Transforaminal Epidural Steroid Injections in Lumbosacral Radiculopathy

A Prospective Randomized Study

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Study Design. A prospective study randomized by patient choice from the private practice of a single physician affiliated with a major teaching hospital was conducted.

Objectives. To compare transforaminal epidural steroid injections with saline trigger-point injections used in the treatment of lumbosacral radiculopathy secondary to a herniated nucleus pulposus.

Summary of Background Data. Epidural steroid injections have been used for more than half a century in the management of lumbosacral radicular pain. At this writing, however, there have been no controlled prospective trials of transforaminal epidural steroid injections in the treatment of lumbar radiculopathy secondary to a herniated nucleus pulposus.

Methods. Randomized by patient choice, patients received either a transforaminal epidural steroid injection or a saline trigger-point injection. Treatment outcome was measured using a patient satisfaction scale with choice options of 0 (poor), 1 (fair), 2 (good), 3 (very good), and 4 (excellent); a Roland-Morris low back pain questionnaire that showed improvement by an increase in score; a measurement of finger-to-floor distance with the patient in fully tolerated hip flexion; and a visual numeric pain scale ranging from 0 to 10. A successful outcome required a patient satisfaction score of 2 (good) or 3 (very good), improvement on the Roland-Morris score of 5 or more, and pain reduction greater than 50% at least 1 year after treatment. The final analysis included 48 patients with an average follow-up period of 16 months (range, 12–21 months).

Results. After an average follow-up period of 1.4 years, the group receiving transforaminal epidural steroid injections had a success rate of 84%, as compared with 48% for the group receiving trigger-point injections ($P < 0.005$).

Conclusion. Fluoroscopically guided transforaminal injections serve as an important tool in the nonsurgical management of lumbosacral radiculopathy secondary to a herniated nucleus pulposus. [Key words: fluoroscopic guidance, lumbosacral radiculopathy, transforaminal epidural injection, trigger point] **Spine 2002;27:11–16**

Sciatica, a commonly used term, represents a prevalent medical and socioeconomic problem.[13,15,21,22,23,28] More than half of the patients with sciatica report a decline in their activities of daily living and ability to work.[15] Intervertebral disc herniations are the most com-

mon cause of lumbosacral radiculopathy, and 10% to 15% of these patients eventually require surgery.[4,7] Overall, the vast majority of patients with lumbosacral radiculopathy recover with conservative care.[34] The continuum of nonsurgical care includes a trial of bed rest, oral medications, lumbar corsets, and physical therapy.[14,20,34,35,37]

Historically, epidural steroid injections (ESIs) have been used as an adjunct in the treatment of sciatica.[25,32] Since the early reports, success rates ranging from 20% to 100% (average, 67%) have been documented.[3,5] However, the efficacy of ESI has lasted, on the average, less than 3 months.[38] Of the 12 controlled trials reviewed (5 for caudal ESI and 7 for lumbar ESI), only 6 have demonstrated that epidural injections are more effective than the control treatment (4 for caudal ESI and only 2 for lumbar ESI).[19]

These disparate results can be explained by several methodologic and technical flaws.[19,25] The inclusion criteria generated a patient population with mixed pathologies (intervertebral disc herniations, spinal stenosis, spondylolisthesis, postsurgical changes). Also, the epidural injections, both the caudal and translaminar types, were performed without the use of fluoroscopy or contrast. In effect, they were performed blindly. Epidural injections performed in this manner are known to miss the perceived target area 30% to 40% of the time.[38]

Fluoroscopic guidance with contrast enhancement ensures that a high concentration of medication reaches the disc nerve interface.[12,17,25,27,29,39] Traditional translaminar and caudal epidural injection routes are dorsal, and corticosteroid spread to the ventral target site occurs by diffusion.[27] Additionally, the dorsal median epidural septum may confine the spread of dorsal epidural flow to the side ipsilateral to the injection.[27] Consequently, it seems improbable that an adequate concentration of corticosteroid could be delivered to the target tissues by traditional caudal or translaminar approaches with or without the use of fluoroscopic guidance.[25]

The lumbar transforaminal ESI (TFESI) technique using fluoroscopic control allows a high concentration of corticosteroid to be delivered precisely to this target site (*i.e.,* the ventral aspect of the lumbar nerve root sleeve and the dorsal aspect of the disc herniation).[9,10] Recently, Bogduk[1] supported the potential usefulness of TFESIs for disc prolapse, and Riew et al[30] have shown early promising results using TFESI in the treatment of lumbar spinal stenosis. At this writing, however, no controlled prospective trials of TFESIs in the treatment of

lumbar radiculitis secondary to a herniated nucleus pulposus (HNP) have been reported in a North American peer-reviewed journal.

The current study was a prospective randomized controlled trial investigating the therapeutic value of TFESIs, as compared with saline trigger-point injections (TPIs) in patients with lumbosacral radiculopathy secondary to HNPs that failed other nonsurgical treatments.

■ Materials and Methods

This study was conducted at a major university hospital, and the protocol was approved by the hospital institutional review board. The participants in this study were recruited in a consecutive manner from referrals to one private practice affiliated with the hospital. Patients were eligible to participate in this study if they were older than 18 years, primarily had leg pain greater than back pain, had been symptomatic longer than 6 weeks, had undergone a lumbar spine magnetic resonance imaging scan documenting an HNP estimated to have less than 50% intervertebral foraminal narrowing, or manifested clinical signs such as radicular pain and sensory or fixed motor deficits consistent with lumbar radiculopathy at the magnetic resonance imaging–documented lumbosacral root level. A series of HNPs at various interspaces (L3–L4, L4–L5, L5–S1) and with differing axial presentations (*e.g.*, far lateral, paracentral, and central protrusion) were examined. The diversity of these magnetic resonance imaging presentations allowed the efficacy of TFESIs with most forms of HNP to be investigated.

Patient's were excluded from this study if they had undergone prior lumbar surgery, had a large HNP with severe central or foraminal stenosis on magnetic resonance imaging, had progressive neurologic deficits, had undergone prior ESIs, had workman's compensation or legal claims pending because of injury, had a blood coagulation disorder, or had experienced an allergic reaction to local anesthetics or corticosteroids. Patients who met the inclusion criteria signed an informed consent that described the trial with its risks, benefits, alternatives, and objectives as per the institutional review board protocol.

The patients were randomly assigned to two treatment groups: Group 1 (TFESI) and Group 2 (TPI). They were not blinded to the treatment protocol. To avoid any therapeutic effect from washout, an office TPI was performed rather than a fluoroscopically guided injection of either normal saline or a contrast material. Afterward, 50 patients were followed for an average of 16 months (range, 12–21 months). The final analysis included 48 patients. Two patients were lost to follow-up evaluation.

All the injections were performed by the primary author (V.B.V.). For the patients in Group 1 (TFESI), a double-needle paramedian technique was used to access the L3–L4, L4–L5, and L5–S1 intervertebral foramens.[9] After sterile preparation, draping, and local anesthesia, a 20-gauge, 3.5-inch spinal needle was advanced to the ipsilateral transverse process, then redirected 1 cm anteriorly and inferiorly. A curved 25-gauge, 6-inch spinal needle was advanced through the 20-gauge introducer needle into the so-called "safe-triangle."[2] The safe triangle is composed of a roof made up by the pedicle, a tangential base that corresponds to the exiting nerve root, and the lateral border of the vertebral body. Both anteroposterior and lateral fluoroscopic projections confirmed proper needle placement. With the lateral view, the needle was positioned just below the pedicle along the ventral aspect of the intervertebral foramen.
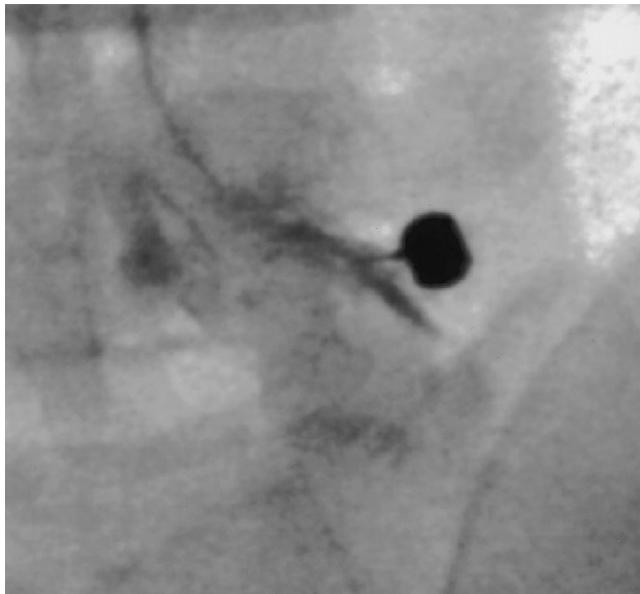

Figure 1. Left L5 transforaminal epidural steroid injection with contrast showing nerve rootoutline.

With the anteroposterior view, the needle was placed just beneath the midportion of the corresponding pedicle (Figure 1).

Access to the first sacral (S1) foramen was achieved with a single-needle technique. A 22-gauge, 3.5-inch spinal needle was advanced into the upper outer quadrant of the ipsilateral S1 foramen under fluoroscopic guidance. At each level, 1 mL of contrast medium (iohexol) was injected and the results of the epidurogram and pain response were recorded. If there was no flow to the corresponding nerve root and the disc space level, the needle was repositioned. Once adequate flow of contrast to the target area was documented and no blood or cerebrospinal fluid was aspirated, 1.5 mL each of betamethasone acetate (9 mg) and 2% preservative-free xylocaine was injected. To avoid systemic side effects of the medication, injections were not performed at more than two levels at one time. The patients in Group 1 (n = 25; average age, 41.3 years) received an average of 1.7 TFESIs (range: 1–3 TFESIs) and were followed up for an average of 1.4 years.

In Group 2 (TPI), the primary author performed all TPIs in the office using the deep lumbar paraspinal muscle injection technique without fluoroscopy. The spinous process of the lumbar vertebral body was palpated, and the point of maximal tenderness corresponding to the ipsilateral paraspinal level of involvement was identified. After sterile preparation and local anesthetic administration to the skin, a 22-gauge, 1.5-inch needle was placed into the skin 2 cm laterally to the lumbar spinous process directed toward this point of maximal tenderness in the lumbar paraspinal muscles. Then 3 mL of normal saline was injected. This procedure was performed in exactly the same manner for each patient on subsequent visits if deemed appropriate. Group 2 (n = 23; average age, 42.1 years) received an average of 1.6 TPIs (range, 1–2 TPIs) and were followed up for an average of 1.4 years.

Groups 1 and 2 both received a self-directed home lumbar stabilization program consisting of four simple exercises emphasizing hip and hamstring flexibility and abdominal and lumbar paraspinal strengthening.[11] This program was combined with the use of a back cryobrace worn for 15 minutes every night.

Table 1. Pre- to Posttreatment Comparisons*

Group 1	Pretreatment	Posttreatment
Roland-Morris score	8.8	22.1
Visual numeric score	8.8	1.6
Finger-to-floor distance (cm)	69.6	20.3
Patient satisfaction score	0.8	2.9

* $P < 0.05$.

Compliance was ensured by reinforcement of the therapeutic exercises during follow-up visits. Treatment outcome was measured by a patient satisfaction scale with choice options of 0 (poor), 1 (fair), 2 (good), 3 (very good), and 4 (excellent); a Roland-Morris[33] low back pain questionnaire that showed improvement by an increase in score; a measurement of finger-to-floor distance with the patient in fully tolerated hip flexion[5]; and a visual numeric pain scale[8] similar to the visual analog scale with a range of options from 0 (no pain) to 10 (severe pain). Outcome measures were collected before and after treatment, then at 3 weeks, 6 weeks, 3 months, 6 months, and 12 months by an independent registered nurse blinded to the treatment protocol. Statistical analysis using Wilcox signed-rank test was used to compare the data obtained. Narcotic or antiinflammatory medication use was disallowed during the duration of participation in the study. A successful outcome from treatment was defined as a patient satisfaction score of 2 (good) or 3 (very good), improvement on the Roland-Morris score of 5 or more, and pain reduction greater than 50% at least 1 year after treatment.

■ **Results**

In Group 1, 21 of 25 patients (84%) showed improvement, whereas only 11 of 23 patients (48%) in Group 2 responded to treatment. No complications such as dural puncture, excessive bleeding, headache, or infection occurred in either group.

By the end of the study period, the mean Roland-Morris score in Group 1 had increased from 8.8 ± 1.2 to 22.1 ± 1.6; the visual numeric pain had decreased from 8.8 ± 1.4 to 1.6 ± 0.8); and the finger-to-floor distance had decreased from 69.6 ± 2.7 cm to 20.3 ± 1.8 cm. The patient satisfaction score had increased from 0.8 ± 0.6) to 2.9 ± 0.7) (Table 1). Overall, 84% of the patients in Group 1 had a successful outcome, attaining maximal improvement within 6 weeks of treatment. The delay between the final injection and the maximal improvement was 4 weeks.

In Group 2, the Roland-Morris score had increased from 9.6 ± 1.3 to 18.3 ± 2.1; the visual numeric pain score had decreased from 9.4 ± 1.4 to 3.6 ± 1.1; and the finger-to-floor distance had decreased from 64.8 ± 1.4 to 24.4 ± 1.6 by the end of the study. The patient satisfaction score had increased from 0.8 ± 0.3 to 1.9 ± 0.7 (Table 2). Overall, 48% of the patients in Group 2 had a successful outcome, reaching maximal improvement within 12 weeks of treatment.

The difference in outcomes between Groups 1 and 2 was statistically significant ($P < 0.05$). This difference was maintained throughout the duration of the study.

Factors associated with the unsuccessful outcome in Group 1 were presence of spondylolisthesis (n = 2) and symptom duration exceeding 1 year (n = 2). However, statistical significance cannot be determined because of the small sample for each subgroup of patients.

■ **Discussion**

The rationale for using epidural steroids stems from studies demonstrating abnormal concentrations of nociceptive and inflammatory mediators around lumbosacral disc herniations leading to a chemical neuroradiculitis.[26,35] Corticosteroids are known to inhibit prostaglandin synthesis, impair both cell-mediated and humoral immune responses, stabilize cellular membranes, and block nociceptive C-fiber conduction.[6,11,16,18,23,31]

In the literature, the efficacy of lumbar epidural spinal injections for radicular pain ranges from 0% to 100% and lasts for less than 3 months.[3,39] A successful outcome in 84% of the current patients was observed over an average follow-up period of 1.4 years. Also, the results were obtained with an average of 1.7 steroid injections, which is significantly fewer than the traditionally prescribed 3 to 4 injections. More importantly, the patients in Group 1 attained maximal improvement in 6 weeks, as compared with 12 weeks in Group 2. Direct delivery of medication to the exact pathology in the transforaminal approach coupled with the additional use of consistent rehabilitation may explain the longer duration of effect and the need for fewer injections. Furthermore, the high efficacy of TFESIs may be explained by their presumed four mechanisms of action: 1) the precise delivery of the steroid and xylocaine solution, both of which have nociceptive properties; 2) the nerve membrane–stabilizing properties of both the steroid and xylocaine; 3) the "washout" effect of the solution, which decreases the regional levels of inflammation mediators such as interleukin-1, tumor necrosis factor, and phospholipase A_2; and 4) the potent antiinflammatory properties of the steroid.[24,36,38]

The 48% success rate observed for patients who received TPIs may be attributed to the postinjection rehabilitation program combined with icing, the injection alone, a placebo effect, or a combination of all these. To prevent a possible therapeutic "washout" effect of normal saline, Group 2 received office TPIs rather than transforaminal normal saline injections.

In contrast to the TFESI technique used in this study,

Table 2. Pre- to Posttreatment Comparisons*

Group 2	Pretreatment	Posttreatment
Roland-Morris score	9.6	18.3
Visual numeric score	9.4	3.6
Finger-to-floor distance (cm)	64.8	24.4
Patient satisfaction score	0.8	1.9

* $P < 0.05$.

caudal or translaminar ESIs typically use 6 to 10 mL of injectant. This volume is distributed over the entire epidural space and not delivered to the specific site of pathology, which may dilute the potential therapeutic effect of the corticosteroid necessary to treat the chemical radiculitis. By contrast, with the transforaminal technique, only 3 mL of injectant (1.5 mL each of betamethasone acetate and 2% xylocaine) is guided specifically to the site of nerve root irritation. Without fluoroscopic guidance, there is a 30% chance of misplacing treatment into areas other than the epidural space at the site of herniation.[38] Also, use of a blind technique to deliver the steroid depends on normal anatomy of the epidural space. The presence of scarring or a midline raphe may inhibit delivery of the injectant.[19,25] The use of fluoroscopically guided TFESIs allows for precise delivery of the medication reliably to the interface between the HNP and the ventral aspect of the irritated nerve root.[25] Modification of the approach around the abnormal anatomy to the exact site of irritation on the side of the symptoms is necessary for adequate administration of the steroid–anesthetic combination. This modification and site-directed treatment cannot be accomplished without the use of fluoroscopy[13,28] The absence of complications such as dural puncture and excessive bleeding commonly associated with blind epidural injection techniques attests to the safety of the fluoroscopic transforaminal approach.[25]

Factors associated with the decreased success experienced by the steroid–anesthetic study group include preexisting spondylolisthesis in addition to disc herniation and duration of symptoms exceeding 1 year. When disc herniation occurs at the level of preexisting spondylolisthesis, the natural history of recovery may change. The mechanical alteration of the disc–bone–nerve root interface in spondylolisthesis cannot be expected to change with the administration of epidural steroids. The preexisting physical alteration in the mechanics of the spine combined with a superimposed disc herniation probably led to the 0% success rate for these patients, although the sample size was very small (n = 2). Therefore, ESI may not a viable long-term conservative treatment option for patients with radicular symptoms in the context of spondylolisthesis. However, a temporary response to TFESI may predict a favorable surgical outcome.[9] Also, the patients with symptoms duration exceeding 1 year had only a 50% success rate. Irreversible changes related to chronic inflammation, including irritation, may take place with chronic neural compression, perhaps rendering the nerve root refractory to management with the local application of steroid. The decreased success rate for patients with symptom duration exceeding 1 year may advocate for early initiation of transforaminal injection treatment.

This prospective controlled study demonstrated a difference in outcomes among the patients receiving TFESIs and TPIs for the treatment of lumbosacral radiculopathy secondary to lumbosacral disc herniations. The group receiving TFESIs had a success rate of 84%, as compared with the 48% for the group receiving TPIs (P < 0.005). Overall, the patients receiving TFESIs fared much better than those receiving TPIs in all the outcome measures including the Roland-Morris questionnaire, the visual numeric pain scale, the finger-to-floor measurement, and the patient satisfaction scale. A successful outcome was achieved in the reduction of radicular back pain secondary to HNP with target-directed corticosteroid local anesthetic injections coupled with a standardized lumbar rehabilitation program. The success of the study protocol highlights the need for target-directed administration of treatment and a continued rehabilitative effort after treatment to increase efficacy and duration of effect. As a tool for the conservative management of lumbosacral radiculopathy caused by HNP, fluoroscopically guided transforaminal injection leads to early, effective, and lasting recovery.

The drawbacks of this prospective study were the small patient population (n = 48) and the fact that the patients were not blinded to the treatment protocol. However, the encouraging result from this small patient study is comparable with a similar good result from a retrospective pilot study.[25] Also, if patients are told that they may receive active intervention or a placebo, their expectations of success are important factors in their outcome ratings. Because the patients were not blinded to the treatment protocol, the success rate of 48% in Group 2 may be attributable to the placebo effect, good home rehabilitation program, cryobrace, TPI itself, or a combination of all four.

Despite the increased up-front costs of the transforaminal injection technique, it may lead to economic savings from earlier return to work, thereby decreasing long-term medical management costs.

In summary, as compared with traditional blind therapeutic spinal injection techniques, the protocol described in this report is equally or more efficacious, has a longer duration of effect when combined with structured rehabilitation, reduces the time to maximal medical improvement, reduces the need for a "series" of injections by protocol, is more physiologically sound, reduces morbidity, may improve return to work times, and may reduce the need for surgical intervention. Future studies should explore which subgroups do not improve.

■ Key Points

• This prospective randomized controlled trial examined the therapeutic value of transforaminal epidural steroid injections *versus* saline trigger-point injections in patients with lumbosacral radiculopathy secondary to a herniated nucleus pulposus that failed other nonsurgical treatments.

• As determined by a patient satisfaction score, a Roland-Morris score, a measurement of finger-to-floor distance, and a visual numeric pain score, fluoroscopically guided transforaminal epidural steroid injections yield better results in the management of lumbosacral radiculopathy caused by a herniated nucleus pulposus.

Acknowledgments

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■   Point of View

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It is widely accepted that most patients treated conservatively for a lumbar disc herniation eventually will improve. Although the exact percentage of patients who improve without surgery is controversial, success rates of approximately 80% are often quoted. In the current study, the transforaminal epidural steroid injection group had a success rate of 84%, whereas the trigger-point injection group had only a 48% success rate. This suggests that the group treated with transforaminal epidural steroid injections will get results similar to the natural history of the disease, whereas those treated with trigger-point injection will do worse.

One possible explanation for this finding may be that transforaminal epidural injections were oversold to the patient, whereas trigger-point injections were undersold. As the authors mention in their discussion, expectations of success may play a significant role in the actual success rate. From the article, it appears that the authors thought transforaminal epidural injections were much more efficacious than trigger-point injections. It is possible that the informed consent and the prestudy explanation by the authors also reflected the bias that trigger-point injections were essentially placebo procedures. The patients knew they were going to be randomized to receive either an injection of epidural corticosteroids or an intramuscular saline injection. It is possible that the trigger-point injection group might have been disappointed that they were undergoing only an injection of saline.

The ideal method for a study such as this would involve a control group that received a transforaminal injection of either saline or local anesthetic. The study then would be determining the efficacy of the injection's corticosteroid portion. Alternatively, the transforaminal epidural injection could be compared with continued physical therapy to determine whether the transforaminal epidural steroid injection offers an advantage over the natural history of the disease.

The authors achieved their objective of proving that patients whose herniated discs are treated with transforaminal epidural steroid injections have a better outcome than those treated with trigger-point injections. What is not proven, however, is whether the effect of trigger-point injections is worse than the natural history of the disease, or whether the transforaminal epidural injection or some combination of both is better. Furthermore, the data is insufficient to determine whether the difference between the two treatment forms results from the corticosteroids, the local anesthetic, the disappointment from being in a control group, the power of persuasion, or other unknown effects.