

# The Efficacy of Lumbar Epidural Steroid Injections in Patients with Lumbar Disc Herniations

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**INTRODUCTION:** Lumbar epidural steroid injection can be accomplished by one of three methods: caudal (C), interlaminar (IL), or transforaminal (TF). In this study we sought to determine the efficacy of these techniques for the management of radicular pain associated with lumbar disk herniations.

**METHODS:** Ninety patients aged 18–60 years with L5-S1 disk herniations and radicular pain were randomly assigned to one of these groups to have epidural steroid injection therapy every 2 wk for a maximum of three injections. Pain relief, disability, and activity levels were assessed.

**RESULTS:** Pain relief was significantly more effective with TF injections. At 24 wk from the initiation of this study, pain relief was as follows: C: complete pain relief: 1/30, partial pain relief: 16/30, and no relief: 13/30; IL: complete pain relief: 3/30, partial pain relief: 15/30, and no relief: 12/30; and TF: complete pain relief: 9/30, partial pain relief: 16/30, and no relief: 5/30.

**CONCLUSIONS:** The TF route of epidural steroid placement is more effective than the C or IL routes. We attribute this observation to a higher incidence of steroid placement in the ventral epidural space when the TF method is used.

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The use of lumbar epidural steroid injections (LESI) for the management of radicular pain associated with lumbar disk herniations is controversial (1). There is no consensus on how epidural injection therapy should be done with respect to the volume and mass of steroid injected. In addition, the methods used for epidural injections vary with different physicians, and no standard for the performance of this procedure has been defined. Positive results from epidural steroids vary from 20% to 95% and may depend on route of injection (2). LESI can be accomplished by one of three methods: caudal (C), interlaminar (IL), or transforaminal (TF). Each technique has been reported to be effective for reducing lower extremity radicular pain (3–6). The goal of this study was to test the null hypothesis that these three methods of LESI therapy are equally effective.

## METHODS

After patient informed consent and IRB approval, 90 patients aged 18–60 yr were randomly assigned to have LESI therapy every 2 wk for a total of three injections. Each patient in this study had a history and

physical examination done prior the initiation of steroid injection therapy. Each patient had radicular pain consistent with the S1 dermatomal distribution. The diagnosis of L5-S1 disk herniations was then documented by magnetic resonance imaging and electromyographic evidence of S1 nerve root involvement.

Subject exclusions included pregnancy, allergies to steroids, steroid use 3 wk or less before beginning this study, bleeding history, infection, use of anticoagulants and allergies to the adjunct medications prescribed while patients were in this study. No patient was included unless they had a pain intensity score >7. Other exclusion criteria were applied after performance of epidural steroid injection (see below) and a complete inclusion/exclusion flow diagram is presented in Figure 1.

LESI was done by one of three methods: (a), C, (b) IL, and (c) TF. Patients were randomly assigned to one of these three treatment groups using computer-generated randomization. IL epidural needle placement was performed with each patient in a prone position. Using an anterior–posterior (AP) view, the L5-S1 interspace was identified by fluoroscopy. The skin was anesthetized with 1% lidocaine and a 22-gauge Touhy needle was directed into the epidural space with fluoroscopic guidance. Each patient received 3 mL of isohexol 300 followed by 4 mL of preservative-free saline with 40 mg (1 mL) of triamcinolone after proper needle placement was determined. This volume was used in this study, as it is the volume in our clinical experience that is effective and is between the range of volumes (2–8 mL) used by

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# **Flow chart for Study Inclusion/Exclusion** HNP=herniated nucleus pulposus

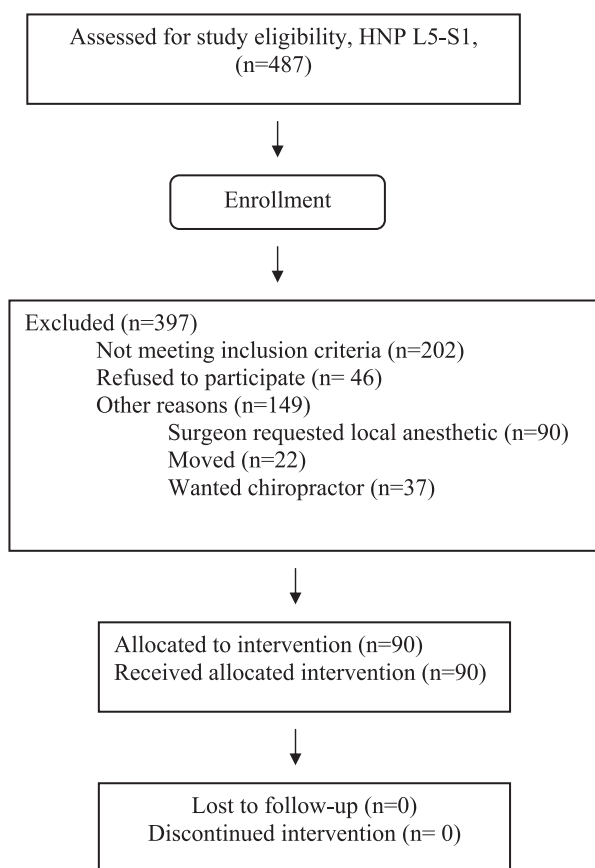


**Figure 1.** Flow chart for study inclusion/exclusion. HNP = herniated nucleus pulposus.

previous investigators that were reported to be effective as well (4,7). Each needle bevel was directed in a cranial direction. Caudal needle placement was done as follows: each patient was placed in the prone position on the fluoroscopy table. A 22-gauge Touhy needle was guided 1.5 cm into the epidural space from the sacrococcygeal membrane after the skin was anesthetized with 1% lidocaine. Each patient received 3 mL of isohexol 300 injected into the epidural space. After proper needle position was confirmed, 19 mL of preservative-free saline with 40 mg (1 mL) of triamcinolone was administered. This total volume was noted in our clinical practice to be the volume necessary to achieve spread to the L5-S1 interspace and was the volume previously reported by Coomes (8) to be effective. TF epidural needle placement was done with each patient in the prone position. The L5 transverse process on the side of the radicular pain was identified with fluoroscopy. After the skin was anesthetized, a 22-gauge Touhy needle was guided to the transverse process of the fifth lumbar vertebra using fluoroscopic needle guidance. The Touhy needle was used to standardize the needle type used for this study and it is our experience that we could facilitate contrast flow to the anterior epidural space with this needle bevel

directed anterior. The needle was withdrawn slightly and advanced medially into the posterior aspect of the L5-S1 foramina. Care was taken to keep the needle tip in the posterior-superior aspect of the foramina because of the increased vascularity in the anterior epidural space and foramina and because of the risk of nerve root injury. The L5-S1 foramen was chosen for the TF group as opposed to the S1 foramen because we noted in our prestudy observations that TF was more effective when the contrast was placed anterior in the epidural space at the level of the disk herniation. Each patient received 3 mL of isohexol 300. Patients were excluded from this study if contrast dispersion with the TF method spread through the foramina at the level of the disk herniation because these subjects would experience postganglion nerve root injection, instead of a TF epidural injection. After correct needle confirmation was obtained, each patient received 40 mg (1 mL) of triamcinolone in 4 mL of preservative-free saline for a total volume of 5 mL (9). For all techniques, IV midazolam 2 mg and 50 µm of fentanyl were used during each procedure. LESI therapy was done without a local anesthetic, as it has been reported that a radicular pain rebound phenomenon occurred when the combination of a steroid and local anesthetic were placed around a nerve root (10).

Patients were observed in a recovery area where hemodynamic variables were monitored and recorded every 5 min for 30 min. Fluoroscopic contrast dispersion was observed at the time of the administration of the steroid saline solution and repeated 30 min post-injection after each patient remained in a supine position in a recovery area. The purpose of the repeat fluoroscopic view was to determine if patient position in the recovery area influenced contrast dispersion. AP and lateral views were analyzed to determine contrast dispersion patterns at the time of the procedure and after patients' recovery time. A physician trained in epidurogram interpretation, who was blinded to the technique used, evaluated each patient's postprocedure epidurogram. Contrast dispersion patterns were identified as ventral (V) (dispersion between the dura and posterior longitudinal ligament); posterior (contrast dispersion between the dura and the ligamentum flavum); and AP (contrast spread both V and posterior) (Fig. 2). Vertical spread was measured to the most cranial vertebral body achieved by the contrast dispersion. Numeric pain intensity scores 0–10 were obtained by an observer blinded to the technique used at the time of each injection and any subsequent injections. Pain relief was placed into one of three categories after each injection: complete pain relief, partial pain relief, and no relief defined by pain scores. The Oswestry Low Back Pain Scale (0–70) and the Beck depression scores (0–63) were recorded by an observer, blinded to the type of LESI that each subject received, at the beginning of this study and 2 wk after each patient's final injection.

Each patient in this study was prescribed tizanidine (6–12 mg/24 hr) as needed for muscle spasms, celecoxib

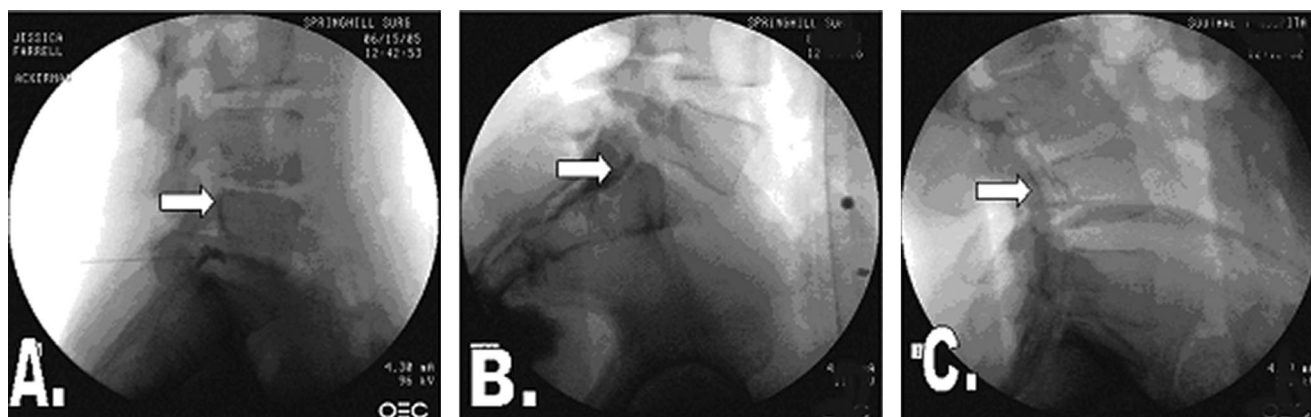


**Figure 2.** Different lumbar epidural steroid contrast dispersion patterns possible with epidural steroid injections. Epidural contrast dispersion patterns (arrows) with needle placement. A demonstrates spread in the anterior epidural space; B demonstrates spread both anterior and posterior, while C demonstrates a posterior spread.

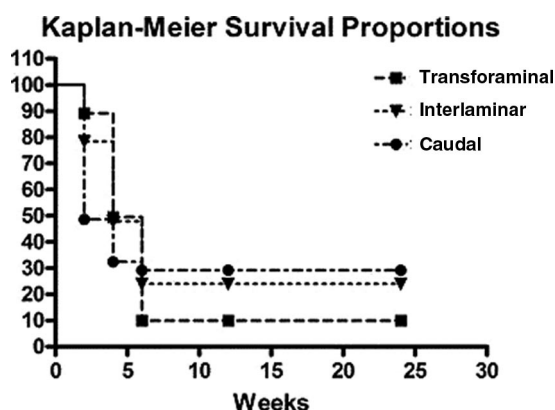


**Figure 3.** The Log-Rank test (with  $\chi^2 = 12.91$ ,  $df = 2$ ,  $P$ -value = 0.0016) indicates that the survival times (that is, time to pain relief) differ across treatment groups. The median time to achieve pain relief was 2 wk, 4 wk, and 6 wk for caudal, interlaminar, and transforaminal treatment groups, respectively. Symbols placed at observation points.

(100–200 mg) each day as needed for pain and amitriptyline (10–50 mg at night) when they were initially evaluated for this study and while they were participating in it. Each patient was reevaluated 2 wk after initial injection. If a patient had a complete or no pain relief, then no further injection therapy was done. If a patient had partial pain relief ( $\geq 4$  d to a week from the time of the injection with a visual analog scale score reduction  $\geq 20\%$ ) at some time from the injection to the 2-wk reevaluation, a repeat LESI was done. These patients were reevaluated in two more weeks and the same process repeated for a third and final LESI if needed. Subsequently, all patients were evaluated at 12 and 24 wk to determine delayed and long-term efficacy.

**Statistical analysis:** On the basis of our previous observations of epidural steroid efficacy and our literature search, we determined that a sample size of 30 patients per group was sufficient for this study using a desired power of 0.8 and  $\alpha = 0.05$ . The primary outcome for power analysis was the pain score.

Statistical analysis was done using Fisher's exact test, ANOVA,  $\chi^2$  analysis, the Tukey test, nonparametric distribution analysis and the Student's paired  $t$ -test

**Table 1.** Patient Demographics

|                                     | Caudal<br>( <i>n</i> = 30) | Interlaminar<br>( <i>n</i> = 30) | Transforaminal<br>( <i>n</i> = 30) |
|-------------------------------------|----------------------------|----------------------------------|------------------------------------|
| Age (yr)                            | 36.4 $\pm$ 4               | 39.2 $\pm$ 6                     | 34 $\pm$ 5                         |
| Females                             | 11                         | 9                                | 10                                 |
| Males                               | 19                         | 21                               | 20                                 |
| Body surface area (m <sup>2</sup> ) | 2.07 $\pm$ 0.22            | 2.11 $\pm$ 0.18                  | 2.10 $\pm$ 0.21                    |
| Duration of symptoms (d)            | 38 $\pm$ 4                 | 33 $\pm$ 7                       | 35 $\pm$ 5                         |

There were no differences among groups with respect to demographics.

where appropriate with  $P \leq 0.05$  required to reject the null hypothesis. Patient data were encoded to protect each patient's identity.

## RESULTS

Four-hundred-eighty-seven patients were screened for study inclusion. Figure 1 displays reasons for exclusion. A total of 90 patients were enrolled, completed the study, and were analyzed in groups in which they were allocated (intent-to-treat, Fig. 3). Demographic data are presented in Table 1. One-hundred-eighty-seven LESI were performed: (C = 74), (IL = 67), (TF = 46). Pain relief and associated epidural contrast dispersion patterns are displayed in Table 2. By the 12 and 24 wk evaluation periods, the TF technique had significantly more patients reporting complete or partial pain relief. Pain scores improved within groups but were also significantly lower with the TF approach. (Fig. 4) In terms of mechanism of increased efficacy of TF technique, there was a more frequent incidence ( $P \leq 0.05$ ) of complete pain relief in those patients with the V spread of contrast which occurred more frequently with the TF approach (Tables 3 and 4). Contrast dispersion was not significantly different with respect to cranial vertebral body spread within or across groups. Disability scores were significantly improved within groups as were depression scores but were not affected by injection technique. Function and depression scores improved

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**Table 2.** Pain Relief and Contrast Dispersion Comparisons Among Groups

| Group            | N     | Complete relief | Partial relief | No relief | V      | AP    | P     |
|------------------|-------|-----------------|----------------|-----------|--------|-------|-------|
| C1               | 30    | 0.133           | 0.333          | 0.534     | 0.000  | 0.533 | 0.467 |
| IL1              | 30    | 0.267           | 0.167          | 0.566     | 0.167  | 0.333 | 0.500 |
| TF1              | 30    | 0.633*          | 0.267          | 0.100     | 0.900* | 0.100 | 0.000 |
| C2               | 26    | 0.308           | 0.346          | 0.345     | 0.077  | 0.654 | 0.269 |
| IL2              | 22    | 0.318           | 0.273          | 0.409     | 0.227  | 0.455 | 0.318 |
| TF2              | 11    | 0.545*          | 0.182          | 0.273     | 0.727  | 0.182 | 0.910 |
| C3               | 18    | 0.444           | 0.444          | 0.112     | 0.000  | 0.778 | 0.222 |
| IL3              | 15    | 0.333           | 0.400          | 0.267     | 0.333  | 0.467 | 0.200 |
| TF3              | 5     | 0.200           | 0.600          | 0.200     | 0.100  | 0.000 | 0.000 |
| C 12             | 30    | 0.200           | 0.367          | 0.433     | 0.270  | 0.635 | 0.338 |
| IL 12            | 30    | 0.267           | 0.200          | 0.553*    | 0.220  | 0.402 | 0.373 |
| TF 12            | 30    | 0.333           | 0.500          | 0.167     | 0.869  | 0.109 | 0.220 |
| C 24             | 30    | 0.033           | 0.533*         | 0.433     | 0.270  | 0.635 | 0.338 |
| IL 24            | 30    | 0.100           | 0.500          | 0.400     | 0.220  | 0.402 | 0.373 |
| TF 24            | 30    | 0.300           | 0.533*         | 0.167     | 0.869  | 0.109 | 0.220 |
| Total injections | 187   | 66              | 57             | 64        | 57     | 79    | 51    |
| C                | 0.396 | 0.303           | 0.474*         | 0.422     | 0.035  | 0.595 | 0.490 |
| IL               | 0.358 | 0.303           | 0.298          | 0.469     | 0.263  | 0.342 | 0.490 |
| TF               | 0.246 | 0.394           | 0.228          | 0.109     | 0.702* | 0.063 | 0.019 |

One-hundred-eighty-seven epidural steroid injections were done (C (caudal) = 74, IL (interlaminar) = 67, and TF (transforaminal) = 46). Pain relief after injection therapy and contrast dispersion patterns (V = anterior epidural space dispersion, AP = both anterior and posterior epidural space dispersion and P = posterior epidural space dispersion) are given. Statistical analysis done with 3 × 3 contingency Tables.

Indicate with asterisk, which values are statistically different. Include 12 and 24 wk pain relief values. Done.

\* Indicates that the proportions of observations in different columns of the contingency table vary from row to row. The two characteristics that define the contingency table are significantly related ( $P < 0.001$ ).

**Intent to Treat Analysis Flow Chart**

lumbar epidural steroid injection=LESI; C=Caudal; IL=Interlaminar; TF=transforaminal; V = anterior epidural space dispersion; AP = both anterior and posterior epidural space dispersion and P = posterior epidural space dispersion; HNP=herniated nucleus pulposus

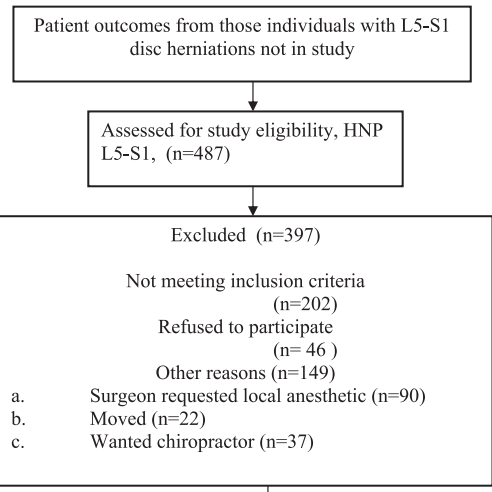


**Figure 4.** Survival analysis for the three study groups. Patients with complete relief had no further injections. The log-rank test (with  $\chi^2 = 12.91$ ,  $df = 2$ ,  $P = 0.0016$ ) indicates that the survival times (that is, time to pain relief) differ across treatment groups. The median time to achieve pain relief was 2, 4, and 6 wk for caudal, interlaminar, and transforaminal treatment groups, respectively. Symbols placed at observation points.

| Group                                   | Procedure  | Number of LESI | Complete relief (12 weeks after last injection) | Partial relief (12 weeks after last injection) | No relief (12 weeks after last injection) | V  | AP  | P  |
|-----------------------------------------|------------|----------------|-------------------------------------------------|------------------------------------------------|-------------------------------------------|----|-----|----|
| Did not meet inclusion criteria (n=202) | IL (n=124) | 298            | 75                                              | 38                                             | 11                                        | 87 | 163 | 48 |
|                                         | TF (n=75)  | 105            | 56                                              | 12                                             | 7                                         | 98 | 7   | 0  |
|                                         | C (n=3)    | 9              | 0                                               | 2                                              | 1                                         | 0  | 7   | 2  |
| Lidocaine used (n=90)                   | IL (n=30)  | 63             | 9                                               | 5                                              | 16                                        | 7  | 42  | 14 |
|                                         | TF (n=30)  | 41             | 11                                              | 16                                             | 3                                         | 37 | 4   | 0  |
|                                         | C (n=30)   | 72             | 7                                               | 11                                             | 12                                        | 0  | 58  | 14 |
| Moved (n=22)                            | 0          | 0              | unknown                                         | unknown                                        | unknown                                   | 0  | 0   | 0  |
| Chiropractic (n=37)                     | 0          | 0              | 3 (18 weeks after initial manipulation)         | 7 (18 weeks after initial manipulation)        | 27 (18 weeks after initial manipulation)  | 0  | 0   | 0  |
| Refused to participate (n=46)           | IL (n=36)  | 79             | 7                                               | 6                                              | 23                                        | 8  | 46  | 25 |
|                                         | TF (n=10)  | 14             | 8                                               | 1                                              | 1                                         | 12 | 2   | 0  |
|                                         | C (n=0)    | 0              | 0                                               | 0                                              | 0                                         | 0  | 0   | 0  |

**Table 3.** Contingency Table Results: Pain Relief and Contrast Spread at 24 wk

|                        | Ventral spread | Nonventral spread | Total       |
|------------------------|----------------|-------------------|-------------|
| Complete pain relief   | 10* (11.11)    | 3 (3.33)          | 13 (14.44)  |
| Incomplete pain relief | 29 (32.22)     | 48 (53.33)        | 77 (85.56)  |
| Total                  | 39 (43.33)     | 51 (56.67)        | 90 (100.00) |

Values inside parentheses indicate percentages.

$\chi^2$  analysis  $2 \times 2$  table. The groups were analyzed comparing complete and incomplete relief with complete ventral and noncomplete ventral contrast dispersion spread. The results are statistically significant ( $P \leq 0.05$ ). Ventral injectate spread positively affects the incidence of pain relief when doing a lumbar epidural steroid injection.

within groups but did not differ among techniques. No patient in this study had an infection, headache, intravascular injection, a reaction to the contrast material, steroid or a subarachnoid injection.

## DISCUSSION

In some patients with lumbar disk herniations, conservative pharmacologic and/or physical therapy may not provide adequate pain relief and more aggressive therapies such as LESI may be helpful. An epidural injection can decrease inflammation in the epidural space and can decrease pain in the affected nerve root (11,12). Our study suggests that a TF approach offers benefit for increased analgesic efficacy when compared to the C or IL approach. This may be due to increased V spread of steroid solution with better contact with the herniated disk and extruded contents. Despite this analgesic benefit, no differences were noted between techniques for depression or function, thus functional efficacy may not have differed among groups.

The lack of functional efficacy noted in this study may be related to the fact that we did not have a normal baseline function evaluation that we could compare the abnormal function to prior to the patient's disk herniation. These data would have been helpful in making a statistical comparison.

In addition to potentially differing efficacy, each method of doing a LESI may have complications such as hypotension related to histamine release from the contrast or steroid, systemic toxic reaction, infection,

or headache. For the C route, there may be an increased risk of needle tip placement anterior to the sacrum or into the rectum. The chance of puncturing the dura may be less with the C method. The TF method carries a risk of trauma to the nerve root during needle placement. This method also includes the risk of paraplegia if an inadvertent, intraarterial injection of particulate steroid is injected into a radicular artery that reinforces the blood supply of the lower end of the spinal cord (13). Furthermore, disk entry can be a complication of the TF method as well as the IL method (14).

In some instances, the inflammatory process associated with a disk herniation may not be alleviated by nonsteroidal antiinflammatory medications or oral steroids but may be decreased with epidural steroid therapy. Patients in the C and IL groups had increased efficacy with repetitive injections. The reason for this observation is not known but we hypothesize that it could be in part related to repetitive systemic steroid uptake from the epidural veins in the posterior epidural space as well as from blood vessels in the subarachnoid space after steroid passive diffusion across the dura.

This study has limitations: We did not use a double-blind, placebo-controlled group because the patients complained of severe pain, and we did not feel that a placebo injection would be ethical in these circumstances. Inclusion criteria into this study included positive electromyographic studies. The study could have targeted the affected nerve root as opposed to the site of the disk herniation, but our study design called for deposition of steroid in the epidural space as opposed to injecting the S1 nerve root sheath. Another limitation of our study was that the volume of solution we used was not identical. However, because of the large volume of the epidural space in the sacral area, we had to use an increased volume in this anatomic area.

We conclude that, because most lumbar disk herniations are posterior to the vertebrae, inflammation occurs primarily in the V epidural space at the site of the disk herniation (15). Deposition of steroid in the anterior epidural space directly at the site of inflammation may be one reason why patients with injectate spread in the V epidural space had better pain relief

**Table 4.** Disability, NPIS, and Depression Scores

| LESI | n  | Oswestry score at the initial LESI (0–70) | Oswestry score 2 wk after the last LESI (0–70) | BDI at the initial LESI (0–63) | BDI 2 wk after the last LESI (0–63) | NPIS at the initial LESI (0–10) | NPIS 2 wk after the last LESI (0–10) |
|------|----|-------------------------------------------|------------------------------------------------|--------------------------------|-------------------------------------|---------------------------------|--------------------------------------|
| C    | 30 | 37 $\pm$ 9                                | 14 $\pm$ 6*                                    | 21 $\pm$ 11                    | 13 $\pm$ 9*                         | 8.9 $\pm$ 0.7                   | 6.1 $\pm$ 0.8*                       |
| IL   | 30 | 33 $\pm$ 4                                | 13 $\pm$ 4*                                    | 19 $\pm$ 4                     | 11 $\pm$ 6*                         | 8.8 $\pm$ 0.8                   | 5.7 $\pm$ 3.3*                       |
| TF   | 30 | 30 $\pm$ 6                                | 14 $\pm$ 9*                                    | 22 $\pm$ 8                     | 12 $\pm$ 4*                         | 8.6 $\pm$ 0.9                   | 2.4 $\pm$ 2.1*†                      |

Oswestry Low Back Pain Scale and the Beck Depression Inventory (BDI) score at the time of the initial lumbar epidural steroid injection (LESI) and at 24 wk. The numeric pain intensity score (NPIS) was analyzed in a similar fashion. Furthermore, the NPIS was recorded prior to any subsequent LESI and patients with NPIS = 0 were not followed for a repeat LESI (C = caudal, IL = translaminar, TF = transforaminal).

\*  $P < 0.01$  within group (means  $\pm$  sd).

†  $P < 0.05$  with respect to groups C and IL.

than those with posterior epidural contrast dispersion patterns.

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