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# **SPINE SECTION**

## **Original Research Article**

Caudal vs Transforaminal Epidural Steroid Injections as Short-Term (6 Months) Pain Relief in Lumbar Spinal Stenosis Patients with Sciatica

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## Abstract

Objective. The aim of this study is to evaluate prospectively the efficacy of caudal epidural steroid injection (CESI) and transforaminal epidural steroid injection (TFESI) in lumbar spinal stenosis patients with sciatic pain. Design. Prospective clinical study.

Setting and Patients. Thirty-one patients (average age 62 years) from two hospitals, with single dermotomal distribution of sciatic pain due to spinal stenosis were included in the study.

Interventions. Patients underwent epidural steroid injections done by the same injectionist. Eleven patients from one hospital were included in the CESI group, while the TFESI group consisted of 20 comparable patients from the second site.

Outcome Measures. Primary outcome measure was the complete relief or at least 50% reduction of pain (visual analog scale [VAS]) at 6 months postinjection. Secondary outcome measures were the improvement of function (of at least 15 points of Oswestry Disability Index [ODI]) at 6 months and the changes of VAS and ODI and at 2 weeks, at 3 months, and at 6 months postinjection.

Results. A significantly greater number of stenosis patients showed pain relief at 6 months postinjection with TFSI (90%) than with CESI (54.54%). All patients with TFSI showed improvement of function at 6 months while only three (27.27%) patients with caudal epidural improved functionally. Out of the total 31 patients, two patients from group A underwent a second CESI at 15 days postinjection and decompressive spine surgery between 3 and 6 months postinjection.

Conclusions. The effectiveness of transforaminal steroid injection for the stenosis patients with sciatica was superior to caudal at 6 months postinjection.

Key Words. Injections; Transforaminal; Caudal; Stenosis

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## Summary

A short-term (6 months) effectiveness study of epidural steroid injections (ESIs) in lumbar spinal stenosis patients with sciatic pain is presented. Thirty-one patients were included in two comparative groups according to the route of injection. The transforaminal route was found more effective in terms of pain and disability than the caudal injections at 6 months postinjection in patients with spinal stenosis.

## Introduction

The lifetime prevalence of low back and sciatic pain has been reported as 54–80% with annual prevalence ranging from 15% to 45%. It is also associated with enormous economic, societal, and health impact [1]. ESIs have been increasingly used lately, and they have become one of the most commonly performed interventions for sciatic pain. Although not definitive, the data strongly suggest that ESIs are beneficial for the shortterm relief of radicular symptoms, but are less compelling for long-term effects or relief of radicular or back pain [2].

Considering the significant risks and great expense associated with surgery, and the similar long-term outcomes in pain and disability of lumbar disc herniation and spinal stenosis patients with or without surgery [3,4], the possibility that ESIs could prevent even a small percentage of surgeries is reasonable arguments in support of ESI before proceeding directly with surgery [2,5].

In addition three types of epidurals, namely transforaminal epidural steroid injection (TFESI), interlaminar epidural steroid injection (ILESI), and caudal epidural steroid injection (CESI), with variable results complicate the picture for practice of interventional pain management [6]. Abdi et al. reported that the evidence for lumbar TFESIs and caudal CESIs in managing lumbar radicular pain is strong for short-term relief (less than 6 weeks) and moderate for long-term relief (more than 6 weeks) [7]. CESI offers a relatively simple (even without fluoroscopy), rapid, and easily performed day-care procedure with improvement noted even 6 months later [8].

Manchikanti et al. showed level 1 evidence for both short-term relief (6 months or less) and long-term relief (longer than 6 months) following fluroscopically assisted TFESI [9,10]. Even though the transforaminal route of ESI has been reported as most effective and beneficial route than CESI for the administration of epidural steroids, this has not been proven clearly by level I studies [11,12].

Our hypothesis is that TFSIs are superior in pain relief of radiculopathy in lumbar stenosis patients to CESIs. This study aims to prove the effectiveness and safety of fluoroscopic TFESIs and CESIs for lumbar radiculopathy within a 6-month time period.

## Materials and Methods

Thirty-one consecutive patients from two adult orthopedic spine centers (at an Army-Veterans Hospital and at a University Hospital, respectively) between 2006 and 2011 were prospectively followed for 6 months following an ESI. Patients were diagnosed with sciatica with or without back pain due to lumbar disc herniation or lumbar spinal stenosis. All patients were proposed surgical treatment in addition to injection but elected to proceed with ESI treatment. Patients were allocated to groups (CESI, group A; TFESI, group, B) according to the site where they were treated by the same injectionist (author AP) always. The same injection technique was offered to all patients depending on the hospital they attended. All patients received initially only one injection and were considered for a second injection only at 2-week follow-up time if adequate pain relief (change of visual analog scale [VAS] score from postinjection less than 20%) has not succeeded. If the injections failed to provide satisfactory relief by 3-month follow-up time, then patients were consulted for surgery at that time. This study was approved by our institution's Scientific Research Board and was conducted in accordance with the ethics in research.

Inclusion criteria consisted of:

- Age > 20 years at time of presentation
- Presenting symptomatology of radicular leg pain with positive (between 30° and 70°) straight leg raise sign (for L5 or S1 nerve roots) or femoral nerve stretch sign (for L4 nerve root) with or without back pain
- Monosegmental dermotomal pain distribution (based on symptomatology and magnetic resonance imaging [MRI] findings) at L4 (medial lower leg), L5 (lateral lower leg, dorsum foot, great toe) or S1 (calf, lateral foot and ankle, 4th–5th toes) root levels
- Recent plain lumbar X-rays and lumbar spine MRI to be available
- Failure of symptomatic treatment with nonsteroid anti-inflammatories or/and physiotherapy for at least 6 weeks

Patients were excluded for any of the following reasons:

- Back or buttock pain only
- · Cauda equina or progressive muscle weakness
- Previous lumbar spine surgery
- · Spondylolysis or spondylolytic spondylolisthesis
- Arterial insufficiency in the legs
- Polyneuropathy or non-concordant pain with MRI findings
- Presence of malignancies
- Severe rheumatic disease
- Spinal infection
- Prior steroid injection within last 3 months
- Blood coagulation disorder or previous allergic reaction to local anesthetics or corticosteroids

Any asymmetry of ankle and knee jerk did not constitute exclusion criterion.

The VAS for leg pain as well as the Oswestry Disability Index (ODI) questionnaire were obtained before injection for all patients and were followed up at 15 days, at 3 weeks, at 3 months, and at 6 months postinjection for both groups. Primary outcome measure was the absence or at least 50% decrease of leg pain (according to VAS) at 6 months postinjection. Secondary outcome measures included 15 or more degrees of functional improvement at 6 months. For these patients who received surgical treatment, the 6-month follow-up time was the preoperative time point.

The injections were performed in a surgical suite with vital signs monitoring including respiratory rate, pulse rate, electrocardiogram, and blood pressure. An intravenous line was inserted and a dose of first generation cephalosporin was infused before every injection.

For the CESI procedure, the patient was placed in a prone position on the operating table. Following skin preparation, the sacral hiatus was identified and both the skin overlying the sacral hiatus and the underlying ligaments were infiltrated with 2 mL of 2% preservative-free Xylocaine (AstraZeneca, Wilmington, DE, USA) without epinephrine. A 22-gauge spinal needle was placed between the sacral cornu at about 45°, with the bevel of the spinal needle facing ventrally until contact with the sacrum was made in the "sacral triangle." The needle was then redirected more cephalad, horizontal, and parallel to the table, advancing it into the sacral canal through the sacrococcygeal ligament and into the epidural space. This was followed by an aspiration test, then the "hoosh" test (injection of air into the caudal epidural space with simultaneous palpation over the lumbosacral spine) was performed. A 20-mL injectate consisting of 3 mL (18 mg) of bemethasone (Chronodose Celestone, Merck Sharp & Dohme AG, Lucerne, Switzerland), 5 mL of lidocaine 2% (preservative-free; AstraZeneca), and 12 mL of contrast medium diluted in water for injection were inserted in the epidural space. Straight after the procedure, a lateral radiographic view of lumbosacral spine was performed to confirm the presence of epidurogram within the canal.

For the TFESI procedure, patients in group B received a TFESI under fluoroscopic guidance. After the usual sterile prep. drape, and local anesthesia, a 22-gauge 3.5-inch spinal needle was advanced to the corresponding transverse process, then redirected 1 cm inferior and anterior. Next, the spinal needle was advanced in the so-called "safe triangle" area (composed of a roof made up by the pedicle, a tangential base that corresponds to the exiting nerve root and a side that is made by the lateral border of the vertebral body). Both anterior-posterior and lateral fluoroscopic projections confirmed proper needle placement. On the lateral view, the needle was positioned just below and slightly lateral to the pedicle in the ventral aspect of the intervertebral foramen. On the anteriorposterior view, the needle was placed just beneath the midportion of the corresponding pedicle. First, 1 to 2 mL of contrast (Omnipaque 240, GE Healthcare AS, Oslo, Norway) was injected, and results of the epidurogram and pain provocation response were recorded. If there was no

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dye flow marking the corresponding nerve root, the needle was repositioned. Once adequate flow of contrast to the target area was documented, 1.5 mL (9 mg) of betamethasone (Chronodose Celestone) and 1 mL of 2% lidocaine (preservative-free) were injected.

Following the injections and during the follow-time, patients could take analgesics or use modalities for pain control as symptomatic treatment.

#### Statistical Evaluation

Statistical analysis was performed with IBM SPSS 21.0 (IBM, Chicago, IL, USA). Numerical data were presented as mean ± standard error (SE). Comparisons between groups in regard of age, ODI, and VAS measurements were tested using nonparametric tests, as data were not considered to be normally distributed. Statistical comparisons regarding gender, diagnosis, root involvement, need for second injection, and ultimate surgical decision were done with chi-square test. Within groups, nonparametric related sample (Friedman's two-way analysis of variance) test was used for significant changes in ODI and VAS at different times of follow-up. All statistical tests were conducted at a 0.05 significance level (*P* value).

#### Results

In the Table 1, the preinjection demographic data (age, gender), data regarding diagnosis (stenosis or herniated disc, dermotomal distribution at L4 or L5 or S1 root) and clinical outcomes (VAS, ODI) are presented. The two groups had comparable characteristics except for ODI before injection, which was significantly worse (P < 0.05) in group B (TFESI) patients. All patients included had neurology of L4, L5, or S1 roots suggesting radiculitis with predominantly pain symptomatology. Ten of the patients had weakness ( $\geq$ 4 Medical Research Council) due to pain and slight decrease of reflexes corresponding to the root involvement.

Of the 31 stenosis patients, central and subarticular stenoses were seen in all patients, and foraminal was found in 11 patients. The degree of stenosis was mild to moderate in all patients.

**Table 1**Demographic and clinical data ofpatients included in the study are presented

Group A (CESI)	Group B (TFESI)	Ρ
67.2 (3.0) 7/4	64.7 (1.8) 12/8	>0.05 >0.05
_, ., .		>0.05
35.8 (2.0) 7.3 (0.5)	42.9 (1.2) 8.1 (0.2)	< <b>0.01</b> >0.05
	(CESI) 67.2 (3.0) 7/4 2/6/3 35.8 (2.0)	(CESI)         (TFESI)           67.2 (3.0)         64.7 (1.8)           7/4         12/8           2/6/3         4/12/4           35.8 (2.0)         42.9 (1.2)

Statistically significant values indicated in bold.

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**Table 2** Results of pain (VAS) and disability (ODI) in CESI patient group based on whether they achieved pain relief (complete or >50% pain reduction) at 6 months postinjection

Outcome Measure	Time	Respondents (N = 6)	Non-Respondents $(N = 5)$	P Value
Mean (SE) VAS leg pain	Preinjection	7.7 (0.3)	6.8 (1.1)	>0.05
	2 weeks postinjection	2.5 (0.2)	4.8 (1.2)	>0.05
	3 months postinjection	2.7 (0.2)	4.2 (1)	>0.05
	6 months postinjection	2.8 (0.2)	5 (0.9)	>0.05
Mean (SE) ODI	Preinjection	38.3 (1.2)	32.8 (3.8)	>0.05
	2 weeks postinjection	21 (2.5)	20.8 (4.1)	>0.05
	3 months postinjection	23 (1.5)	18 (3.7)	>0.05
	6 months postinjection	27 (2.7)	22.4 (3.7)	>0.05

CESI = caudal epidural steroid injections; ODI = Oswestry Disability Index; SE = standard error; VAS = visual analog scale.

Significantly, more (P < 0.05) patients in TFESI group (18 patients, 90%) achieved pain relief (complete or >50% of preinjection VAS score) compared with patients in CESI group (6 patients, 54.54%) (Tables 2 and 3). Pain relief more than 70% of preinjection VAS score achieved four (20%) patients in TFESI group and one (9%) patient in CESI group.

Regarding function (ODI) at 6 months postinjection, all 20 patients (100%) in TFESI group had substantially improved function (at least 15 degrees reduction of ODI) while only 3 of 11 patients (27.27%) in CESI group showed 15° of ODI improvement in function. This outcome in ODI was significantly better (P < 0.001) for TFESI patients.

When compared, VAS and ODI as categorical data, the TFESI (group B) patients had significantly more improvement (P < 0.05) of symptoms (VAS and ODI) than CESI (group A) patients at 6 months postinjection. At 2 weeks and 3 months postinjection, VAS score improvement was significantly better (P < 0.05) in group B than group A patients. Mean VAS and ODI outcomes are shown as diagrams in Figures 1 and 2.

All caudal epidural injections were considered successful as an epidurogram was seen in postinjection lateral lumbosacral radiograph. For the transforaminal epidurals, the injection of steroid solution was performed only if adequate epidurogram was seen.

No major complications were seen following the injections. Minor complications included vagal reactions in four patients (two in each group) before the start of procedure, which necessitated rescheduling to another day.

Of the total 31 patients, only two (18.2%) patients of group A and no patient in group B (P < 0.05) required a second injection because of inadequate pain reduction (only 20% or less reduction of pain) at 15-day follow-up time. These two (18.2%) patients from group A (and no patient from group B) underwent decompressive surgery between 3 and 6 months following initial injection.

#### Discussion

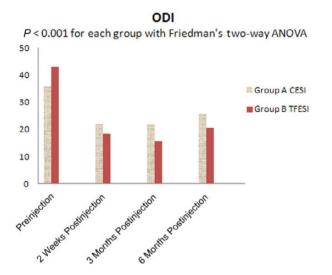
In our prospective case control study of ESIs, two comparable groups of lumbar stenosis patients with sciatic

**Table 3**Results of pain (VAS) and disability (ODI) in TFESI patient group based on whether theyachieved pain relief (complete or >50% pain reduction) at 6 months postinjection

Outcome Measure	Time	Respondents (N = 18)	Non-Respondents $(N = 2)$	<i>P</i> Value
		(	()	, value
Mean (SE) VAS leg pain	Preinjection	8.2 (0.2)	7.5 (0.5)	>0.05
	2 weeks postinjection	3.5 (0.3)	3 (0)	>0.05
	3 months postinjection	2.2 (0.2)	2.5 (0.5)	>0.05
	6 months postinjection	2.8 (0.2)	4 (0)	=0.04
Mean (SE) ODI	Preinjection	43.3 (1.3)	39 (1)	>0.05
	2 weeks postinjection	19.8 (1.4)	14 (4)	>0.05
	3 months postinjection	16.9 (1.2)	14 (4)	>0.05
	6 months postinjection	18 (1)	20 (0)	>0.05

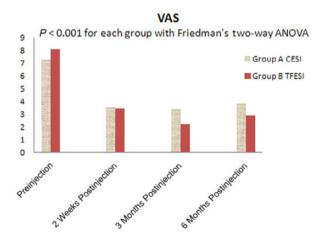
Statistically significant values indicated in bold.

ODI = Oswestry Disability Index; SE = standard error; TFESI = transforaminal epidural steroid injections; VAS = visual analog scale.



**Figure 1** Diagram showing mean Oswestry Disability Index (ODI) of patients at different follow-up time points. ANOVA = analysis of variance; CESI = caudal epidural steroid injections; TFESI = transforaminal epidural steroid injections; VAS = visual analog scale.

pain were injected by the same interventional physician/ spine surgeon in different facilities by different techniques (caudal epidural injection and fluroscopically assisted transforaminal epidural injection). At 6 months postinjection, there were significantly more (18/20) respondents (pain relief of at least 50%) to TFESI than respondents (6/11) to CESI. Functionally, all patients in TFESI group had at least 15 ODI degrees improvement



**Figure 2** Diagram showing mean visual analog scale (VAS) of patients at different follow-up time points. ANOVA = analysis of variance; CESI = caudal epidural steroid injections; TFESI = transforminal epidural steroid injections.

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while only 3/11 patients in CESI group. Clinical outcomes in terms of disability and pain (as means ODI and VAS) have shown improvement at 2 weeks, 3 months, and 6 months postinjection compared with preinjection for stenosis patients receiving injection by both techniques. Stenosis patients in TFESI group appeared with better outcomes at 6 months postinjection, compared with CESI group. Only two patients (both from CESI group) out of the 31 total required a second injection at 15 days postinjection and, finally, these two patients underwent surgery within 6 months postinjection.

The most beneficial and effective route of administration for epidural steroids remain controversial. Caudal epidural injections are deemed as the safest and easiest epidural injections, with minimal risk of inadvertent dural puncture or other side effects. They have also been shown to be significantly effective compared with interlaminar epidural injections [7,13]. Interlaminar epidural injections have shown ventral contrast flow in only 36% of the injections and bilateral contrast flow occurred in 16% of the injections [14]. Three years later, the same group of injectionists who reported on the epiduropgraphy patterns of interlaminar injections, reported fluoroscopically guided caudal ESIs may help reduce bilateral radicular pain and improve standing and walking tolerance in patients with degenerative lumbar spinal stenosis [15]. It is accepted that the caudal epidural injections performed without fluoroscopic assistance are inaccurate [16,17]; however, studies on patients with low back pain and/or sciatica treated with CESI have shown adequate effectiveness [18]. In the present study, one group of patients was treated by caudal epidural injections and postinjection radiograph to check for epidurograms. According to postinjection epidurograms and clinical outcomes, CESI injections were precise and successful in all of these patients.

Most experts believe that TFESI, which directly deposits the injectate into the ventral epidural space, is superior to CESI [14,19]. There are only a few comparative studies of TFESI and CESI. Lee et al. in a retrospective study of 233 patients with radiculopathy secondary to spinal stenosis or herniated disc, found that satisfaction and pain scores up to 2 months were superior for patients who underwent TFESI than CESI. However, different injectate volumes did not affect the final outcome irrespective of administration route [12]. In the randomized evaluator-blinded study for subjects with S1 radiculopathy secondary to L5-S1 herniated nucleus pulposus treated with TFESIs, ILESIs, or CESIs, the transforaminal route of epidural steroid placement was more effective (regarding pain and function) than the caudal at 12 and 24 weeks; and the patients with ventral epidural spread, more common in TFESI group, had better outcomes [11]. In the study presented by our group, stenosis patients who received TFESIs had significantly better outcomes than patients in CESI group at 6 months, even though we elected to use double steroid dosage with high injectate volume in the caudal route. This supports the proximity of the injection to the inflammation (TFESI) is more important than the high steroid dosage (CESI).

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One characteristic of CESI that differentiate it from TFESI is that the CESI reach its maximum effect at 2 weeks postinjection, while TFESI achieve a plateau at 6 weeks postinjection [11]. By this way, it is explained that the significant difference found in VAS and ODI of patients in TFESI group is between 2 weeks and 3 months, but not for CESI patients group.

The duration of pain relief from ESI varies and can reach up to a year [18,20]. In our 6-month follow-up study, the improvement of symptomatology at 6 months remained significant compared with preinjection data both for CESI and TFESI.

Patients undergoing TFESI have been shown lower need for reinjection to achieve adequate pain reduction compared with CESI. In the study by Ackerman et al [11], reinjection rate per case for TFESI was 1.5 injections compared with 2.5 injections in the caudal group. In our study, only 2 out of 11 patients in CESI and none out of 21 patients in TFESI needed an injection repeat at 2 weeks postinjection.

Spine surgeons are urged to order ESIs prior to considering surgery but should be aware of the low likelihood of benefit from the blind interlaminar epidural approach as it may fail to precisely place maximum concentration/ controlled volume of corticosteroid at the inflamed area [21]. There is good evidence that TFESIs should be used as a surgery-sparing intervention [5,22], and that TFESIs are superior to ILESIs and CESIs for radicular pain [11]. At 6 months postinjection of the patients presented in this study, two patients from CESI and no patient from TFESI group underwent spinal surgery.

Limitations to this study were the small number of patients included even if the original plan was to include at least 50 consecutive patients in each group so that significant differences in clinical outcomes could be identified. This is attributed to the limited number of patients in the CESI group, one hospital, and the premature closure of the study as the interim analysis (necessitated from our Scientific Research Board) showed improved results from TFESIs. Initially, we also planned to include in the study patients with the diagnosis of disc herniation, as a separate subgroup. Due to the small number of disc herniation patients, we included only the stenosis patients in the statistical analysis of group comparison. Another limitation of our study was that the volume of solution and corticosteroid dosage used were not identical between the two groups. However, because of the large volume of the epidural space in the sacral area and the distance from the inflammation site, an increased injectate volume and steroid concentrate in this anatomic area were chosen to be used for the CESI group.

## Conclusions

Even though CESI and TFESI provided adequate pain reduction and function improvement for 6 months when performed for stenosis patients with radicular symptoms, patients who received TFESI had superior VAS and ODI results than CESI at 6 months postinjection.

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