treatment modality, reduce symptoms in the short-term, but according to a subgroup analysis from the Spine Patient Outcomes Research Trial (SPORT) they reduce the amount of improvement after subsequent surgical or nonoperative treatment.

Methods. The data of 281 patients with lumbar spinal stenosis who had completed baseline and 6-month follow-up assessments were analyzed. Patients completed the Spinal Stenosis Measure (SSM). Changes in the SSM scores from baseline to follow-up were compared between patients with and without prior ESI, for the surgical and nonsurgical treatment groups.

Results. The mean (SD) age of the patients was 75 (8.7) years. 229 patients underwent surgery and 111 of these had received an ESI in the 12 months before surgery. Of the 52 patients treated nonoperatively, 29 had received a prior ESI. The unadjusted changes (improvement) in the SSM-symptom scores between baseline and 6 months' follow up were: surgery and prior ESI 0.95, surgery and no prior ESI 0.78 ($P = 0.15$); no surgery and prior ESI 0.28, no surgery and no prior ESI 0.29 ($P = 0.85$). When adjusted for confounding factors, the reduction in SSM-symptom score was greater for surgery than for nonoperative treatment by 0.41 points ($P < 0.001$); the effect of having had an ESI prior to study entry was –0.08 ($P = 0.40$).

Conclusion. The analysis of outcomes in the LSOS cohort provided no evidence that ESIs have a negative effect on the short-term outcome of surgery or nonoperative treatment in patients with lumbar spinal stenosis.

Key words: lumbar spinal stenosis, epidural steroid injection, surgical treatment, nonoperative treatment, Spinal Stenosis Measure.

Level of Evidence: 3

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Patients with lumbar spinal stenosis and neurogenic claudication can be offered 3 different treatment modalities with increasing invasiveness: nonoperative treatment with physical exercise and/or analgesics, epidural injections of steroids and/or analgesics, and surgical decompression with or without fusion.[1] Although the efficacy of epidural steroid injections (ESIs) in patients with lumbar stenosis is still a matter of debate, the number of injections in such patients tripled in the Medicare population from 1994 to 2001.[2] Some trial results indicate a short-term benefit of ESIs in patients with lumbar spinal stenosis,[3–7] but the majority of the studies evaluating the longer-term efficacy (6 mo to 2 yr) show no clinically relevant improvement compared with physical therapy[1] and the Guideline of the "North American Spine Society" recommends ESIs with some reluctance in patients with lumbar stenosis.[8,9]

Done in the correct manner, under contrast-enhanced fluoroscopy, or CT-guided, ESIs are considered safe. The complication rate, including infection and bleeding, is very low. However, a recent study evaluating clinical outcome after ESIs reported disquieting results: those patients treated with ESIs were less likely to benefit from subsequent surgical or nonoperative treatment compared with patients who had not received ESIs.[10] In both groups of patients, treated surgically or nonoperatively, pain and physical function were worse in the subsequent 4-year follow-up period in patients

From the *Schulthess Clinic, Spine Center Division, Zürich, Switzerland; †Balgrist University Hospital, Department of Orthopedics, University of Zürich, Zürich, Switzerland; ‡Schulthess Clinic, Department Research and Development, Spine Center Division, Zürich, Switzerland; §Horten Centre for Patient Oriented Research and Knowledge Transfer, University Zürich, Zürich, Switzerland; and ¶Triemli City Hospital, Zürich, Switzerland.

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Address correspondence and reprint requests to Johann Steurer, MD, Horten Centre, University Zürich, Pestalozzistrasse 24, CH 8091 Zürich, Switzerland; E-mail johann.steurer@usz.ch

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who had undergone ESIs in the 3 months prior to treatment. This result was unexpected, and the study was criticized for various reasons,[11,12] including the failure to use a condition-specific instrument such as the Spinal Stenosis Measure (SSM) as the primary outcome measure. Further studies were recommended in order to establish whether the findings could be reproduced.

The aim of this study is to report the clinical outcome after surgical or nonoperative treatment in patients participating in the Lumbar Spinal Stenosis Outcome Study (LSOS)[13] who either did or did not receive an ESI within the 12 months prior to enrollment.

PATIENTS AND METHODS

The LSOS working group was established in Switzerland in 2009, to perform a multicenter observational study evaluating the treatment and prognosis of patients with lumbar spinal stenosis.[13] This substudy is part of the LSOS. The study was approved by the local ethical committee and conducted in accordance with the Declaration of Helsinki.[14] All patients received written and oral information about the study and gave their written informed consent to participate.

Eligibility Criteria and Patients

The inclusion criteria were: (1) aged 50 years or more; (2) uni- or bilateral neurogenic claudication (defined by pain in the buttocks and/or lower extremities provoked by walking or extended standing and relieved by rest and/or bending forward; (3) verified diagnosis of spinal stenosis by Magnetic Resonance Imaging (MRI) or Computer tomography (CT); (4) expected life expectancy of more than 1 year; (5) able to give informed consent; (6) available for follow-up and able to complete questionnaires in the German language. The exclusion criteria were: (1) cauda equina syndrome requiring urgent surgery; (2) current fracture, infection, or significant deformity (>15° lumbar scoliosis); (3) current enrolment in another spine related treatment study; (4) clinically relevant peripheral arterial disease (confirmed by vascular specialist in patients without palpable pulses in the lower limb).

For the assessment of a potentially harmful effect of ESIs—*i.e.,* less improvement after surgical or nonoperative treatment—all patients in the LSOS cohort with a 6-month follow-up were identified. These patients were included and allocated to 1 of 4 groups: (1) Patients who had undergone surgery (decompression, with or without fusion) between baseline and 6 months' follow-up, and with ESI in the 12 months before surgery; (2) Patients who had undergone surgery between baseline and 6 months' follow-up, without any prior ESI; (3) Patients treated nonoperatively (physical therapy and/or oral analgesics, but no epidural injections) between baseline and 6 months' follow-up, with ESI in the 12 months before inclusion in the study; (4) Patients treated nonoperatively (physical therapy and/or oral analgesics) between baseline and 6 months' follow-up, without any prior ESI.

Data Collection

Demographic data, and information about the duration of symptoms and epidural injections in the past were collected at baseline. At baseline and 6 months' follow-up, the following patient-oriented questionnaires (German language versions) were used to gather information about the patients' complaints:

1. the SSM, a disease specific questionnaire[15,16] with 3 subscales assessing the severity of symptoms (SSM symptom severity scale), physical function (SSM physical function), and satisfaction with treatment results (SSM satisfaction). The SSM symptom severity scale comprises a pain subdomain and a neuroischemic subdomain. Each item is rated on a Likert scale. Response options on the SSM symptom severity scale range from "no symptoms" [1] to "very severe symptoms" [5]; on the SSM function scale, from "yes, comfortably" [1] to "no, could not perform" [5], and on the SSM satisfaction scale, from "very satisfied" [1] to "very dissatisfied" [4];
2. the Roland Morris Disability Questionnaire, assessing back pain related functional disability [score 0 (no disability) to 24 (severe disability)] [17];
3. pain intensity scale (numeric rating scale NRS), quantifying the intensity of leg pain within the last 7 days [score 0 (no pain) to 10 (extreme pain)][18];
4. EuroQol-5D (EQ-5D) for the measurement of quality of life (sum score 0–100; higher values indicate higher quality of life).[19,20]
5. The Hospital Anxiety and Depression Score (HADS) at baseline only (sum score for anxiety 0–21, and sum score for depression 0–21; 21 indicates severe anxiety or severe depression)[21]
6. Chronic Illness Rating Scale for the measurement of comorbidities (sum score 0–56; higher values indicate a higher number of and/or more severe comorbidities)[22]

In addition, detailed information was recorded about treatments received between baseline and 6 months' follow-up.

Imaging Procedures

MRI of the lumbar spine was carried out at baseline, if not already done in the 3 months prior to inclusion in the study. In patients with contraindications to MRI, computer tomography was performed. Board-certified, experienced radiologists evaluated images from all patients and confirmed the presence of radiological lumbar spinal stenosis.

Data Analysis

All data were collected on paper forms and were entered independently by 2 persons into a Filemaker database (FileMaker Inc.) and checked for inconsistencies. Descriptive statistics are presented as means and standard deviations for continuous variables and as numbers and percentages of total for categorical variables. The primary analyses comprised comparisons of the change in the SSM score and its subscale scores from baseline to 6 months' follow-up between those with and without previous epidural steroid injections, for each of the

2 treatment groups (surgical and nonsurgical treatment). In addition, changes in the SSM scores between baseline and 6 months' follow-up were compared between patients with 1 or more than 1 previous epidural steroid injections, for each of the 2 treatment groups. The Wilcoxon rank sum test was used to evaluate raw differences between the groups.

Additionally, multiple linear regression models were fitted separately to the 4 SSM subscales Function, Symptoms, Pain Domain, and Neuroischemic Pain at 6 months. The independent variables were surgical treatment (yes/no) and epidural steroid injection prior to baseline (yes/no). Additionally, the respective SSM subscale baseline score, age, gender, HADS score anxiety, HADS score depression, pain duration more than 6 months, and the CIRS comorbidity score were included in the regression model to adjust for potential confounding. We also included an interaction term between surgical treatment and ESI, to determine whether any effect of ESI might differ between the treatment groups. If the *P*-value for the interaction effect was 0.05 or more, the interaction term was removed from the model. *P*-values less than 0.05 were considered statistically significant. All analyses were conducted with R for Windows (R Core Team (2014). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/.)

RESULTS

By June 1, 2014, 415 patients were enrolled in the study. Data at baseline and 6 months' follow-up were available for 369 patients in the LSOS (Figure 1). Of these, 88 had received 1 or more ESIs between baseline and 6 months' follow up and were excluded from further analyses. For 46 patients, no data were available for the 6-month follow-up. The remaining 281 were included in the present study. A total of 229 patients had undergone surgery between baseline and 6 months' follow-up: 111 of these had received an ESI in the 12 months prior to surgery and 118 had not. 52 patients were treated nonoperatively: 29 had received an ESI in the 12 months before study entry and 23 had not. The exact number of ESIs received by the patients in the previous 12 months are shown in Table 1.

The patients' demographic details and other baseline data are shown in Table 2. The mean age of the patients was 75 (SD 8.7) years. In the nonoperative treatment arm, 60% were female, and in the surgical group, 50%. In about (2/3) of the patients, symptoms of lumbar spinal stenosis had been present for more than 1 year and in about 10%, less than 3 months. More than 80% of the patients were retired.

The surgical interventions comprised posterior lumbar decompression (with the specific technique being dependent on the surgeon's preference and including bilateral (hemi) laminotomy through a unilateral approach, interlaminar laminotomy, or laminectomy), with or without additional fusion, depending on the surgeon's assessment of the individual pathology (Table 3). In the group with prior ESI, 3 patients were reoperated between baseline and 6 months' follow-up; in the group with no prior ESI, 4 patients were reoperated.

Mean baseline scores for all subdomains of the SSM were higher in patients undergoing surgery compared with patients in the nonoperative treatment group (Table 4). The same was true for leg pain and Roland Morris disability scores (Table 5).

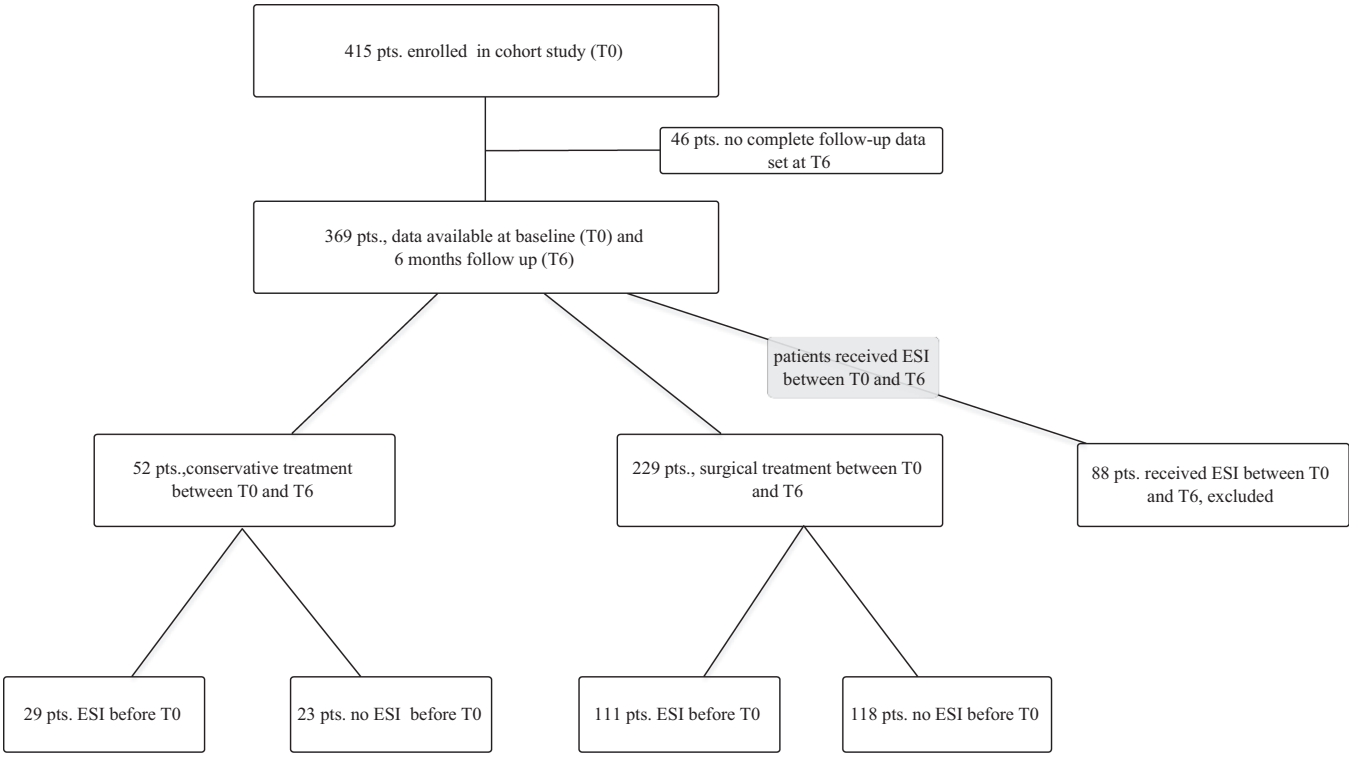

Figure 1. Patient flow: number of eligible patients (pts.) at baseline with and without prior (antecedent yr) epidural steroid injections (ESI) undergoing surgical or nonoperative treatment.

TABLE 1. Number of Epidural Steroid Injections Before Baseline/Before Surgery for Patients With Conservative Treatment and Surgical Treatment

Number of Steroid Injections	Conservative Treatment (Number of Patients)	Surgery (Number of Patients)
1	20	54
2	5	27
3	2	11
4	1	10
5	0	4
>5	1	5
	29	111

Quality of life at baseline, quantified by the EQ-5D questionnaire, was lower in the group undergoing surgery (Table 5).

At 6 months' follow-up, improvements in unadjusted SSM scores, Roland Morris and EQ-5D were more pronounced in the surgical group compared with the nonoperative group (Tables 4 and 5).

Changes in the unadjusted SSM scores between baseline and 6 months' follow-up were not statistically significantly different between patients with and without prior ESI, in either the surgical or nonoperative patient groups (Table 4). Similarly, changes in the unadjusted SSM scores between patients with 1 previous ESI and patients with more than 1 ESI were not statistically significantly different (Table 6).

Adjusted mean change scores from baseline in SSM Symptoms, SSM Function, SSM Pain Domain, and SSM Neuroischemic Pain in relation to the treatment modality (surgery yes/no, epidural steroid injection yes/no) are displayed in Figure 2. The adjusted effect of surgery (*vs.* nonoperative treatment; negative values indicate greater improvement with surgery) was −0.41 ($P < 0.001$) for SSM Symptoms, −0.03 ($P = 0.81$) for SSM Function, −0.48 ($P = 0.002$) for SSM Pain, and −0.34 ($P = 0.002$) for SSM Neuroischemic Pain. The adjusted effect of ESI prior to study entry (versus no prior ESI; negative values indicate greater improvement with ESI) was −0.08 ($P = 0.40$) for SSM Symptoms, 0.37 ($P = 0.02$) for SSM Function, 0.0003 ($P = 0.99$) for SSM Pain, and −0.10 ($P = 0.24$) for SSM Neuroischemic Pain.

TABLE 2. Baseline Data of the Patients in the Four Specified Groups: Demographics, Comorbidities, and Duration of Symptoms (ESI)

	Nonoperative Treatment		Surgical Treatment	
	ESI (n = 29)	No-ESI (n = 23)	ESI (n = 111)	No-ESI (n = 118)
Age, mean (SD), yr	76.2 ± 10.1	74.1 ± 8.3	74.2 ± 9.2	75.4 ± 8.0
Female no. (%)	17 (59%)	14 (61%)	55 (50%)	59 (50%)
Educational level no. (%)				
Compulsory education	6 (21%)	6 (26%)	21 (19%)	26 (22%)
Baccalaureate/apprenticeship	22 (76%)	16 (70%)	76 (68%)	78 (66%)
University degree	1 (3%)	1 (4%)	14 (13%)	14 (12%)
Employment status no. (%)				
Employed full or part time	5 (17%)	3 (13%)	23 (21%)	16 (14%)
Retired	24 (83%)	20 (87%)	88 (79%)	102 (86%)
Comorbidities no. (%)				
Osteoarthritis of the hip	4 (14%)	2 (9%)	15 (14%)	17 (14%)
Gonarthrosis	8 (28%)	3 (10%)	16 (14%)	17 (14%)
Peripheral neuropathy	3 (10%)	1 (3%)	8 (7%)	11 (9%)
Obstructive lung disease	3 (10%)	2 (9%)	5 (5%)	6 (5%)
Heart failure	3 (10%)	1 (3%)	3 (3%)	7 (6%)
Coronary heart disease	2 (7%)	0	6 (6%)	8 (7%)
M. Parkinson	1 (3%)	0	1 (1%)	2 (2%)
Duration of symptoms no. (%)				
<3 months	4 (14%)	3 (10%)	10 (9%)	14 (12%)
3–6 months	2 (7%)	2 (9%)	16 (14%)	17 (14%)
6–12 months	2 (7%)	4 (17%)	19 (17%)	13 (11%)
>12 months	21 (72%)	14 (61%)	65 (59%)	72 (61%)

TABLE 3. Surgical Procedures Performed and Number of Decompressed Levels in Patients With (ESI) and Without (No ESI) Prior Epidural Injections

Surgical Procedure, n (%)	ESI (n = 118)	No-ESI (n = 111)
Decompression only	94 (80%)	85 (77%)
Decompression and noninstrumented fusion	0	1 (1%)
Decompression and instrumented fusion	24 (20%)	25 (22%)
Multilevel fusion, n (%)	12 (10%)	15 (14%)
Levels decompressed, n (%)		
1	41 (35%)	41 (37%)
2	44 (37%)	50 (45%)
3	29 (25%)	17 (15%)
4	4 (3%)	3 (3%)

TABLE 4. Differences in the Swiss SSM Scores (Mean ± SD) Between Baseline (T_0) and 6 Months' Follow-up (T_6) in Patients With Lumbar Spinal Stenosis Treated Surgically or Nonoperatively, With and Without Prior ESI

Nonoperative Treatment	ESI (n = 29)			No ESI (n = 23)			
	T_0	T_6	Improvement	T_0	T_6	Improvement	*P**
SSM-symptom	2.9 ± 0.7	2.6 ± 0.7	0.3	2.9 ± 0.9	2.6 ± 1.0	0.3	0.847
SSM-function	2.4 ± 0.9	2.1 ± 0.8	0.3	2.3 ± 0.9	1.8 ± 0.7	0.5	0.241
SSM-pain	3.6 ± 0.8	3.2 ± 0.9	0.4	3.5 ± 1.1	2.9 ± 1.1	0.6	0.589
SSM-neuroischemic	2.4 ± 0.9	2.2 ± 0.8	0.2	2.4 ± 1.0	2.4 ± 1.2	0.0	0.584
SSM-satisfaction		2.0 ± 0.7			2.0 ± 0.8		
Surgical Treatment	**ESI (n = 111)**			**No ESI (n = 118)**			
	T_0	T_6		T_0	T_6		
SSM-symptom	3.2 ± 0.5	2.3 ± 0.8	0.9	3.1 ± 0.6	2.3 ± 0.8	0.8	0.148
SSM-function	2.3 ± 0.7	1.6 ± 0.6	0.7	2.3 ± 0.7	1.7 ± 0.6	0.6	0.450
SSM-pain	3.8 ± 0.7	2.5 ± 1.0	1.3	3.7 ± 0.7	2.6 ± 1.1	1.1	0.517
SSM-neuroischemic	2.8 ± 0.7	2.1 ± 0.8	0.7	2.6 ± 0.8	2.1 ± 0.9	0.5	0.179
SSM-satisfaction		1.7 ± 0.6			1.8 ± 0.7		

** P-values of comparison between the changes in patients with ESI and without ESI, Wilcoxon rank sum test.*

There was just 1 significant interaction between surgery and ESI prior to study entry, for SSM Function: the interaction effect was −0.46 ($P = 0.01$) (having had an ESI led to less improvement in the nonoperative group but not the surgical group).

The change-scores for the NRS, Roland Morris, and EQ-5D followed the same pattern as the SSM, with 2 exceptions: compared with no prior ESI, nonoperative patients who had received a prior ESI showed a reduced quality of life (EQ-5D) and a slight increase of NRS values between baseline and 6 months' follow-up, indicating a worsening of the symptom state (Table 5).

DISCUSSION

The results of our study indicate that ESIs administered to patients with lumbar spinal stenosis in the year prior to surgery have no relevant impact on the outcome of surgical treatment, as measured by the disease-specific SSM. The changes in SSM scores between baseline and 6 months' follow-up were not significantly different between patients with and without prior ESI. At baseline, the SSM scores were higher (indicating more severe symptoms) in the patients undergoing surgery compared with patients treated by nonoperative measures. Improvement after 6 months was more pronounced in the surgically treated group. Similar findings were observed for the other outcome

TABLE 5. Differences in the Numeric Rating Scale, Roland Morris Disability Questionnaire, and EQ-5D (Mean ± SD) Between Baseline (T_0) and 6 Months' Follow-up (T_6) in Patients With Lumbar Spinal Stenosis Treated Surgically or Nonoperatively, With and Without Prior Epidural Steroid Injections (ESI)

Nonoperative Treatment	ESI (n = 29)			No ESI (n = 23)			*P**
	T_0	T_6	Improvement	T_0	T_6	Improvement	
NRS	4.9 ± 2.4	5.4 ± 2.8	–0.5	5.1 ± 3.0	4.4 ± 2.9	0.7	0.316
Roland Morris	10.6 ± 6.2	8.9 ± 5.7	1.7	10.1 ± 6.7	8.8 ± 5.9	1.3	0.283
EQ-5D	72.8 ± 21.7	70.0 ± 20.0	– 2.8	68.7 ± 20.1	77.0 ± 15.2	8.3	0.047
Surgical Treatment	**ESI (n = 111)**			**No ESI (n = 118)**			
	T_0	T_6		T_0	T_6		
NRS	6.8 ± 1.8	3.7 ± 4.6	3.1	6.3 ± 2.1	3.2 ± 2.6	3.1	0.656
Roland Morris	12.7 ± 4.9	8.2 ± 5.9	4.5	12.2 ± 5.1	8.1 ± 5.4	4.2	0.592
EQ-5D	65.4 ± 15.5	81.2 ± 15.0	15.8	66.6 ± 14.5	80.6 ± 16.8	14.0	0.337

**P-values of comparison between the changes in patients with ESI and without ESI, Wilcoxon rank sum test.*

TABLE 6. Differences in the Swiss SSM Scores (Mean ± SD) between Baseline (T_0) and 6 Months of Follow-up (T_6) in Patients With Lumbar Spinal Stenosis Treated Surgically or Conservative, With 1 and More Than 1 Prior ESI

Conservative Treatment	1 ESI (n = 20)			More Than 1 ESI (n = 9)			
	T_0	T_6	Improvement	T_0	T_6	Improvement	*P*
SSM-symptom	2.9 ± 0.8	2.5 ± 0.6	0.4	3.0 ± 0.7	3.0 ± 0.9	0.0	0.4222
SSM-function	2.4 ± 0.9	2.1 ± 0.8	0.3	2.4 ± 0.8	2.1 ± 0.8	0.3	0.887
SSM-pain	3.6 ± 0.8	3.0 ± 0.9	0.6	3.7 ± 0.8	3.5 ± 0.8	0.2	0.379
SSM-neuroischemic	2.3 ± 0.9	2.1 ± 0.7	0.2	2.6 ± 0.9	2.6 ± 0.9	0.0	0.722
SSM-satisfaction		2.0 ± 0.6			2.1 ± 0.8		
Surgical Treatment	**1 Single ESI (n = 54)**			**More Than 1 ESI (n = 47)**			
	T_0	T_6		T_0	T_6		
SSM-symptom	3.2 ± 0.5	2.2 ± 0.8	1.0	3.2 ± 0.6	2.3 ± 0.8	0.9	0.335
SSM-function	2.2 ± 0.7	1.5 ± 0.5	0.7	2.3 ± 0.7	1.6 ± 0.6	0.7	0.735
SSM-pain	3.8 ± 0.6	2.4 ± 1.1	1.4	3.8 ± 0.7	2.7 ± 0.9	1.1	0.157
SSM-neuroischemic	2.8 ± 0.6	2.0 ± 0.8	0.8	2.7 ± 0.8	2.1 ± 0.8	0.6	0.622
SSM-satisfaction		1.7 ± 0.7			1.8 ± 0.6		

measures—quality of life, leg pain, and disability, except that patients in the nonoperative treatment group with prior ESIs showed a worsening of quality of life and leg pain between baseline and 6 months' follow up. An explanation for the differences in leg pain and quality of life could be the higher proportion of patients with the 2 comorbidities (gonarthritis 28% *vs.* 10% and heart failure 10% *vs.* 3%) in the group of patients with prior ESIs, compared with those without.

Radcliff *et al*[10] reported that ESIs were associated with significantly less improvement during 4 years' follow-up in patients treated either surgically or nonoperatively for lumbar spinal stenosis. In several studies, detrimental complications after epidural steroid injections have been reported, such as infections, bleeding and spinal cord injuries, although the incidence is very low.[23,24] Until the results of the Spine Patient Outcomes Research Trial (SPORT) were published,[10]

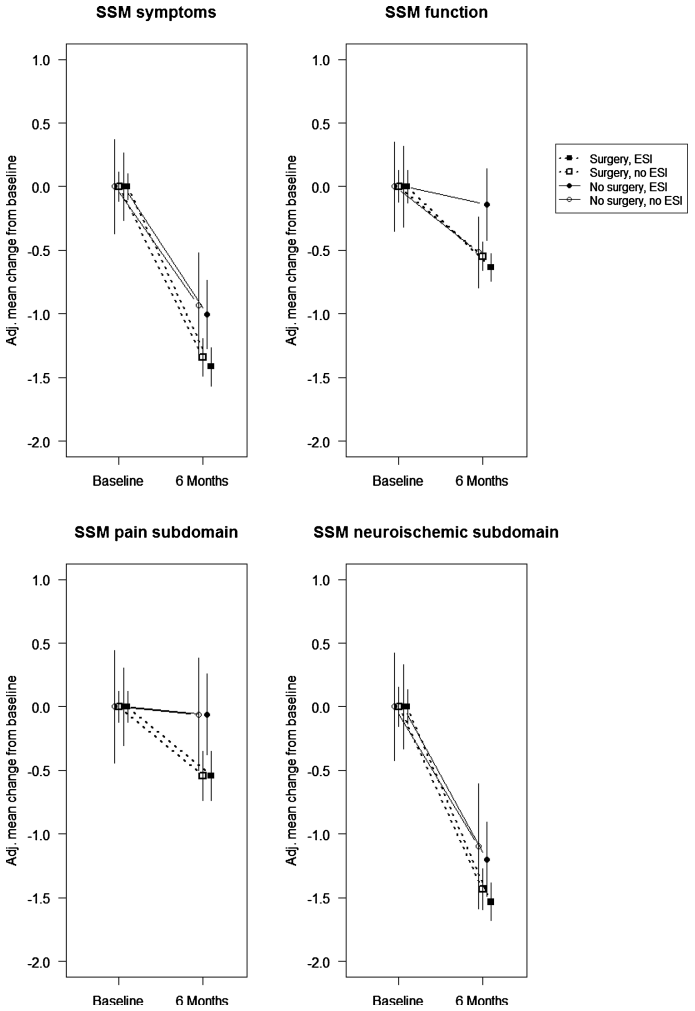

Figure 2. Adjusted mean changes (± SD) from baseline at 6 months' follow-up for the SSM domains and subdomains.

no negative consequences of ESIs in relation to subsequent treatment outcome had been suspected.

Our results do not support the findings of the subgroup analysis in the SPORT, although the patient populations of the 2 studies were slightly different. The SPORT also included patients with radicular pain,[10] whereas our study included only patients with neurogenic claudication. Furthermore, we did not exclude patients with any form of spondylolisthesis per se. We only excluded patients with significant (>15°) scoliosis. Concerns regarding the validity of the conclusions of the SPORT trial, based on objections to some of the methodology, have been raised since its publication.[11,12]

The number of patients treated with epidural steroid injections has increased enormously in the last 2 decades, although there is ongoing discussion concerning their efficacy. The authors of a recently published randomized trial concluded that the combination of steroids and lidicocaine, compared with lidocaine only, offered a minimal benefit after 3 weeks, but not after 6 weeks.[7] In the United States, more than 10 million injections per annum are administered, not only—but to a large extent—in patients with lumbar stenosis.[25] Some insurance companies in the United States reimburse costs for surgery, only when a trial of treatment with epidural steroids has failed.[26]

Our study has some limitations. The patients were not assigned randomly, either to surgical or nonoperative treatment, or to ESIs or not. The LSOS is an observational study and the specific treatment to be administered was at the discretion of the physicians and their patients. This explains the differences in the SSM scores at baseline between surgical and nonoperative patients, with higher SSM scores in the surgically treated group. In both treatment groups (operative and nonoperative) there were no significant differences between the 2 subgroups—ESI versus no ESI—for the adjusted SSM change scores from baseline to 6 months' follow-up, except for SSM function in the nonoperative group. Patients in the ESI subgroups were similar with respect to age, sex, duration of symptoms, and SSM scores; however, we concede that other potentially relevant prognostic indicators could have been unevenly distributed between the groups, masking real differences in outcome. A second limitation of our study was the shorter follow-up of just 6 months compared with 4 years in the SPORT. However, Radcliff *et al*[10] reported the differences in outcome at regular time-points during 4-year period, and according to the figure in their publication, the negative effect of ESIs on improvement in both the surgical and nonoperative groups was already noticeable after 6 months. A third limitation of the present study is the small number of patients in the nonoperative treatment group, limiting the precision of the results and potentially leading to a type II error (failure to reject a false null hypothesis).

The results of our study do not support the conclusion of the subanalysis of the SPORT. The analysis of outcomes after 6 months in the LSOS cohort provides no evidence that ESIs have a negative effect on the short-term outcome after surgery or nonoperative treatment in patients with lumbar spinal stenosis.

➢Key Points

- ESIs are frequently used in the treatment of patients with lumbar spinal stenosis.
- A recent publication from the SPORT reported that ESIs had a negative impact on the subsequent outcome of surgery and nonoperative treatment.
- The results of the present study did not support those of SPORT and instead suggested no influence of prior ESIs on the outcome of surgical or nonoperative treatment for lumbar spinal stenosis.

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