Effectiveness of Transforaminal Epidural Steroid Injection by Using a Preganglionic Approach: A Prospective Randomized Controlled Study[1]

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Purpose: To prospectively evaluate the short- and midterm effectiveness of transforaminal epidural steroid injection (TFESI) for lumbosacral radiculopathy with respect to injection level.

Materials and Methods: Institutional review board approval and written informed consent were obtained. From March 2005 to February 2006, 239 consecutive patients (106 male, 133 female; mean age, 49.8 years; range, 13–82 years) who were scheduled to undergo lumbar TFESI were enrolled. The patients were randomly assigned to either the ganglionic (TFESI at the location of the exiting nerve root) or preganglionic group (TFESI at the supraadjacent intervertebral disk level). Follow-up was conducted within 1 month (short term) and more than 6 months (midterm) after injections. Short- and midterm outcomes were measured by using a visual analog scale and a four-grade scale. Univariate analysis (by using the Fisher exact and χ^2 tests) and multiple logistic regression analysis were performed to evaluate the relationship between possible outcome predictors (ganglionic or preganglionic injection levels, cause of radiculopathy, duration of symptoms, age group, and sex) and the therapeutic effect.

Results: Univariate analysis showed that the preganglionic group had a better treatment effect (99 of 112, 88.4%) than did the ganglionic group (90 of 127, 70.9%) at short-term follow-up ($P = .001$). Multiple logistic regression analysis showed that the only significant outcome predictor at short-term follow-up was injection level (odds ratio = 2.232, $P = .037$). No significant difference was identified regarding TFESI approach or cause of radiculopathy at midterm follow-up.

Conclusion: TFESI for lumbosacral radiculopathy with a preganglionic approach is more effective than TFESI with a ganglionic approach at short-term follow-up.

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Lumbosacral radiculopathy is a common medical and socioeconomic problem (1–3), with a lifetime prevalence estimated to be around 40%–60% (4–5). Intervertebral disk herniation and degenerative lumbar spinal stenosis are the two most common causes of lumbosacral radiculopathy (1,6–9).

Lumbar transforaminal epidural steroid injection (TFESI) is a procedure designed to deliver an aliquot of a corticosteroid preparation to the immediate vicinity of a lumbar spinal nerve and its root via the intervertebral foramen in which the target nerve lies (10). Compared with an interlaminar or caudal epidural steroid injection, a transforaminal approach provides minimal risk of dural puncture, better delivery of medication to the site of radiculopathy, and increased spread into the ventral epidural space. Subsequently, only a low volume of concentrated medication is necessary to produce the desired effect (11–13). Currently, TFESI is widely used for the management of lumbosacral radiculopathy (10,13).

In our daily practice, when we encountered nerve root compression caused by either subarticular or paracentral disk herniation or central canal and/or lateral recess stenosis supraadjacent to the intervertebral disk, we frequently wondered whether TFESI should be performed at the neural foramen near the exit zone of the compressed nerve root (eg, at the L5-S1 neural foramen for an L5 nerve root compressed at the L4-5 disk) or at the neural foramen near the compression level (eg, at the L4-5 neural foramen for an L5 nerve root compressed at the L4-5 disk). The latter has been called the "preganglionic approach" (14). There is no clear-cut consensus regarding the ideal injection level to perform TFESI in these situations, and determination of the injection level appears to rely heavily on personal experience.

Lee et al (15) evaluated the effectiveness of TFESI by using a preganglionic approach for treating lumbosacral radiculopathy when the nerve root compression was located supraadjacent to the intervertebral disk. To our knowledge, Lee et al conducted the only comparative study that has assessed the effectiveness of TFESI with respect to injection level. However, the study by Lee et al was retrospective, used a small number of patients, and focused only on short-term therapeutic effect. Thus, the purpose of our study was to prospectively evaluate the short- and midterm effectiveness of TFESI for lumbosacral radiculopathy with respect to the injection level.

Materials and Methods

Patients

Institutional review board approval and written informed consent were obtained for this study. During a 1-year period from March 2005 to February 2006, 239 consecutive patients (106 male and 133 female patients; mean age, 49.8 years; range, 13–82 years) who underwent lumbar TFESI at our radiology department were enrolled in our prospective study, having met the following inclusion criteria: *(a)* the presence of lumbosacral radiculopathy, *(b)* clear documentation of nerve root compression with either subarticular or paracentral disk herniation or central canal and/or lateral recess stenosis at the supraadjacent intervertebral disk (eg, L5 nerve root compressed at L4-5 disk) by using clinical and cross-sectional imaging studies (either computed tomography [CT] or magnetic resonance [MR] imaging) with consensus of three radiologists, and *(c)* one-level TFESI from L1 to S1.

The patients were randomly assigned to either the ganglionic or the preganglionic group on the basis of the neural foramen level of the injection (Fig 1). Patients in the ganglionic group underwent TFESI at the location of the exiting nerve root (eg, TFESI for L5 radiculopathy was performed at L5-S1 neural foramen, when L5 nerve root impingement was at the L4-5 disk). In the preganglionic group, patients underwent TFESI at the supraadjacent intervertebral disk level (for example, at L4-5 neural foramen for an L5 nerve root compression). The ganglionic group included 127 patients (61 male and 66 female patients; mean age, 49 years; range, 15–82 years) and the preganglionic group included 112 patients (45 male and 67 female patients; mean age, 50 years; range, 13–78 years).

All patients underwent short-term follow-up within 1 month after injections (mean interval, 15 days; range, 7–30 days). Outcomes were measured by using a visual analog scale (VAS) and a four-grade scale (see below)

Advance in Knowledge

- The use of transforaminal epidural steroid injection with a preganglionic approach is more effective (99 of 112 patients) than a ganglionic approach (90 of 127 patients) at short-term follow-up and is almost as effective (64 of 106 patients) as a ganglionic approach (80 of 116 patients) at midterm follow-up.

Implication for Patient Care

- A preganglionic approach may be considered an alternative to a ganglionic approach when the needle tip cannot be advanced adjacent to the neural foramen or when adequate amounts of the drug cannot be injected into the epidural space through the neural foramen owing to severe neural foraminal stenosis.

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Abbreviations:
TFESI = transforaminal epidural steroid injection
VAS = visual analog scale

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(7,16,17). By September 2006, more than 6 months after injections, midterm follow-up (mean interval, 373 days; range, 216–547 days) interviews were conducted by telephone (see below) by using the VAS and four-grade scale. VAS forms were mailed or faxed to patients. Out of 239 patients, 17 were lost to midterm follow-up.

Injection Technique

TFESIs were performed in our department by three radiologists (S.H.K., J.W.L., and H.S.J., with 5, 3, and 2 years experience in spine injections, respectively). The injections were performed in an angiography suite equipped with biplanar fluoroscopy while the patient lay prone.

After sterile preparation, draping, and local anesthesia with 1% lidocaine, a 12-cm-long, 22-gauge spinal needle was advanced into the region of the involved nerve root by using fluoroscopic guidance. The target point was around the neural foramen. The needle position was checked by using biplanar fluoroscopy. Next, approximately 1 mL of contrast material (Omnipaque 300 [iohexol, 300 mg iodine per milliliter]; Amersham Health, Princeton, NJ) was injected to confirm epidural flow and to avoid intravascular, intradural, or soft-tissue infiltration. Bupivacaine hydrochloride (0.5 mL, Marcaine Spinal 0.5% Heavy; AstraZeneca, Westborough, Mass) and 40 mg (1 mL) of triamcinolone acetonide suspension (Tamceton [40 mg per milliliter]; Hanall Pharmaceutical, Seoul, Korea) were slowly injected. Posteroanterior and lateral spot radiographs were obtained to document distribution of the contrast material.

According to Lew et al (14), the fluoroscopic landmarks for the preganglionic approach are similar to those used for intradisk procedures (lateral to the superior articular process and parallel to the superior endplate of the vertebral body). The final needle position is at the inferior aspect of the supraadjacent neural foramen, with the bevel immediately dorsal to the annulus and/or posterior longitudinal ligament. Injection at this position places the aliquot at the epidural preganglionic site of neural impingement, where the traversing nerve root is closest to the disk. The injectant may also descend to the intraforaminal and epidural portions of the exiting nerve root. Lee et al (15) modified this method. The landmark they used for needle insertion is just lateral to the pars interarticularis on the oblique view and at the neural foramen near the nerve root impingement site at the supraadjacent disk level. We used this modified method by Lee et al for the preganglionic approach (Fig 2).

Clinical Assessment

Before the injection, one of two radiologists (S.H.K., J.W.L.) recorded the duration of symptoms, level, and cause of nerve root impingement on the CT or MR images and the affected dermatomal distribution on the medical charts.

Patient outcomes were assessed within 1 month (short term) by another radiologist who was blinded to the injection level (ganglionic or preganglionic) by using a VAS that ranged from 0 to 100 and a four-grade scale that was subjectively expressed by the patients with regard to the degree of improvement (excellent, good, fair, or poor) (2,7,11). The patients were also not informed of the injection method to ensure a double-blinded protocol for our study. The patients with a reduction in the VAS of more than 50% after the injection and with excellent or good improvement were classified as receiving effective treatment, and the patients with a reduction in the VAS of less than 50% after the injection and with fair or poor improvement were classified as having ineffective treatment.

Midterm outcome was assessed in September 2006 by telephone interview more than 6 months (mean interval, 373 days; range, 216–547 days) after injections. A nurse who did not know the injection level (ganglionic or preganglionic) queried the patients in the same manner as for the short-term follow-up by using a VAS and a four-grade scale. Midterm results were similarly classi-

Figure 1

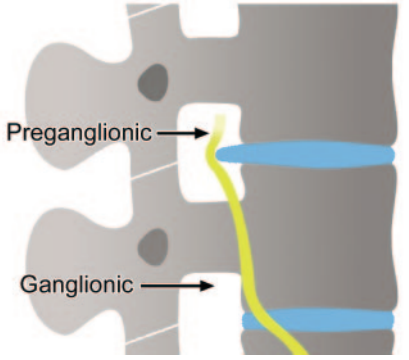
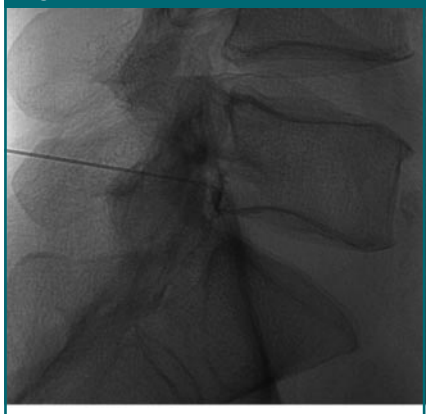
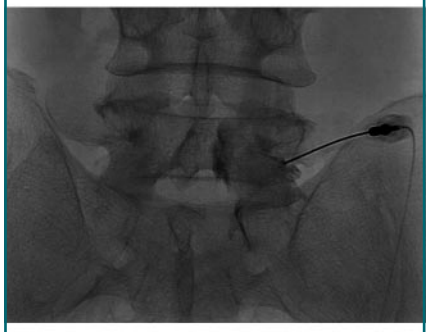


Figure 1: Graph of TFESI with preganglionic and ganglionic approach.

Figure 2



a.



b.

Figure 2: Radiographs of 49-year-old man with radiating pain to right buttock and lower leg in the S1 dermatome. MR image (not shown) revealed right paracentral L5-S1 disk herniation with compression of right S1 nerve root. TFESI with preganglionic approach was performed at L5-S1 neural foramen. **(a)** Lateral spot radiograph shows needle tip in posterior aspect of the L5-S1 neural foramen. **(b)** Posteroanterior spot radiograph shows contrast material has spread to L5-S1 disk through the epidural space.

fied as either effective or ineffective treatment.

Statistical Analysis

The patients were divided into six age groups for statistical analysis: aged 29 years or younger, 30–39, 40–49, 50–59, 60–69, and 70 years or older (1). The duration of symptoms was classified as less than or more than 6 months (15,17).

The Mann-Whitney *U* test was used to evaluate for age differences between the ganglionic and the preganglionic group. The Fisher exact test was used to analyze differences in sex, cause of radiculopathy, and duration of symptoms between the two patient groups.

Univariate analysis was performed to evaluate the relationship between possible outcome predictors and the therapeutic effect by using the Fisher exact test and the χ^2 test. Fisher exact tests were used for the injection level, cause of radiculopathy, symptom duration, and sex. The χ^2 test was used for age groups. Multiple logistic regression analysis was also performed to evaluate the relationship between possible outcome predictors and their therapeutic effects. Analyses were performed for both short- and midterm therapeutic effect. Data were analyzed by using a software program (SPSS, version 10.0; SPSS, Chicago, Ill). A *P* value of less than .05 was considered to indicate a significant difference.

Table 1

Comparison of Ganglionic and Preganglionic Groups

Characteristic	Ganglionic ($n = 127$)	Preganglionic ($n = 112$)	*P* Value
Age group (y)			
<29	19 (15.0)	13 (11.6)	.542
30–39	18 (14.2)	16 (14.3)	
40–49	23 (18.1)	22 (19.6)	
50–59	24 (18.9)	27 (24.1)	
60–69	22 (17.3)	24 (21.4)	
70>	21 (16.5)	10 (8.9)	
Sex			
Male	61 (48.0)	45 (40.2)	.242
Female	66 (52.0)	67 (59.8)	
Cause of radiculopathy			
Spinal stenosis	23 (18.1)	23 (20.5)	.743
Intervertebral herniated disc	104 (81.9)	89 (79.5)	
Duration of symptoms (mo)			
<6	81 (63.8)	63 (56.3)	.289
>6	46 (36.2)	49 (43.7)	

Note.—Data are number of patients. Numbers in parentheses are percentages.

Table 2

Four-Grade Scale at Short-term Follow-up

TFESI Approach	Excellent	Good	Fair	Poor
Ganglionic ($n = 127$)	59 (46.5)	31 (24.4)	17 (13.4)	20 (15.7)
Preganglionic ($n = 112$)	82 (73.2)	17 (15.2)	2 (1.8)	11 (9.8)

Note.—Data are number of patients. Numbers in parentheses are percentages.

Table 3

Four-Grade Scale at Midterm Follow-up

TFESI Approach	Excellent	Good	Fair	Poor
Ganglionic ($n = 116$)	39 (33.6)	39 (33.6)	2 (1.7)	36 (31.1)
Preganglionic ($n = 106$)	39 (36.8)	25 (23.6)	4 (3.8)	38 (35.8)

Note.—Data are number of patients. Numbers in parentheses are percentages.

Results

There were no significant differences between the ganglionic and the preganglionic group with respect to age ($P = .542$) and sex ($P = .242$). Age was 49.1 years ± 17.6 (mean age ± standard deviation) in the ganglionic group and 50.5 years ± 17.4 in the preganglionic group. There were no significant differences between the two groups with respect to cause of radiculopathy and duration of symptoms (Table 1). In the ganglionic group, TFESIs at L5-S1 were performed in 42 patients, at L4-5 in 74 patients, at L3-4 in eight patients, and at L2-3 in three patients. In the preganglionic group, TFESIs were performed at L5-S1 in 49 patients, at L4-5 in 58 patients, at L3-4 in three patients, and at L2-3 in two patients. There were no reported complications of dural puncture, nerve root injury, excessive bleeding, or infection.

Short-term and Midterm Results

At short-term follow-up, the preganglionic group had more patients with excellent results (82 of 112, 73.2%) than did the ganglionic group (59 of 127, 46.5%) (Tables 2, 3). However, at midterm follow-up, there was little difference in the number of patients with excellent results between the two groups.

Univariate analysis showed that the preganglionic group had better thera-

peutic effect (99 of 112, 88.4%) than did the ganglionic group (90 of 127, 70.9%) at short-term follow-up (P = .001) (Tables 4, 5). Multiple logistic regression analysis showed that the only significant outcome predictor at short-term follow-up was the injection level (ganglionic or preganglionic) (odds ratio = 2.232, P = .037). The cause of radiculopathy showed borderline significance at short-term follow-up (odds ratio = 3.460, P = .052) according to multiple logistic regression analysis.

No significant differences were identified regarding the injection level or the cause of radiculopathy at midterm follow-up (Tables 6, 7) by using univariate and multiple logistic regression analyses, contrary to the short-term results. At univariate analysis, patients with symptom duration of less than 6 months had better therapeutic effect than did those with symptom duration of more than 6 months at midterm follow-up. Multiple logistic regression analysis did not show a significant relationship between symptom duration and therapeutic effect at midterm follow-up.

Table 4

Univariate Analysis of Possible Outcome Predictors for TFESI Effectiveness at Short-term Follow-up

Characteristic	Effective (n = 189)	Ineffective (n = 50)	P Value
TFESI Approach			.001
Ganglionic	90 (47.6)	37 (74)	
Preganglionic	99 (52.4)	13 (26)	
Cause of radiculopathy			.162
Spinal stenosis	41 (21.7)	6 (12.0)	
Intervertebral herniated disc	148 (78.3)	44 (88.0)	
Age group (y)			.383
<29	22 (12.2)	9 (23.7)	
30–39	23 (12.8)	7 (18.4)	
40–49	38 (21.1)	5 (13.2)	
50–59	35 (19.4)	7 (18.4)	
60–69	37 (20.6)	6 (15.8)	
70>	25 (13.9)	4 (10.5)	
Sex			.263
Male	80 (42.3)	26 (52.0)	
Female	109 (57.7)	24 (48.0)	

Note.—Data are number of patients. Numbers in parentheses are percentages.

Table 5

Multiple Logistic Regression Analysis for Possible Outcome Predictors for TFESI Effectiveness at Short-term Follow-up

Characteristic	Regression Coefficient*	Standard Error	Wald Statistic	P Value	Odds Ratio
TFESI approach	0.803	0.385	3.783	.037	2.232
Cause of radiculopathy	1.241	0.638	3.783	.052	3.460
Age group	−0.203	0.119	2.895	.089	0.816
Sex	−0.397	0.377	1.106	.293	0.672
Duration of symptoms	0.090	0.397	0.051	.821	1.094
Constant	−4.335	1.642	6.967	.008	0.013

* df = 1 for all comparisons.

Discussion

According to our prospective randomized study, TFESI with a preganglionic approach was more effective than a ganglionic approach at short-term follow-up. These results were similar to those of Lee et al (15). This finding supports the idea that TFESI, by using a preganglionic technique, can place the injectant closer to the site of neural impingement and allow the delivery of medicine more directly to reduce inflammation and relieve pain (14,16). The preganglionic approach may be considered an alternative to the ganglionic approach when the needle tip cannot be advanced evenly adjacent to the neural foramen or adequate amounts of the drug cannot be injected into the epidural space through the neural foramen owing to severe neural foraminal stenosis. Another advantage of the preganglionic approach is that the injectant distributes itself predominantly in the epidural space at the disk level (15).

Lew et al (14) suggested a TFESI approach similar to that used for standard lumbar discography. There were two other studies (16,18) in which the therapeutic effect of the TFESI approach by using the anatomic landmarks for intradisk procedures was reported. However, those two studies focused only on the injection technique, and not on the injection level.

For the preganglionic approach, Lee et al (15) modified the injection technique in a manner similar to the retroneural technique described by the International Spine Intervention Society (10). The objective of the retroneural technique is to place the tip of the needle immediately dorsal to, but not in, the spinal nerve (10). We used the retroneural technique for the preganglionic approach. From our experience, the TFESI approach similar to that used for standard lumbar discography may carry a higher risk of intradisk placement of contrast medium. This is important to identify because serious potential complications, such as diskitis, may occur (19). By using the retroneural technique, we could deposit most of the

injectant into the epidural space and avoid placing the injectant directly in the spinal nerve. This technique also enabled us to avoid pricking the nerve root.

According to our results, there was no significant difference in therapeutic effect due to symptom duration at short-term follow-up. Interestingly, shorter symptom duration favors a better outcome than does longer symptom duration at midterm follow-up. This may mean that the patients with longer symptom duration have a tendency toward experiencing recurrent pain attacks. Patients with spinal stenosis exhibited a similar therapeutic effect when compared with those who had intervertebral herniated disk at short-term follow-up (41 of 47, 87.2%). Our results regarding spinal stenosis at short-term follow-up showed a higher success rate than did those of previous reports (6,9,20) and were in discord with the results of one comparative study (9).

One criticism of epidural steroid injections is that their benefit lasts only for a short duration (21–24). Ridley et al (21) reported that the therapeutic benefits disappeared within 6 months of treatment. However, we achieved a success rate of 69.0% in the ganglionic group and 60.4% in the preganglionic group at the follow-up interval of more than 6 months. Lutz et al (17) showed that 75.4% of patients who underwent TFESI also had a successful midterm outcome at an average follow-up of 20 months. Other previous prospective randomized trials studying the effectiveness of TFESI concluded that these injections can provide positive long-term relief (1,25).

In our study, an interesting point was that at short-term follow-up the outcome was ineffective, but by midterm follow-up the outcome was effective for 32 patients. This result may suggest that in some situations, the patient's symptoms can improve due to spontaneous regression of inflammation around the nerve root.

Our study had several limitations. First, this study did not evaluate if other factors such as physical examination findings, patient mood, general health, smoking status, or the frequency of injections might influence therapeutic effectiveness and are correlated with outcomes. This study focused on the influence of the injection level on the therapeutic effect after TFESI. Second, patient outcome was measured only with a pain score and not according to physical function. However, the most appropriate goal for TFESI may be pain reduction, not functional restoration. Third, follow-up was less than 1 year, which did not include a long-term period. However, in our opinion, the midterm follow-up is enough to evaluate the influence of injection level on the therapeutic effect.

In conclusion, the results of our study indicate that use of TFESI with a preganglionic approach is more effective than a ganglionic approach at short-term follow-up and is almost as effective

Table 6

Univariate Analysis for Possible Outcome Predictors for TFESI Effectiveness at Midterm Follow-up

Characteristic	Effective ($n = 144$)	Ineffective ($n = 78$)	*P* Value
TFESI approach			.206
Ganglionic	80 (55.6)	36 (46.2)	
Preganglionic	64 (44.4)	42 (53.8)	
Cause of radiculopathy			.382
Spinal stenosis	26 (18.1)	18 (23.1)	
Intervertebral herniated disc	118 (81.9)	60 (76.9)	
Age group (y)			.670
<29	18 (13.4)	13 (18.8)	
30–39	15 (11.2)	11 (15.9)	
40–49	28 (20.9)	13 (18.8)	
50–59	28 (20.9)	11 (15.9)	
60–69	25 (18.7)	14 (20.3)	
70>	20 (14.9)	7 (10.1)	
Sex			.322
Male	66 (45.8)	30 (38.5)	
Female	78 (54.2)	48 (61.5)	
Duration of symptoms (mo)			.010
<6	96 (66.7)	38 (48.7)	
>6	48 (33.3)	40 (51.3)	

Note.—Data are number of patients. Numbers in parentheses are percentages.

Table 7

Multiple Logistic Regression Analysis for Possible Outcome Predictors for TFESI Effectiveness at Midterm Follow-up

Characteristic	Regression Coefficient*	Standard Error	Wald Statistics	*P* Value	Odds Ratio
TFESI approach	−0.462	0.309	2.230	.135	0.630
Cause of radiculopathy	−0.156	0.372	0.177	.674	0.855
Age group	−0.100	0.095	1.115	.291	0.905
Sex	0.260	0.315	0.682	.409	1.297
Duration of symptoms	0.541	0.314	2.967	.085	1.718
Constant	−0.276	1.086	0.064	.800	0.759

* $df = 1$ for all comparisons.

as a ganglionic approach at midterm follow-up.

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