# **EFFECTIVENESS OF TRANSFORAMINAL EPIDURAL STEROID INJECTIONS** IN PATIENTS WITH DEGENERATIVE LUMBAR SCOLIOTIC STENOSIS AND RADICULOPATHY

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*Background:* The use of epidural steroid injections as a treatment for patients with degenerative lumbar scoliotic spinal stenosis and radiculopathy has received sparse attention in the literature. Even though it has been reported that patients with scoliosis may respond differently than other patient groups to conservative therapeutic interventions for low back pain and radiculopathy, patients with scoliosis have rarely, if ever, been excluded from clinical studies of epidural steroid injections. To date, there are no studies investigating the efficacy of fluoroscopic transforaminal epidural steroid injections as a treatment for patients with radiculopathy and radiographic evidence of degenerative lumbar scoliotic stenosis.

Objective: To evaluate the effectiveness of fluoroscopically guided transforaminal epidural steroid injections as a conserva-

Common conservative medical treatments for low back pain (LBP) and/ or radiculopathy include oral medications, exercise therapies, manual therapies, back school, lifestyle modifications, and epidural steroid injections (ESIs). ESIs were first advocated as a treatment for LBP in 1952 by Robecchi and Capra (1). Since then, over 4,000 cases in more than 60 publications have addressed the evidence-based role for ESIs in the treatment of LBP and radiculopathy (2).

Steroid injections may be delivered to the epidural space via a percutaneous caudal, interlaminar, or transforaminal approach. Reported success rates for tive treatment for patients with degenerative lumbar scoliotic stenosis and radiculopathy. Design: Retrospective case series.

Methods: The study was performed in an academic outpatient physical medicine and rehabilitation spine practice. Participants included 61 patients with radiographic evidence of degenerative lumbar scoliotic stenosis and radiculopathy. Patients who had undergone at least one fluoroscopicguided transforaminal epidural steroid and anesthetic injection were included.

Main Outcome Measures: Numeric Rating Scale (NRS) for worst pain experienced, North American Spine Society (NASS) satisfaction scale, amount of pain medication used, and adapted Stucki questionnaire to assess function and pain status.

Results: We obtained follow-up on 52 (85.2%) of 61 included patients. We defined

ESIs range from 20% to 100%, with an average success rate of 67% (3). Two major criticisms of previous reports may account for their discrepant results. 1) Previous investigations have evaluated a mixed patient pathology (disc herniation, spinal stenosis, scoliosis, spondylolisthesis) with mixed symptomatology (primarily axial LBP, primarily radicular pain, and/or radiculopathy). 2) Previous investigations have evaluated a mixture of the three steroid delivery approaches (caudal, interlaminar, transforaminal) and different techniques (amount and type of medication used, size of needle), each of which may also have different efficacy rates. Finally, most previous studies failed to use fluoroscopic guidance with pre-injection contrast enhancement to document the epidurogram and proper flow to the target tissue. ESIs performed without fluoroscopic guidance are known to miss the perceived target area 30% to 40% of the time (4).

Studying the effects of ESIs on patients with LBP is useful in helping to establish general guidelines for patient care. a successful outcome as a patient who was both satisfied with his or her results and experienced at least a 2-points improvement in NRS, Summary Pain, and Summary Function scores. Using these criteria for success, 59.6% of our patients had a successful outcome at one week post-injection, 55.8% at one month post-injection, 37.2% at one year post-injection, and 27.3% had a successful outcome at two years post-injection (p < 0.01).

Conclusion: Fluoroscopic transforaminal epidural steroid injections appear to be an effective nonsurgical treatment option for patients with degenerative lumbar scoliotic stenosis and radiculopathy and should be considered before surgical intervention.

Keywords: Transforaminal epidulumbar spinal stenosis, scoliosis, radiculopathy, rehabilitation

However, failing to apply a specific treatment to a specific population of patients may dilute or inflate true efficacy rates, obscuring our understanding of what types of ESIs, if any, should be used for select sub-populations of patients. Illustrating this point, in 1998, Lutz et al (3) reported an uncontrolled prospective study in which 69 patients were treated with fluoroscopically guided transforaminal ESIs. All 69 patients had a history and physical examination consistent with lumbar radiculopathy and MRI results documenting a herniated nucleus pulposus. The authors found that in this select patient population, fluoroscopically guided transforaminal ESIs had a 75.4% efficacy rate. By applying a specific treatment to a select patient population, the results of this study led to specific treatment recommendations for specific patients.

Vad et al (4), in 2002, reported a controlled prospective unblinded study of 48 patients comparing treatment with fluoroscopically guided transforaminal ESIs versus trigger point injections. Their re-

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sults confirmed the results of Lutz et al (3). All 48 of Vad et al's (4) patients were selected through inclusion/exclusion criteria similar to the ones used by Lutz et al (3). The results were that 84% of patients treated with transforaminal ESIs showed improvement, compared with 48% improvement in the group treated with trigger point injections.

The use of ESIs as a treatment for patients with degenerative lumbar scoliotic spinal stenosis and radiculopathy has received sparse attention in the literature. In 2000, Simotas et al (5) evaluated the efficacy of conservative management, including ESIs, in patients with lumbar stenosis and symptoms of neurogenic claudication. They observed that a subset of patients who had radiographic evidence of scoliosis responded significantly less to treatment (p < 0.05). However, the sample size of patients with scoliosis was small (n = 15), and patients received different conservative treatments including nonsteroidal anti-inflammatory drugs, oral corticosteroids, and different routes of administration of ESIs. Indeed, in a followup paper in 2001, Simotas (6) concluded that factors such as radiographically documented scoliosis and spondylolisthesis have an "unknown effect" on nonoperative conservative treatment outcomes for patients with lumbar stenosis.

Although it has been noted that patients with scoliosis may respond differently than other patient groups to conservative therapeutic interventions for LBP and radiculopathy, patients with scoliosis have rarely, if ever, been excluded from clinical studies of ESIs (7, 8). This subpopulation of scoliotic patients, therefore, may be altering the reported efficacy rates of ESIs in more general patient populations.

To date, no study has investigated the efficacy of fluoroscopic transforaminal ESIs as a treatment for patients with radiculopathy and radiographic evidence of degenerative lumbar scoliotic stenosis. The purpose of our current study, therefore, was to evaluate the efficacy of fluoroscopically guided transforaminal ESIs in this specific population of patients.

#### **M**ETHODS

Patients who were seen in an academic outpatient physical medicine and rehabilitation spine practice between 1996 and 2003 and who had received at least one fluoroscopically guided transforaminal ESI were considered for the study. Inclusion criteria included (1) radiculopathy, (2) radiographic evidence of scoliosis greater than 10 degrees, and (3) age greater than or equal to 50 years. Exclusion criteria included patients for whom there was less than one month of follow-up time available at the time of data collection. All transforaminal ESIs were administered by the same author (GEL). The study was done with Institutional Review Board approval from the host institution, Hospital for Special Surgery. Informed consent was obtained and strict patient confidentiality was maintained.

All patients who qualified for the study were telephoned by an independent examiner (IE) and presented with a numerical rating scale (NRS) for worst pain experienced, with 0 representing one end of the pain intensity scale (no pain) and 10 representing the other extreme of pain intensity (worst pain imaginable). Patients were also given a Patient Satisfaction Index adapted from the North American Spine Society's low back pain outcome instrument (NASS Patient Satisfaction Index) in which they were asked to choose from one of four possible responses based on their satisfaction with treatment (Table I). Responses of 1 or 2 on this scale were scored as NASS satisfaction successes. Patients were also asked questions regarding interventions and medication use both prior to and subsequent to their transforaminal ESI.

Finally, patients were administered an outcome questionnaire adapted from Stucki et al (9). The adapted Stucki outcome questionnaire includes seven questions on pain and six questions on function. The answers to each of the 13 questions were coded, and pain and function categories were summed to give Summary Pain and Summary Function scores, respectively.

All outcome questions, including the NRS and the adapted Stucki ques-

tionnaire, were asked in reference to the average severity of their symptoms over a one-week period of time immediately before their first transforaminal ESI. All outcome questions were also asked with reference to the average severity of the patient's symptoms over a one-week period of time prior to the phone call by the IE. If the patient received symptom relief for a period of time shorter than the total follow-up time, then the patient was asked to respond to the follow-up questions with regard to an average of his or her symptoms one week prior to the end of maximal symptom relief. These answers were then used in lieu of total follow-up time, and the duration of symptom relief was noted.

Charts were also reviewed for MRI or X-ray-documented evidence of scoliosis greater than 10 degrees, age, duration of symptoms prior to injection, number of injections, prior surgery, MRI or X-ray-documented evidence of spondylolisthesis, and type of insurance. Significance was set at p < 0.05 with 95% confidence intervals. Data were analyzed using SPSS version 9.0 software run by Windows operating system.

All patients received a transforaminal ESI under fluoroscopic guidance (Figure. 1). After the usual sterile prep, drape, and local anesthesia, a 20-gauge 3.5-inch spinal needle was advanced to the corresponding transverse process, then redirected 1cm inferior and anterior. A curved 25-gauge 6-inch spinal needle was advanced through the 20-gauge introducer needle 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 is positioned just below the pedicle in the ventral aspect of the intervertebral foramen. On the an-

Score
Image: Table 1. Patient Satisfaction Index (North American Spine Society)

Score
Image: Table 1. The treatment met my expectations.

Image: Image: Table 1. Patient Met My expectations.
Image: Table 1. The treatment met my expectations.

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2	I did not improve as much as I had hoped, but I would undergo the same treatment for the same outcome.
3	I did not improve as much as I had hoped, and I would not undergo the same treatment for the same outcome.
4	I am the same or worse than before treatment.

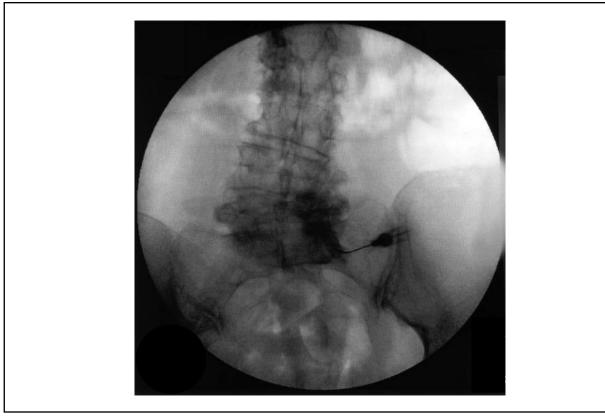


Fig. 1. Fluoroscopically guided transforaminal epidural steroid injection

terior-posterior view, the needle is placed just beneath the midportion of the corresponding pedicle. At the S1 level, a single needle is advanced under fluoroscopic guidance. At each level, 1 to 2 mL of contrast (Omnipaque 240, Amersham Health, Arlington Heights, IL) was injected, and results of the epidurogram and pain response were recorded. If there was no flow to the corresponding nerve root and disc space level, the needle was repositioned. Once adequate flow of contrast to the target area was documented, 80mg of Kenalog (ER Squibb & Sons, Princeton, NJ) and 1.5 mL of 2% lidocaine (preservative free) were injected.

If the patient had severe foraminal stenosis, the injection was administered at the segment below and the medication was pushed up to the segment of involvement. We felt this approach was less risky to the patient and better tolerated.

## RESULTS

We reviewed 1,466 charts to identify 62 patients who met our inclusion/ exclusion criteria. One patient had died and could not be included in the study. The demographic description of the patient population is described in Table 2. Sixty-one (61) patients, 41 female and 20

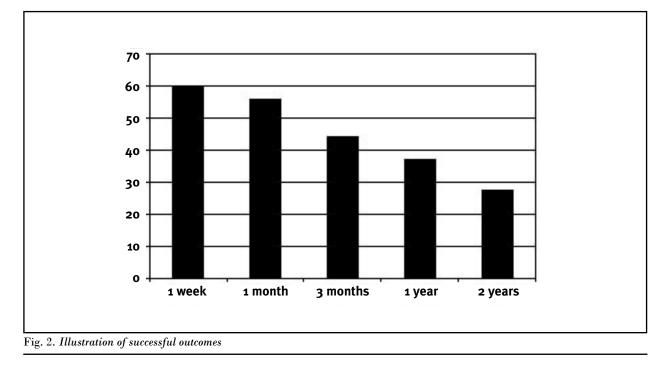
pre-injection duration of symptoms was 72.4 weeks (range 3-960). Follow-up data male, with a mean age of 68.6 (range 50- were obtained by telephone on 52 patients 90), were included in the study. Average (85.2%). Of these 52 patients, nine had

Table 2. Descriptive Characteristics		
	Mean	69
Age (years)	Range	50 - 90
Gender	Male	20
Gender	Female	41
Follow up time (weeks)	Mean	85.5
Follow-up time (weeks)	Range	20 - 152
Pre-injection duration of symptoms (weeks)	Mean	72.4
Pre-injection duration of symptoms (weeks)	Range	3 - 960
Wayst NDC noin nyiny to typothemut	Mean	8.5
Worst NRS pain prior to treatment	Range	5 - 10
Duration of noin valiat (waska)	Mean	32.4
Duration of pain relief (weeks)	Range	0 - 144
Number of patients with 2 injections	12	
Number of patients with 3 injections	5	
Number of S1 injections	21	
Number of L5-S1 injections	41	
Number of L4-5 injections	10	
Number of L3-4 injections	11	

Table 3. Participants reporting successful outcomes at five time periods post-intervention (N=52)

	1 week	1 month	3 months	12 months	24 months
% reporting successful outcomes	59.6*	55.8*	44.2*	37.2*	27.3*

\* Significantly different from no success by chi-square statistic,  $\,p<0.01$ 



spondylolisthesis, two had prior surgery (one laminectomy, one fusion), four had previous fluoroscopic caudal ESI, one patient had No-Fault insurance, and none had Workman's Compensation.

In our patient population, 50% of the treated pathology was at the L5-S1 level, 25% was at the S1 level, 13% was at the L3-L4 level, and 12% was at the L4-L5 level. The average worst NRS score prior to injection was 8.56 (range 5-10). The average pre-injection adapted Stucki Summary Pain score was 18.5 (range 11-29). The average pre-injection adapted Stucki Summary Function score was 11.9 (range 5-19). The average follow-up time was 85.5 weeks (range 20-152). Patients received an average of 1.3 injections/patient. The average duration of symptom relief was 32.4 weeks (range 0-144).

Table 3 describes the success of the intervention, which is also depicted in Figure 2. We defined a successful outcome as a patient who was both satisfied with her results (NASS=1 or 2) and experienced at least a 2-point improvement in NRS, Summary Pain, and Summary Function scores. Using these cri-

teria, 31 of our patients (59.6%) had a successful outcome at one week post-injection, 29 (55.8%) still had a successful outcome at one month post-injection, 23 (44.2%) continued with their successful outcome at three months post-injection, 16 (37.2%) of our patients had a successful outcome at one year post-injection, and six (27.3%) had a successful outcome at two years post-injection. The success at each of these time periods is impressive and is statistically significant by chi-square test from a baseline expected frequency of no relief.  $(X^2(1) > 170, p)$ < 0.01). In addition, 14 (27%) of our patients had complete symptom relief for an average of 1.5 years, and 34 patients (65%) reported taking less medication than before their injection  $(X^2(1) = 5.58)$ , p < 0.02). Only five (9.6%) of our patients did not experience any transient relief of their symptoms.

Comparisons were made between the groups of failures and successes for differences in type of insurance, mean pre-injection Summary Pain, Summary Function, NRS, age, sex, duration of symptoms prior to first transforaminal ESI, level and side of ESI, presence of spondylolisthesis, and patients with and without classic symptoms of neurogenic claudication (defined as pain radiating into the lower extremities that begins and worsens with ambulation). None of these results proved to be statistically significant (p > 0.05). We also examined correlations between these pre-injection variables and success rates. None of the correlations achieved statistical significance (p > 0.05). Finally, we examined correlations between these pre-injection variables and duration of symptom relief. Again, no correlations achieved statistical significance (p > 0.05).

The outcome data that were presented in Table 3 were unpacked to examine the difference between patients with acute vs chronic symptoms. There were 14 patients with acute symptoms (less than or equal to three months of symptoms) prior to their first injection. As can be seen in Table 4 and depicted in Figure 3, there was a tendency for patients with acute symptoms to experience higher success rates than patients with pre-injection symptoms of greater than three months. This

Table 4. Successful outcomes for patients with acute (n=14) vs. chronic (n=38) symptoms at five time periods post-intervention

	1 week	1 month	3 months	12 months	24 months
Acute Symptoms	64.3*a	64.3* <sub>a</sub>	57.1 <sup>*</sup> a	57.1 <sup>*</sup> a	50.0* <sub>a</sub>
Chronic Symptoms	57•9 <sup>*</sup> a	55.2 <sup>*</sup> a	47.4 <sup>*</sup> a	36.8* <sub>a</sub>	21.1* <sub>a</sub>

\* Significantly different from no success by chi-square statistic, p < 0.01

Note: Entries with subscripts within columns are different from each other by chi-square test, p < 0.05

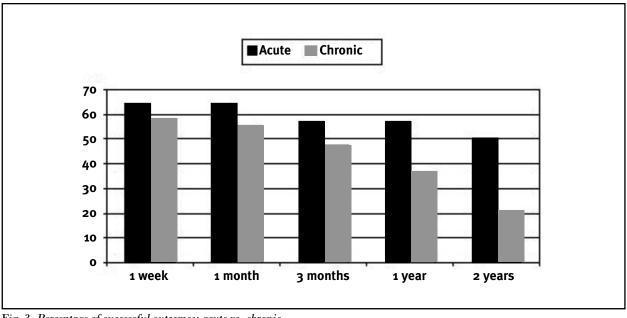


Fig. 3. Percentage of successful outcomes: acute vs. chronic

difference did not achieve statistical significance at any of the assessment periods except at the 24-month post-intervention assessment (X<sup>2</sup>(3)= 8.73, p < 0.05). Interestingly, we found that even those patients whose symptoms were considered chronic (> three months) showed significant improvement in those symptoms at every time period tested,  $(X^2(1) > 65.7, p)$ < 0.01).

Four patients had one fluoroscopic caudal ESI, which did not provide any of them with symptom relief, prior to their transforaminal ESI. Three of these patients (75%) had successful outcomes.

Two patients had surgery prior to their injection. One had an L3-5 fusion 30 years prior to injection. The other patient had an L3-5 laminectomy four years prior to injection. Both patients had successful outcomes from their injections.

Fifteen patients had at least two transforaminal ESIs. All 15 of these patients had at least some transient relief from their symptoms after their first injection. Seven of the 15 patients (47%) had successful outcomes after their first injection. Three of these seven patients with successful outcomes had their second injection at a different level than the first (in each case the first injection was L5 and the second was at S1). All eight of the failed second injections were performed at the same level as the first injection.

There were no documented consistent differences in the anatomy, pathology, or scoliotic curves between patients who had successful outcomes and those with failed outcomes.

#### DISCUSSION

In this retrospective follow-up investigation, we studied clinical outcomes of patients with degenerative lumbar scoliotic stenosis and radiculopathy treated with fluoroscopic transforaminal epidural steroid injections (ESIs). The aim of our study was to answer the following three questions: (1) If a patient with degenerative lumbar scoliotic stenosis presents with radiculopathy, what degree of improvement may she/he anticipate if she is treated with a fluoroscopic transforaminal ESI, and how long will that improvement last? (2) If the first fluoroscopic transfo-

raminal ESI is unsuccessful in providing lasting symptom relief, what is the prognosis of a repeat injection? (3) What effect does the presence of spondylolisthesis, duration of symptoms before injection, worst pre-injection pain and function scores, gender, age, level and side of ESI, distribution of pain symptoms, prior surgery, type of insurance, and prior unsuccessful caudal ESI have on the efficacy of a fluoroscopic transforaminal ESI in this population of patients?

Thirty-one (59.6%) of our patients experienced successful outcomes from their fluoroscopic transforaminal ESI. Specifically, 59.6% of our patients had a successful outcome at one week post-injection, 55.8% had a successful outcome at one month post-injection, 44.2% had a successful outcome at three months postinjection, 37.2% had a successful outcome at one year post-injection, and 27.3% had successful outcome at two years post-iniection.

Short-term relief from pain and increase in function is clinically significant, especially as ESIs may be repeated safely as many as four times per year. In addition, 65% of patients were taking less pain medications after their injection. In an older population (mean age = 69.5), reducing the number of medications that a patient is taking is especially significant as this population of patients is prone to adverse reactions from, and adverse interactions between, medications.

Fifteen (29%) of our 52 patients received multiple injections. To answer our second question, we examined the results of these 15 patients. Only patients who received at least a transient improvement in their symptoms -- defined as verbal report of any reduction in pain post-injection following their first transforaminal ESI -- were offered a second injection. Seven (47%) of the 15 patients had a successful outcome following their second injection. All second injections were delivered at least one week after the initial injection.

Only three of the 15 patients had their repeat injections at a different level from their first. In each instance, the first injection was at the L5 level and the repeat injection was at S1. All three of these patients had successful outcomes from their second injection. This may be related to the following: It has been the authors' clinical experience that in a stenotic foramen, the contrast on the epidurogram may have suboptimal flow to the target tissue. In addition, because there is less epidural fat, needle placement will most likely be too close to or actually in the exiting nerve root. In these cases, injecting medication into the spinal level beneath the pathologic level may allow the medication to flow up and bathe the symptomatic level

We analyzed the relative role of insurance, the presence of spondylolisthesis, duration of symptoms before injection, pre-injection NRS, Summary Pain, and Summary Function scores, gender, age, level and side of ESI, distribution of pain symptoms, prior surgery, and prior unsuccessful caudal ESI as they affected the efficacy of a fluoroscopic transforaminal ESI in our patients with degenerative lumbar scoliotic stenosis and radiculopathy.

We first looked at the duration of symptoms prior to first transforaminal ESI, which seemed to affect efficacy rates. Patients with acute symptoms (less than or equal to 12 weeks of symptoms) prior to injection had higher rates of successful outcomes than did patients with chronic symptoms (Figure 3). At 24 months postintervention, this difference was significant (p < 0.05) although the difference across all of the time periods was not significant (p = 0.274). This failure to reach statistical significance was probably due to the small sample size of patients with acute symptoms (n = 14).

The trend for patients with more acute symptoms to experience greater clinical improvement has been previously reported with significance (3). One explanation for this relationship discussed by Lutz et al. in their 1998 study is that the effect of the delivered steroid may achieve greater potency during the acute phase of pain prior to the occurrence of irreversible neurophysiological changes. An alternative explanation is that the natural history of radiculopathy and LBP in patients with acute symptoms is more favorable than in patients with chronic symptoms, and some of the patients with acute symptoms may have recovered without the benefit of our intervention. Nevertheless, bolstered by previously reported similar results, the trend we see in patients with acute symptoms responding more favorably is impressive and deserves consideration in treatment recommendations.

Four patients had a fluoroscopic caudal ESI that failed to relieve the patients' symptoms prior to their transforaminal ESI. Three of those patients had successful outcomes. Although this sample size is too small to draw any definitive conclusions, it would seem reasonable to offer a fluoroscopic transforaminal ESI to patients who have failed one prior caudal ESI.

Two patients had prior surgeries (one laminectomy, one fusion) and both had successful outcomes. This sample size is too small for us to draw conclusions from; however, it would appear that prior surgery should not be considered a contraindication, or a negative outcome predictor, to treatment with a fluoroscopic transforaminal ESI.

Gender, age, type of insurance, level and side of pathology had no effect on clinical efficacy of the fluoroscopic transforaminal ESI and should not be considered as significant factors when considering treatment recommendations.

The limitations of our study include those inherent to any retrospective study, including selection bias, lack of blinding, and lack of a control group with which to compare results. In addition, collecting information via telephone interviews may introduce an additional bias. Patients may be reticent to provide negative feedback to a person identifying him or herself as a member of the medical profession, even when that person is an independent examiner and not involved in the patient's care.

Another criticism of this study is the way we diagnosed patients with degenerative lumbar scoliotic spinal stenosis. All patients had radiographic evidence of scoliosis; however, the way we differentiated degenerative lumbar scoliosis from idiopathic lumbar scoliosis was by the age of the patient (patients older than 50 were considered to have degenerative lumbar scoliosis). We believe this was a reasonable and practical assumption on our part. The incidence of idiopathic lumbar scoliosis is less than 1% to 3%, and only approximately 35% of these patients will experience chronic LBP (10). Despite these low numbers, however, it is reasonable to speculate that we may have inadvertently included one or more patients with idiopathic lumbar scoliosis, or idiopathic lumbar scoliosis with superimposed degenerative changes within the curve. The argument may be made, therefore, that our results, and the conclusions we draw from our results, are more applicable to patients with lumbar scoliosis and age greater than 50 years. An interesting future study would be to directly compare the efficacy of specific nonsurgical conservative treatment regimens for patients with known degenerative and known idiopathic lumbar scoliosis.

An additional criticism of our study is that, due to the sometimes incomplete radiographic records, we were unable to correlate size and precise location of curve to transforaminal ESI efficacy. A future study may seek to more specifically investigate this potential correlation.

# CONCLUSION

We conclude that fluoroscopic transforaminal epidural steroid injections (ESIs) appear to be an effective non-surgical option for patients with degenerative lumbar scoliotic stenosis and radiculopathy. We conclude that if a patient experiences transient relief from a first fluoroscopic transforaminal ESI, an identical second injection is indicated. However, if pre-injection contrast is not seen to adequately bathe the target tissue on the first injection's epidurogram, then the second injection should be considered at the inferior spinal segment. Finally, we conclude that prior surgery and prior unsuccessful caudal ESIs do not appear to be negative predictors of fluoroscopic transforaminal ESI success and should not be considered relative contraindications. Future prospective, controlled clinical trials are necessary to make more definitive conclusions.

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