Original Article

Comparing the clinical efficacy of preganglionic and preganglionic plus ganglionic transforaminal epidural steroid injections for lumbosacral radicular pain

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ABSTRACT

الأهداف: مقارنة فعالية حقن الستيرويد فوق الجافية عبر الثقبة الفقرية قبل العقدة (TFESI) مع حقن الستيرويد عبر الثقبة الفقرية قبل العقدة بالإضافة إلى حقن الستيرويد عبر الثقبة الفقرية بعد العقدة.

المنهجية: اشتملت الدراسة على المرضى الذين يعانون من آلام جذرية أحادية الجانب وأمراض القرص بشكل عشوائي إما في مجموعة ما قبل العقدة أو مجموعة ما قبل العقدة بالإضافة إلى حقن الستيرويد عبر الثقبة الفقرية بعد العقدة. أجرينا تقييم جميع المرضى باستخدام مقياس التصنيف العددي (NRS) ومقياس رضا المريض (PSS) في الأسبوع الثالث والشهر الثالث بعد العلاج.

النتائج: كانت هناك فروق كبيرة بين درجات NRS للمرضى بعد حقن الستيرويد عبر الثقبة الفقرية بعد حقن الستيرويد عبر الثقبة الفقرية لكلا المجموعتين. من حيث تخفيف الألم بنسبة >50% في 3 أسابيع و 3 أشهر بعد العلاج، لم يتم العثور على فروق كبيرة بين المجموعتين (p>0.05). كانت درجات PSS للمجموعة ما قبل العقدة بالإضافة إلى حقن الستيرويد عبر الثقبة الفقرية أقل بشكل ملحوظ في الشهر الثالث مقارنة بالأسبوع الثالث (p=0.046). كانت درجات PSS للمجموعتين متشابهة في الأسبوع الثالث والشهر الثالث (p>0.05). وُجد ارتباط سلبي ضعيف بين العمر وتسكين الألم بشكل ملحوظ في الشهر الثالث (p=0.024, Rho=.278). وُجد ارتباط إيجابي معتدل بين تسكين الألم بشكل ملحوظ في الأسبوع الثالث وتسكين الألم بشكل ملحوظ في الشهر الثالث (p<0.001, Rho=.465). وأظهر الجنس الذكري ارتباطًا إيجابيًا ضعيفًا مع تسكين الألم بشكل ملحوظ في الأسبوع الثالث (p=0.022, Rho=.281) والشهر الثالث (p=0.038, Rho=.256).

الخلاصة: لم يؤثر النهج المشترك قبل العقدة بالإضافة إلى النهج بعد العقدة لـ TFESI على النتائج لدى المرضى الذين يعانون من آلام جذرية قرصية أحادية الجانب. كان نهج TFESI قبل العقدة وحده على مستوى القرص كافيًا لتحقيق تسكين الألم.

Objectives: To compare the effectiveness of preganglionic transforaminal epidural steroid injection (TFESI) with preganglionic plus postganglionic TFESI.

Methods: Patients with unilateral radicular pain and disc pathology were randomly assigned to either the preganglionic group or the preganglionic plus postganglionic group. All patients were evaluated using a numeric rating scale (NRS) and a patient satisfaction scale (PSS) at the third week and the third month after treatment.

Results: There were significant differences between the patients' NRS scores after TFESI for both groups. In terms of >50% pain relief at three weeks and 3 months post-treatment, no significant differences were found between the groups (p>0.05). The PSS scores of the preganglionic plus postganglionic group were significantly lower at third month than at the third week (p=0.046). The PSS scores of the two groups were similar at third week and third month (p>0.05). A weak negative correlation was found between age and meaningful pain relief at the third month (Rho=.278, p=0.024). A moderate positive correlation was found between meaningful pain relief at the third week and meaningful pain relief the third month (Rho=.465, p<0.001). Male gender showed a weak positive correlation with meaningful pain relief at the third week (Rho=.281, p=0.022) and the third month (Rho=.256, p=0.038)

Conclusion: The combined preganglionic plus postganglionic approach for TFESI did not affect the outcomes in patients with unilateral discogenic radicular pain. The preganglionic TFESI approach alone at the disc level was sufficient to achieve pain relief.

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Low back pain is a worldwide health problem that affects many people at some point in their lives. Low back pain (LBP) affects almost 600 million people worldwide, and the number of cases is expected to increase with population growth and aging.[1] Lumbar disc herniation is one of the most common causes of low back pain and lumbosacral radiculopathy. Lumbar disc herniation is a pathology of the herniated nucleus pulposus, which puts pressure on neural structures, leading to back and/or leg pain. Nonoperative treatment is the first choice for most patients. Conservative treatments include medications, physical therapy modalities and exercise, spinal manipulation, and traction (manual or mechanical). Therefore, invasive pain modalities include epidural steroid injections and dorsal root ganglion pulsed radiofrequency treatment.[2–4] Epidural steroid injections have been used to treat low back pain and sciatica since 1901, and their effectiveness has been shown in many studies.[5,6] Epidural steroid injections can be performed in an interlaminar, caudal, or transforaminal way. However, the difference in efficacy between the 3 approaches is unclear; preganglionic transforaminal epidural steroid injection (TFESI) has been reported to be more effective than the other approaches.[7,8] Although TFESI has been applied for a long time, there is much variation in application methods, including the level of injection and the type and dose of steroids and local anesthetics.[6–9] One of the uncertainties in using TFESI is the disagreements among clinicians about the optimal application method, including the level of injections.[10,11] Some authors have reported that TFESI performed at the level of the disc with pathology (preganglionic) was more effective than TFESI administered at the symptomatic nerve root level (postganglionic). Therefore, this study aimed to compare preganglionic TFESI with preganglionic plus postganglionic TFESI.

Methods. ***Design and setting.*** This prospective randomized study was conducted according to the principles of the Helsinki Declaration. Ethical approval was obtained from the local ethics committee, and all participants provided their written informed consent. Patients admitted to the algology outpatient clinic between January 2021 and October 2021 who met the inclusion criteria were enrolled in the study. The inclusion criteria included the following: patients aged 20–60 years with radicular low back pain ≥6 on the NRS for at least 3 months and one-level disc herniation confirmed by magnetic resonance imaging (MRI). Patients with disc sequestration, disc herniation at more than one level, a history of spinal surgery or trauma, spinal stenosis, a history of epidural injection in the previous three months, those who were participating in a physical treatment program, had systemic or local infection, were pregnant, were allergic to steroids or local anesthetics, had a bleeding disorder, were in poor general health, or had mental or neurological diseases were excluded from the study. After computerized randomization and assignment to one of the 2 groups, TFESI was administered by a specialized algologist, and another specialist doctor assessed outcomes. Patients were asked to take only nonsteroidal anti-inflammatory drugs for severe pain. The consumption of analgesic medication in a week before treatment and the week after treatment was recorded. However, because of the heterogeneous medications that the patients were taking, we did not analyze analgesic consumption.

TFESI technique. After monitoring, the patients were laid prone. Sterile preparation and draping were conducted. For local anesthesia, 1% prilocaine was used. Then, using the safe triangle method, a 20-gauge transforaminal blunt needle (Epimed Co. NY, USA) was advanced with an oblique approach under fluoroscopy guidance. The needle position was confirmed in both the anteroposterior and lateral views. Approximately 300 mg/1 ml of iohexol (Omnipaque®, GE Healthcare, Dublin, Ireland) was injected. After a proper contrast distribution pattern for the anteroposterior and lateral views was observed, a mixture of 8 mg of dexamethasone (Dekort®, Deva Holding Health, Safety, and Environment, Turkey) and 1 ml of 2% lidocaine (Aritmal®, Osel Drug Industry, and Trade. Inc., Turkey) was slowly injected. For the preganglionic plus postganglionic group, the injection was administered at the disc level (preganglionic approach) and below the disc level, in other words, at the symptomatic nerve root level (postganglionic approach).

Patient assessment. The patients self-assessed the pain they experienced using a 10-pointnumeric rating scale (NRS) before treatment, at the third week, and at the third month after the treatment. A reduction in pain greater than 50% was accepted as meaningful pain relief. In addition, the patients completed a 5-point Likert-type patient satisfaction scale (PSS), in which 0=poor, 1=fair, 2=good, 3=very good, and 4 = excellent,

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Table 1 - Demographic and clinical features of the patients according to group.

	Preganglionic group (n=31)	Preganglionic and postganglionic group (n=35)	*P*-value
	Mean±standard deviation		
Age(years)	45.42±13.51	45.66±12.20	.940[a]
Gender (n/%)			
Female	16(51.6)	22(62.9)	.356[b]
Male	15(4.4)	13(37.1)	
Side of pain (n/%)			
Right	18(58.1)	13(37.1)	.089[b]
Left	13(41.9)	22(62.9)	
Disc level (n/%)			
L3–4	5(16.1)	2(5.7)	.248[b]
L4–5	15(39.5)	23(65.7)	
L5–S1	11(35.5)	10(28.6)	
Duration of pain (weeks)	15.78±13.58	16.91±12.89	.728[a]
NRS – pretreatment	7.90±1.16	8.06±0.99	.565[a]
NRS – third week	4.45±2.74	3.29±2.17	.059[a]
PSS – third week	2.26±1.36	2.69±1.40	.216[a]
NRS – third month	4.55±2.60	4.23±2.54	.616[a]
PSS – thirdmonth	2.03±1.49	2.31±1.53	.453[a]

[a]Independent samples t-test;[b]chi-squared test; NRS =numeric rating scale; PSS=patient satisfaction scale

at the third week and the third month following the treatment to evaluate patients' self-reported improvement. The patients were not informed about which group they were assigned to in order to ensure a double-blinded protocol for our study.

Statistical analysis. Before the study, G-power analysis was performed. With an error level of 0.05 at 95% power, it was calculated that 60 patients, 30 in each group, should be included in the study. All analyses were conducted using IBM SPSS version 25. Mean and standard deviation were used to present quantitative data. A statistical significance threshold of $p<0.05$ was considered significant. Independent samples, t-test, and Mann-Whitney U test were conducted to compare numerical data between the groups. Categorical data from the 2 groups were analyzed and compared using the chi-squared test. A comparison of the change in NRS scores in the 2 groups over time was conducted using two-way ANOVA. Meaningful pain relief between the 2 groups was compared using the Pearson's chi-squared test. The change in the PSS scores over time of the 2 groups were compared using the paired samples t-test. The differences in the PSS scores between the 2 groups at different time points were assessed using the chi-squared test. Spearman correlation analysis was performed to determine the variables associated with meaningful pain relief at follow-up.

Table 2 - Comparison of groups in terms of PSS scores over time

	Preganglionic group (n=31)	Preganglionic plus ganglionic group (n=35)	*P*-value*
PSS	N/%		
At third week			
Poor	3 (9.7)	3 (8.6)	0.352
Fair	8 (25.8)	5 (14.3)	
Good	6 (19.4)	8 (22.9)	
Very good	6 (19.4)	3 (8.6)	
Excellent	8 (11.3)	16 (45.7)	
At third month			
Poor	7 (6.1)	6 (17.1)	0.671
Fair	5 (5.6)	7 (20.0)	
Good	6 (19.4)	3 (8.6)	
Very good	6 (19.4)	8 (22.9)	
Excellent	7 (22.6)	11 (31.4)	

*Chi-squared test; PSS =patient satisfaction scale

Results. The demographic and clinical features of the patients in the 2 groups are presented in **Table 1**. The patients' average age was 45.4±13.51 for the preganglionic group and 45.66±12.20 for the preganglionic plus postganglionic group. In the preganglionic group, 51.6% of the patients were females, while in the preganglionic plus postganglionic group, 62.6% of the patients were female. The duration of pain was 15.78±13.58 weeks and 16.91±12.89 weeks in the preganglionic and the preganglionic plus postganglionic groups, respectively. The most affected disc level was L4–5 for both groups (39.5% in the preganglionic group, and 65.7% in the preganglionic plus postganglionic group). There was no significant difference between the groups with regard to age ($p=0.910$), gender ($p=0.356$), side of pain ($p=0.089$), duration of pain ($p=0.728$), level of disc pathology ($p=0.248$), or NRS scores before treatment ($p=0.565$), at the third week ($p=0.059$), and at the third month ($p=0.616$) following treatment. The patients' PPS scores at the third week ($p=0.216$) and third month ($p=0.453$) after treatment were similar in the 2 groups ($p>0.05$). For both groups, two-way ANOVA analysis showed significant differences between patients' NRS scores before treatment and their NRS scores at 3 weeks ($p<0.001$), as well as between the patients' NRS scores at 3 weeks and at 3 months ($p=0.015$). Therefore, no effect of the group variable was found in the NRS score changes with time ($p=0.262$). Changes in the NRS scores for both groups are shown in **Figure 1**.

Table 3 - Correlation analysis for variables associated with meaningful pain relief.

Variables	Meaningful pain relief at third week	Meaningful pain relief at third month
Age		
Rho	-.131	-.278
P	.296	.024*
Gender		
Rho	.281	.256
P	.022*	.038*
Pain duration prior to treatment		
Rho	-.120	-.203
P	.337	.102
Disc lesion level		
Rho	0.47	.045
P	.708	.721
Preganglionic or preganglionic plus ganglionic group		
Rho	.180	.071
P	.147	.573

*A *p*-value less than 0.05 is considered to be statistically significant

At the third week after treatment, 41.9% of the patients in the preganglionic group and 60.0% of the patients in the preganglionic plus postganglionic group experienced meaningful pain relief, which was determined as >50% pain reduction. At the third month, meaningful pain relief rates were 38.7% for the preganglionic group and 45.7% for the preganglionic plus postganglionic group. No significant difference was found between the groups at the third week and the third month (p=0.143, p=0.566, respectively) in terms of their experience of meaningful pain relief. When all the patients were included in the analysis, a weak negative correlation was found between age and meaningful pain relief only at the third month (Rho=.278, p=0.024). A moderate positive correlation was found between meaningful pain relief at the third week and meaningful pain relief at the third month (Rho=.465, p<0.001). Male gender showed a weak positive correlation with meaningful pain relief at the third week (Rho=.281, p=0.022) and the third month (Rho=.256, p=0.038) (**Table 3**).

In the preganglionic group, the patients' PSS scores showed no differences between the third week and the third month (p=0.070). However, in the preganglionic plus postganglionic group, the patients' PSS scores were significantly lower at the third month compared to the third week (p=0.046). The PPS scores for the 2 groups were similar at 3 weeks and 3 months (p=0.352, p=0.671, respectively) (**Table 2**).

Discussion. In this study, meaningful pain relief was similar between the 2 groups; however, the PSS scores of the patients in the preganglionic group were significantly lower than those of the patients in the preganglionic plus postganglionic group. Our study showed that adding the postganglionic option to preganglionic TFESI did not increase pain relief or patient satisfaction. Many previous studies have compared the preganglionic and ganglionic approaches, but no studies with this focus have been conducted in the last 5 years. Three studies showed that preganglionic TFESI was more effective than TFESI performed at the postganglionic level.[6,10] These findings support the idea that preganglionic injection allows drug administration closer to the neural impingement to reduce inflammation and relieve pain. However, no previous studies have compared the preganglionic approach with the preganglionic approach combined with the ganglionic approach to treat lumbosacral radicular pain. In our research, in the preganglionic plus postganglionic group, 60.0% of the patients reported >50% pain relief at 3 weeks and 45.7% reported the same at three months. In this study, age was negatively correlated with meaningful pain relief. Although younger patients are thought to recover faster, Shrestha et al[12] found no significant differences in meaningful pain relief at 3 months in younger and older patients with lumbar radiculopathy. Jain et al[13] also found age and gender were not associated with ≥50% pain relief at the third month after TFESI. In our study, meaningful pain relief was similar to previous studies, but we could not find any studies to compare our findings. The positive correlation of meaningful pain relief at the third week with meaningful pain relief at the third month may be considered an expected result. Şencan et al[14] showed that pain score reduction in the first week after TFESI was predictive of pain score reduction in the third month The duration of pain prior to the treatment was not associated with meaningful pain relief. Jain et al[13] found that pain duration did not correlate with meaningful pain relief in the third month. However, Sarıyıldız et al[15] showed that shorter pain duration was associated with meaningful pain relief at the third month after TFES for lumbar disc herniation.

Our study has some limitations. These include alack of neurological and pain distribution analysis, a small sample size, a short follow-up period, the absence of a health or disability questionnaire, and the failure to analyze the patients' consumption of analgesics. Further studies are needed with larger sample sizes,

longer follow-up durations, and the use of specific questionnaires to assess back pain.

Conclusion. This study found that the combined preganglionic and postganglionic approach did not affect patient outcomes. Therefore, there was no meaningful benefit to adding a postganglionic approach to preganglionic TFESI. The preganglionic approach alone at the herniated disc level appears to be sufficient to relieve pain.

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