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Efficacy of Interlaminar vs Transforaminal Epidural Steroid Injection for the Treatment of Chronic Unilateral Radicular Pain: Prospective, Randomized Study

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Abstract

Objective, Design and Settings. The purpose of this randomized, prospective study is to compare the efficacy of two different routes in administering epidural steroid injections interlaminar (IL) vs transforaminal (TF) in patients with unilateral radicular pain.

Patients. We randomly enrolled and followed 64 patients with chronic radiculopathy.

Results. Significant improvements were maintained throughout 6 months (24 weeks) of follow-up ($P < 0.001$, respectively). The average visual analog scale (VAS) pain scores at 24 weeks improved to 4.0 ± 2.2 cm in the IL group and 3.8 ± 2.1 cm in the TF group ($P = 0.717$). Baseline functional capacity was comparable for the IL and the TF group (52% vs

53%) when assessed using Oswestry ($P = 0.647$). At 6 months, both groups improved, 39% for the IL group and 38% for the TF group, suggesting change from severe to moderate disability scoring range. There were 24 out of the 32 (75%) patients in the IL group at 24 weeks who improved more than 2 cm on the VAS scale and 17 patients (53%) had >50% of the pain relief. In the TF group, there were 27 out of the 32 (84%) patients with >2 cm improvement on VAS pain scale, and 20 of 32 (63%) with >50% improvement at 24 weeks. Functional capacity changes were similar, 16 out of the 32 patients (50%) improved 10 points or more on the Oswestry scale in the IL group and 21 out of the 32 in the TF group (66%).

Conclusions. Using either route of epidural injections to deliver steroids for unilateral chronic radiculopathy secondary to herniated intervertebral disc provided significant improvements in patients function and pain relief. However, we could not find a statistically significant difference between two indicated groups either in functional improvement or in reduction in pain, although half-dose of steroids delivered via TF route provided somewhat better long-term pain relief and functional capacity improvements.

Key Words. Interventional; Chronic Radiculopathy; Transforaminal Epidural Steroid Injection; Disc Herniation

Introduction

Epidural steroid injection is frequently used therapeutic modality in the management of radicular pain. It is believed that depositing steroids close to the nerve roots results in more efficacious control of the local inflammation. However, questions regarding the efficacy of epidural steroids abound as studies on epidural steroid injections have traditionally suffered from inadequate design and inconsistent outcomes [1–3]. Several systematic reviews and meta-analyses have concluded that epidural steroid injections are efficacious when used to relieve pain in patients with lumbosacral radicular pain [2–4]. Patients receiving such treatment are allowed adequate analgesia to conduct physical therapy, aqua therapy, and other forms of rehabilitation. To date, most studies on lumbar

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epidural steroid injections involved classical, interlaminar (IL) approach [5]. The use of this technique results in deposition of medication in the posterior epidural space. Conversely, disc/nerve root pathology occurs in the anterior epidural space. Only a handful of clinical trials have looked at the transforaminal (TF) approach to lumbar epidural steroid injections [6–10], and there are currently no prospective studies comparing the classical IL approach with the TF approach when used for unilateral radicular pain [5]. Still, the IL approach could be safer but less effective than the TF approach [10,11]. Similarly to IL epidural steroid injection studies, there has been no real attempt at identifying the best candidates to receive TF epidural steroid injections.

The purpose of this randomized, prospective study is to compare the efficacy of two different routes for administering epidural steroid injections using the IL vs TF in patients with unilateral radicular pain.

The TF approach to epidural injections results in deposition of the steroids in the anterior epidural space in close proximity to the site of pathology and may require lesser steroid dose [5,12]. Therefore, our hypothesis is that by targeting the steroid to the site of pathology near the herniated intervertebral disc and affected nerve root, the TF approach using one-half of the total steroid dose will be superior in improving function at 24 weeks when compared with twice the dose administered in an IL approach.

Methods

Design of this randomized, prospective study was approved by the University of Osijek Medical Center Institutional Review Board. All subjects gave their written informed consent for participation in the study. After the patient's informed consent was obtained, 64 patients with chronic lumbar radicular pain caused by herniated disc were randomly allocated to receive either IL or TF epidural steroid injections under the fluoroscopic guidance using the computer generated randomization. All patients were recruited from the Department of Anesthesiology, Clinical Center Osijek, Croatia.

In order to be included in the study, patients had to have unilateral lumbosacral radicular leg pain that was greater than the back pain and unresponsive to at least 6 weeks of conservative management and absence of motor or bowel/bladder impairment. Patients had to have a pain score of 5 or higher to undergo epidural injections. All of the patients had to have both, magnetic resonance imaging (MRI) of the lumbar spine and electromyography (EMG) studies completed.

Those excluded were patients with presence of MRI or X-ray documented lumbar canal stenosis that could potentially explain the patient's signs and symptoms, pregnant patients, patients with allergies to steroids, bleeding history, infections, who are on anticoagulants, neurological deficits secondary to pathology in

spine, previous lumbar spinal surgery, previous caudal or lumbar epidural steroid injections, history of opioid abuse or those currently on long acting opioids and those with radicular pain for more than 1 year. The participants in the study were blinded throughout the study to the type of treatment given, while the authors were not blinded.

Epidural IL or TF injections were given at the level of pathology, and appropriate dermatomal level for injection was determined by characteristic distribution of the patient's pain and corresponding MRI and/or EMG findings.

In order to perform IL epidural steroid injections (IL group; 13), the patients were placed in the prone position with a pillow underneath the abdomen to partially correct lumbar lordosis and facilitate the opening of interspinous spaces. That way, we facilitated the access to the epidural space. The back area was prepped and draped. True fluoroscopic anteroposterior view was obtained and 19 G Touhy needle advanced in combined coaxial anterior–posterior (AP) view and lateral view until advanced just a few millimeters posterior to the epidural space. At this point, loss of resistance (LOR) was performed using glass syringe with simultaneous advancement of a needle. The nonionic contrast media was administered under fluoroscopic guidance in the lateral view, and confirmation on appropriate contrast spread was obtained in the AP view. A solution of 80 mg of methylprednisolone mixed with 8 cc of 0.5% lidocaine was then injected.

For the TF epidural steroid injections (TF group 13), the patients were placed in the prone position on fluoroscopic table. The back area was prepped and draped in appropriate manner. The fluoroscopic beam was turned 20–30 degrees in oblique direction (to the side of pathology). The entry site was identified at desired foraminal level and a 22-gauge needle advanced until change in resistance felt. Then, lateral view was taken to assure needle tip placement within the epidural space. A “real time” injection of nonionic contrast assured proximal spread and no vascular uptake and it was completed in AP view. If the vascular uptake noticed, needle was repositioned until appropriate contrast spread observed. For the confirmation of anterior epidural spread, lateral fluoroscopic image was obtained. A solution of 40 mg of methylprednisolone with 3 cc of 0.5% lidocaine was injected.

The patients received a series of three IL or TF lumbar epidural steroid injections spaced 2 weeks apart. No anti-convulsants or antidepressants were allowed during the study period. For breakthrough pain, the patients were allowed to use tramadol one to two tablets, 50 mg q 6 hours as the rescue medication as needed (max 400 mg/24 hour). The patients were then followed and assessed at each visit at 3 and 6 months following the first injection using visual analog scale (VAS) pain scores, Oswestry, and Global Perceived Effect questionnaires.

There were three patients in the IL and three patients in the TF group who were lost to follow-up before the

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completion of the series of injections. Randomization continued until 32 patients enrolled in each group. There were no patients lost to follow-up from the completion of all three injections until the last patient's office visit.

Baseline assessment was completed just before the randomization and the first injection, first follow-up assessment was just before the second epidural steroid injection, third follow-up just before third injection, and fourth follow-up assessment was 2 weeks later. Fifth and sixth follow-up assessments were 12 and 24 weeks after the baseline assessment, respectively. Again, all of the patients received three epidural steroid injections.

Statistics

The statistical analysis included basic methods of descriptive statistics. The differences in the categorical variables were tested with the χ^2 test. The Student *t*-test and Mann-Whitney *U*-test Bonferroni was used in comparing the two groups of examinees regarding the technique of injecting the steroids. The Wilcoxon test and the *t*-test of differentiation were used in determining the differences between the two gauging. In ascertaining the differences by all measurements (visits) within each group in regard of manner of injection of the steroids, analysis of variance was used for repeated measurements, as was the Friedman test. The statistical analysis was completed using the program SPSS for Windows (Version 9.0, New York, NY, USA) with a significance level of 0.05.

Sample size estimate was made using SAS (Cary, NC) statistical software's POWER procedure. Basically, 64 patients enrolled ($N = 32/\text{group}$) we will have 90% power at the 0.05 significance level to detect differences of 10 points or more on the Oswestry score between groups in the change from the baseline to 12 months [11,14].

Results

We randomly enrolled and then followed 64 patients of which 41 were male (64.1%) and 23 (35.9%) patients were female (Table 1). Randomization produced a similar distribution of the female and male patients to the IL (21 male and 11 female patients) and the TF (20 male and 12 female patients) study group. The average age of the patients within the IL group was 49.2 years and within the

TF group, 48.8 years. The average body mass index of the patients in the IL group was 28.51 kg/m² and 28.14 kg/m² in the TF group. A total of 39 (60.9%) patients were employed, out of which 22 (68.8%) was from the IL group and 17 (53.1%) from the TF group. A large percentage of those employed patients were on sick leave while receiving injections (84.6%). In the IL group, 20 out of the 22 (90.9%) and in the TF group, 13 out of the 17 (76.5%) were on sick leave. On average, the IL group spent 304.3 days on sick leave and the TF group spent 205.69 days before receiving their first epidural injection. All of the patients in both groups underwent intensive physical therapy program before receiving epidural steroid injection, achieving varying improvements. Partial functional improvement after the physical therapy was claimed by 59.4% of the patients in the IL group and 46.9% in the TF group. There were only 6.3% of the patients in the IL group and 15.6% in the TF group who used any opioids. Mostly, tramadol was the opioid of choice. Most commonly, fear of addiction was the reason not to take an opioid (64.1% stated in the IL group vs 62.5% in the TF group).

All of the patients had either L4–5 or L5–S1 level pathology (L5/S1 in 36 and L4/L5 in 28 patients). In the IL group, the L5/S1 disc was involved in 19 patients while L4/L5 in 13. Similarly, in the TF group, L5/S1 was involved in 17 patients and L4/L5 in 13 patients. Baseline pain scores taken on the day of first injection were also comparable and not significantly different at 7.36 ± 1.6 cm for the IL group vs 6.72 ± 1.8 cm for the TF group ($P < 0.126$; Figure 1). Statistically significant improvements were seen in both groups and those were maintained throughout 6 months (24 weeks) of follow-up ($P < 0.001$, respectively; Figure 1). The average VAS pain scores at 24 weeks were 4.0 ± 2.2 cm in the IL group and 3.8 ± 2.1 cm in the TF group and were not significantly different ($P = 0.717$; Figure 1).

Baseline functional capacity was comparable for both the IL and the TF group (52% vs 53%, which, on average, signifies severe disability) when assessed using the Oswestry Disability Index (ODI) ($P = 0.647$). At 6 months, both groups improved in function with an average of 39% for the IL group and 38% for the TF group, suggesting change from severe to moderate disability scoring range. Again, there is no statistically significant difference between the two groups ($P = 0.774$; Figure 2).

Table 1 Baseline data of patients enrolled in study*

| Baseline data | Age | Female | Male | BMI (kg/m ²) | L4–L5 Disc Herniation | L5–S1 Disc Herniation | VAS | ODI (%) |
|----------------|-------|--------|------|--------------------------|-----------------------|-----------------------|-------|---------|
| IL group | 49.2 | 11 | 21 | 28.51 | 13 | 19 | 7.36 | 52 |
| TF group | 48.8 | 12 | 20 | 28.14 | 13 | 17 | 6.72 | 53 |
| <i>P</i> value | 0.907 | | | 0.898 | | | 0.126 | 0.647 |

*Forty-one male and 33 female patients were enrolled with comparable VAS pain scales and Oswestry Disability Index (ODI) baseline values.

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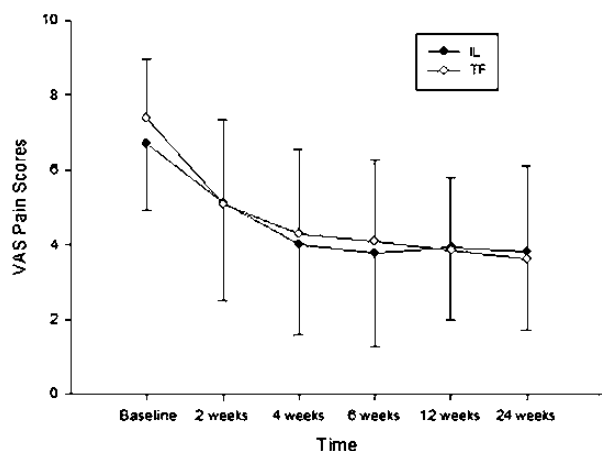


Figure 1 The average changes of visual analog scale (VAS) pain scores (cm) in two patient groups following either interlaminar or transforaminal epidural injection of methylprednisolone. Patients in both groups improved with their VAS pain scores; however, there were no significant differences between the two groups.

In order to clearly assess how many patients in each group actually benefited from the epidural steroid injections, we analyzed the VAS pain score and ODI changes for every individual in either group. There were 24 out of the 32 (75%) patients in the IL group at 24 weeks who improved more than 2 cm on the VAS scale [15,16] and 17 patients (53%) had >50% of the pain relief. In the TF group, there were 27 out of the 32 (84%) patients with >2 cm improvement on the VAS pain scale and 20 of the 32 (63%) with >50% of improvement in pain scores at 24 weeks. Functional capacity changes were consistent with changes in pain scores where 16 out of the 32 patients (50%) improved 10 points or more on the Oswestry scale in the IL group and 21 out of the 32 in the TF group (66%).

Discussion

When it comes to objective outcomes of IL and TF epidural steroid injections, very few studies reported previously on functional capacity assessment using validated questionnaires and most analyzed just short-term (less than 6 weeks) and long-term (greater than 6 weeks) pain relief using verbal or VAS pain scores [10,11,17,18]. This is a first randomized, prospective study to compare TF epidural injection of steroids to IL approach for the treatment of unilateral chronic radicular pain.

There is no consensus on how epidural injection therapy should be conducted with respect to the volume and dose of steroids injected [5,19,20]. In this study, we examined two different and very common routes in delivering steroids for the treatment of chronic unilateral radicular pain. Our steroid doses and volumes injected for the two

groups studied were different (40 mg in 3 cc of saline for the TF group and 80 mg in 8 cc of saline for the IL group), reflecting a common practice around the world (and especially in Europe) when methylprednisolone is used to treat any radicular pain secondary to disc herniation, although there is no literature that supports such practice or equivalency of these doses [5,19–21].

It is possible that the ceiling effect of relatively large dose (80 mg) of steroids injected into the epidural space was already achieved and that even lower doses of interlaminarily delivered steroids would produce a comparable effect similar to TF lower steroid amount [20]. Dose-response, fluoroscopically guided [5] studies on the epidural steroid therapeutic effect when delivered via the IL route do not exist [20]. Once such dose-response relationship is clearly established, this article could be re-analyzed in the light of dose-dependent improvements in pain scores over the wide range of injected amount of methylprednisolone.

If given steroid dose can be reduced, it would be possible to provide certain patient groups with more frequent injections [5]. Those who are at the increased risk of steroid side effects include elderly, poorly controlled diabetics and those receiving chronic systemic steroids. If the TF injection route produces similar or even better pain relief and functional capacity improvement while using only half of the IL steroid dose, such route should be preferable for majority of the patients with chronic radicular pain (Figures 1 and 2). Still, risks and complications associated with the use of TF route could be significant as more of the severe complications are described with increased utilization of such approach [12,13,22–25].

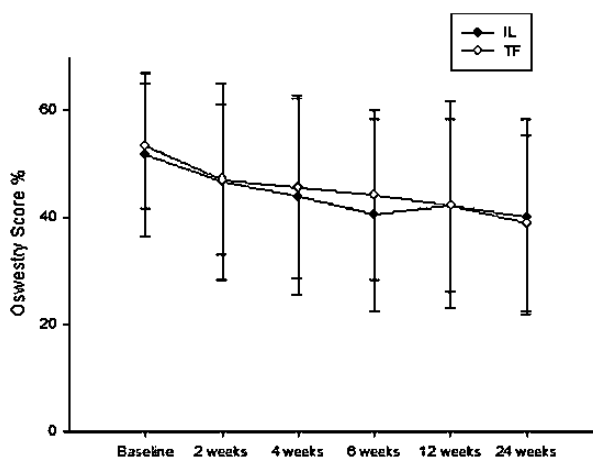


Figure 2 Improvement of Oswestry Disability Index (ODI) scores after either transforaminal (TF; 40 mg) or interlaminar (IL) injection (80 mg) of methylprednisolone to epidural space. Data are shown as mean \pm SD. Improvements were shown in both groups, and there was no difference between them.

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Multiple factors may influence long-term and short-term results of the epidural steroid injections. Aside from the clinician's experience and training, other factors that may play an important role include patient selection, symptom duration, underlying pathophysiology, epidural steroid injection approach, use of fluoroscopy, vocational and socioeconomic status, and possible psychological issues within the patient group undergoing such conservative treatment.

In general, patients who are symptomatic for less than 3 months do have a better response rate (90%) than those with radicular pain for less than 6 months (70%), and those symptomatic for more than a year (50%). In our study, overall symptom duration was about 250 days (8–9 months). Considering the chronicity of the radicular pain in our patient group, it seems that the epidural steroid injections, when used in conjunction with physical therapy, even in this chronic type of radiculopathy, were fairly successful (Figures 1 and 2). In addition, all of the injections were completed by the same interventional pain physician (IR), eliminating variability in outcomes related to interphysician technique differences.

The weakness of this study is that the comparison was made only between the patients who received epidural steroids either via the TF or the IL route without utilizing placebo group. Still, our intention was to compare two standard epidural injection treatments for the painful lower extremity radiculopathy. One could argue that not accounting for three dropouts in each study group could change the final outcomes. The intention-to-treat principle was followed but restricted to those patients who received treatment ("for-protocol analysis"). Three patients in each group dropped out either after the first, second, or third injection. Considering an equal number of patients in both groups who were lost to follow-up, and a relatively large size (32 patients) in either randomized groups, inability to account for data of those patients was unlikely to affect our comparison.

Finally, using either route of epidural injections to deliver steroids for unilateral chronic radiculopathy secondary to herniated intervertebral disc provided significant improvements in patient function (Figure 2). Despite the absence of the control group, such improvement is unlikely to occur spontaneously [26,27] >200 days after the original injury. Overall percentage of the patients with significant functional improvements and pain scores after receiving steroids via the TF route was significantly higher. Dose-response studies of the epidural steroids are also needed to either confirm or refute the fact that TF route may require lesser therapeutic steroid doses and provide somewhat better pain relief and improved function.

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