Original Article

Comparison of 1-Year Results of Single Transforaminal Epidural Steroid Injection Among Patients with Different Spinal Pathologies-Related Radicular Pain

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Received: 14-Jan-2019;
Revision: 07-Feb-2019;
Accepted: 15-Jan-2020;
Published: 11-Jun-2020

ABSTRACT

Aims: This study aims to investigate the effectiveness of transforaminal epidural steroid injection (TFESI) in patients with lumbar radicular pain or radiculopathy caused by different spinal pathologies. **Methods:** One hundred and seventy seven patients who underwent single transforaminal epidural steroid injection were included in the study group and divided into 3 subgroups (central spinal stenosis + lateral recess stenosis, foraminal stenosis, lumbar disc herniation) according to existing spinal pathology. Patients' visuel analogue scale (VAS) measures and Oswestry Disability Index (ODI) scores were recorded and the patients who give favourable response to treatment were called respondents and who were not called as non-respondents. Subgroups were compared statistically at the end of 12 months. **Results:** Sixty patients (33.9%) were considered as respondents and 117 patients (66.1%) were non-respondents in the entire study group. Patients with foraminal stenosis included the vast majority of the respondents and showed better results of pain relief as opposed to patients of other groups at the end of 12 months ($P < 0.001$). **Conclusion:** TFESI was an effective treatment modality for pain relief and functional improvement in patients with foraminal stenosis. However, it could not produce the same results in patients with central spinal stenosis and lumbar disc herniations.

KEYWORDS: *Radicular pain, spinal pathology, transforaminal epidural steroid injection*

INTRODUCTION

In the aging population, radicular pain is the most common problem among acute and chronic pain disorders which has significant implications.[1] Radiculopathy is caused by pressure exertion on the nerve root that in turn results in an increased inflammatory response and neuronal sensitivity.[2,3]

Transforaminal epidural steroid injection (TFESI) is a well-known minimally invasive intervention and is often preferred by clinicians for treating radicular pain and radiculopathy.[4-6] Pain relief is usually achieved with this intervention when conservative treatment modalities fail. Besides, diagnostic value of this procedure in cases with multiple foraminal stenosis renders it superior to the other minimally invasive interventions.[7]

Access this article online

Quick Response Code:

Website: www.njcponline.com

DOI: 10.4103/njcp.njcp_24_19

While there are many studies in the literature on the clinical efficacy of TFESI, what kind of spinal pathologies respond well to this treatment still remains controversial. Therefore, we aimed to retrospectively review the one year results of TFESI performed in 177 patients and compare the results to determine the pathologies in which the best results are achieved.

METHODS

We reviewed retrospectively the charts of 373 patients who underwent peri-radicular injection with radicular

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How to cite this article: Olguner SK, Celiktas M, Oktay K, Arslan A, Bilgin E, Gezercan Y, *et al.* Comparison of 1-year results of single transforaminal epidural steroid injection among patients with different spinal pathologies-related radicular pain. Niger J Clin Pract 2020;23:835-41.

pain or radiculopathy between 2015-2017 in a spine center. All the injections were performed for the purpose of treatment. We selected 177 patients who meet the inclusion criteria with regular 1-year records. Inclusion criteria were as follows:

1) Patient with unilateral radiating leg pain below hip/knee joint
2) Patients who had failed conservative treatment modalities (medication and physical therapy)
3) Patients whose magnetic resonance imaging (MRI) scans revealed central spinal stenosis + lateral recess stenosis (CSS + LRS), lumbar disc herniation (LDH) and foraminal stenosis (FS)
4) Patients who underwent unilateral, single level and one session TFESI procedure with 1 year regular records
5) Patients who did not undergo surgery or other surgical options following TFESI before 1 year.

Lumbar MRI was performed to all patients after detailed neurological examination. The affected nerve root was diagnosed by neurological examination and MRI and unilateral, single-level nerve root injection was performed under fluoroscopy. The patients were divided into 3 subgroups according to the existing spinal pathologies; CSS + LRS, FS and LDH. Before and 2 hours after injection, 15th day, 6th and 12th month the visual analogue scale (VAS, 0 = no pain 10 = the worst pain imaginable) and the pre-injection, 6th and 12th month Oswestry disability index (ODI) was assessed. The validated version of ODI for Turkish population was carried out.[8] The efficacy of treatment was accepted as meeting 50% reduction in VAS score and 40% reduction in the ODI score. Those who met the criteria were named respondent and who did not were called non-respondents. "Non-respondents or responded partially to TFESI before one year according to criterias mentioned above offered surgery or other minimal invasive surgical options and those underwent surgical procedures excluded from study.

Respondents and non-respondents who refused to undergo surgery or other surgical invasive options formed study group and then taken into a routine follow up programme.

Patients were excluded if they had lack of data, previous lumbar surgery, underwent a repeat or multilevel TFESI, who had surgery prior to 1-year follow-up, instrumentation, neurologic deficits, other spinal pathologies. All the pain assesments and ODI questionnaire interviews were obtained from patients by a nurse independent from the study via telephone call or visit.

Radiological assessment

Magnetic resonance imaging scans of the subgroups were obtained from the picture archiving and communication system (PACS) and radiologically graded for each subgroup by an experienced radiologist. For CSS and LRS, lumbar MRI scans were graded according to the maximal severity of stenosis by observing Lee *et al*.'s classification on axial T2-weighted images.[9] Patients were classified as Grade 0 no lumbar stenosis, Grade 1 mild stenosis, Grade 2 moderate stenosis, and Grade 3 severe stenosis. FS classification was performed according to the classification by Lee *et al*. on sagittal T1-weighted images.[10] Patients were classified as Grade 0 absence of foraminal stenosis, Grade 1 mild stenosis, Grade 2 moderate stenosis and Grade 3 severe stenosis. LDH classification was assessed as described in Pfirrmann *et al*.'s study according to nerve root compression on axial T2-weighted images.[11] Patients were classified as no compromise, contact of disc material with nerve root, deviation of nerve root and compression of nerve root.

Statistical analysis

The SPSS 24.0 (IBM Corporation, Armonk, New York, United States) and PAST 3 (Hammer, Ø, Harper, D.A.T., Ryan, P.D. 2001, Paleontological statistics) programs were used to analyze the variables. The conformity of the univariate data to a normal distribution was evaluated by the Shapiro-Wilk test, the conformity of the multivariate data to a normal distribution was evaluated by the Mardia (Dornik and Hansen omnibus) test and the variance homogeneity was evaluated by the Levene test. One-way ANOVA was used for parametric comparison of independent multiple groups and Fisher's Least Significant Difference (LSD) test was used for *post hoc* analysis. Kruskal-Wallis H test was used for nonparametric test and Monte Carlo simulation test results were used for Dunn's test It was used. The one-way ANOVA test, one of the parametric methods, was used to compare the independent multiple groups according to the quantitative data, and the Fisher's Least Significant Difference (LSD) test was used for the *post hoc* analyzes, while the Kruskal-Wallis H Test, one of the nonparametric tests, was used with the Monte Carlo simulation method's results. The Dunn's Test however was used for *post hoc* analyzes.

The Mc-Nemar test was used with the Exact results in comparing two repeated measurements of the two-categorical dependent variables. The Dunn's Test and the LSD tests were used for *post hoc* analyzes while the General Linear Model-Repeated ANOVA test and the Friedman's Two-Way tests were used to analyze the interaction of repeated quantitative measurements of the

dependent quantitative variables according to groups. For the comparison of the categorical variables, the Pearson's Chi-Square and the Fisher-Freeman-Holton tests were used with the Monte Carlo Simulation technique and the column ratios were compared with each other and expressed according to Bonferroni corrected *P* value results. The quantitative variables were expressed as the mean ± standard deviation (std) and the median Range (maximum-minimum), and the categorical variables as n (%). The variables were examined at 95% confidence level and the $P < 0.05$ was accepted as significant.

Results

There were 65 (36.7%) male and 112 (63.3%) female patients in the study cohort. The mean age of the patients was 66 years (18-87 years). 56 patients (31.6%) were in CSS + LRS group, 61 patients (34.5%) were in FS group and 60 patients (33.9%) were in LDH group. The mean follow-up period of the patients was 13 months (12-30 months). The injected levels were L4-5 (85 patients), L3-4 (43 patients), L5-S1 (41 patients) [Figure 1], and L2-3 (8) patients), respectively. Radiological grading of subgroups was performed. In the CSS + LRS, FS and LDH subgroups, there were predominantly grade 3 pathologies (75%, 67.2%, 71.7%) [Table 1A].

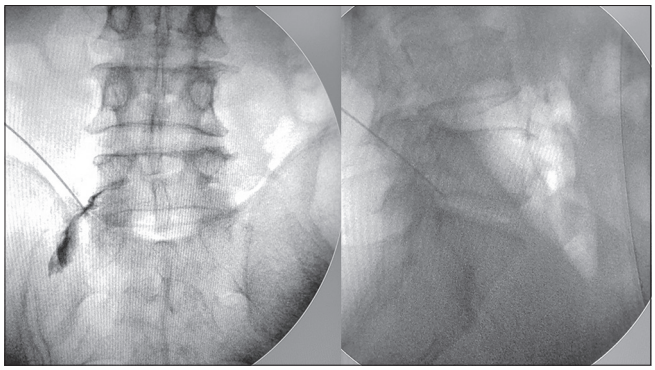

Figure 1: The Anteroposterior and lateral x-ray image demonstrates staining of nerve root

Gender distribution of study group did not affect the outcomes. 18 male (%27.7) and 42 female (%37.5) patients were accepted as responder at the end of 12 months, but the results were not statistically significant ($P = 0.193$) [Table 1B]. There were no complications causing neurological deterioration after the procedures. 12 patients (21.4%) in the CSS group, 38 patients (62.3%) in the FS group and 19 patients (31.7%) in the LDH group demonstrated 50% or more decrease in the VAS scores at the end of 12 months [Table 2A]. 12 patients (21.4%) in the CSS group, 39 patients (63.9%) in the FS group and 16 patients (26.7%) in the LDH group demonstrated 40% or more decrease in the ODI scores at the end of 12 months [Table 2B]. When VAS change between subgroups was analysed, statistically significant improvements were detected in FS group compared to CSS + LRS and LDH groups at the end of 12 months ($P < 0.001$, $P = 0.004$) [Table 3]. There was no significant difference between CSS + LRS and LDH groups in terms of change during follow-up ($P > 0.05$). According to ODI changes between subgroups, FS group showed better results comparing to CSS + LS group at the end of 12 th month ($P = 0.02$).

The efficacy of the treatment was accepted as meeting both of the criteria of 50% reduction in VAS score and 40% reduction in ODI score and 60 out of 177 patients (33.9%) responded favorably to TFESI procedure in the entire study group. At the end of the 12 months, the success rates were 59% in the FS group, 23.3% in the LDH group and 17.9% in the CSS + LRS group [Table 4]. When VAS respond among injection applied foraminas was questioned there was no statistically significant difference detected at the end of 6^{th} and 12^{th} months ($P = 0.367$ and 0.717 respectively) [Table 5].

At the end of the first year, surgical intervention was recommended again to non-respondents who refused to go undersurgery. Seven patients underwent surgery,

Table 1A: The demographic and radiological data of the study group

		Central spinal stenosis	Foraminal stenosis	Lumbar disc herniation	Total	*P*
		n (%)	*n* (%)	*n* (%)	*n* (%)	
Gender	Male	16 (28.6)	20 (32.8)	29 (48.3)	65 (36.7)	0.066
	Female	40 (71.4)	41 (67.2)	31 (51.7)	112 (63.3)	
Foramina	L2-3	0 (0)	4 (6.6)	4 (6.7)	8 (4.5)	<0.001
	L3-4	20 (35.7)	10 (16.4)	13 (21.7)	43 (24.3)	
	L4-5	30 (53.6)	25 (41)	30 (50)	85 (48)	
	L5-S1	6 (10.7)	22 (36.1)	13 (21.7)	41 (23.2)	
Radiological grade	2	14 (25)	20 (32.8)	17 (28.3)	51 (28.8)	0.666
	3	42 (75)	41 (67.2)	43 (71.7)	126 (71.2)	

Fisher Freeman Halton (Monte Carlo)/Pearson Chi Square Test (Monte Carlo)/a: significant according to CSS+ LRS group b: significant according to FS group c: significant according to LDH group

Table 1B: Patients outcomes according to gender at the end of 12th month

Bothresponder	Male (*n*=65) *n* (%)	Female (*n*=112) *n* (%)	*P*
Nonresponder	47 (72.3)	70 (62.5)	0.193
Responder	18 (27.7)	42 (37.5)	

Pearson Chi Square Test (Exact)

16 patients declined surgery and seek for other treatment options (physical therapy and pain clinics) in CSS + LRS subgroup. In the FS subgroup, 16 patients underwent surgery, 14 patients declined surgery and seek for other treatmant options. In the LDH subgroup, 13 patients underwent surgery and 19 patients seek for other treatment options.

Table 2A: The distribution of patients corresponding to 50% reduction in visual analog scale pain scores at the end of the 6th and 12th month

VAS Response		Central spinal stenosis a *n* (%)	Foraminal stenosis B *n* (%)	Lumbar disc herniation c *n* (%)	Total *n* (%)	*P*
6th month	Non-respondents	38 (67.9)[b]	22 (36.1)	39 (65)[b]	99 (55.9)	0.001
	Respondents	18 (32.1)	39 (63.9)[ac]	21 (35)	78 (44.1)	
12th month	Non-respondents	44 (78.6)[b]	23 (37.7)	41 (68.3)[b]	108 (61)	<0.001
	Respondents	12 (21.4)	38 (62.3)[ac]	19 (31.7)	69 (39)	
Intragroup *P* (6-12 month)		0.109	0.999	0.687	0.049	

Pearson Chi-square test (Monte Carlo)/McNemar's test (exact)/a: Significant compared with the CSS group; b: Significant compared with the FS group; c: Significant compared with the LDH group; VAS: Visual analog scale

Table 2B: The detailed follow-up data of patients according to 40% reduction in Oswestry disability indices

		Central spinal stenosis a	Foraminal stenosis B	Lumbar disc herniation c	Total	*P*
ODI response		*n* (%)	*n* (%)	*n* (%)	*n* (%)	
6th month	Non-respondents	40 (71.4)[b]	27 (44.3)	40 (66.7)[b]	107 (60.5)	0.007
	Respondents	16 (28.6)	34 (55.7)[ac]	20 (33.3)	70 (39.5)	
12th month	Non-respondents	44 (78.6)[b]	22 (36.1)	44 (73.3)[b]	110 (62.1)	<0.001
	Respondents	12 (21.4)	39 (63,9)[ac]	16 (26.7)	67 (37.9)	
Intragroup *P* (6-12 month)		0.289	0.125	0.289	0.678	

Pearson Chi-square test (Monte Carlo)/McNemar's test (exact)/a: Significant compared with CSS group; b: Significant compared with FS group; c: Significant compared with LDH group, ODI: Oswestry Disability Index

Table 3: The change of visual analog scale pain scores among subgroups at the end of 12 months

Change of VAS	Central spinal stenosis A Med (min-max)	Foraminal stenosis B Med (min-max)	Lumbar disc herniation C Med (min-max)	Total	*P*	Comparison of subgroups A-B *P*	A-C *P*	B-C *P*
Preinjection-postinjection	7 (0/9)	7 (0/10)	6 (1/10)	7 (0/10)	0.501	ns	ns	ns
Preinjection-15 days	5 (0/8)	5 (0/10)	4 (0/9)	5 (0/10)	0.004	0.752	0.113	0.003
Preinjection-6 months	3 (0/7)	5 (0/10)	3 (0/8)	4 (0/10)	0.002	0.007	0.999	0.011
Preinjection-12 months	3 (1/9)	5 (0/10)	3 (0/9)	4 (1/10)	<0.001	<0.001	0.637	0.004

Friedman Test (Monte Carlo)–Kruskal–Wallis Test (Monte Carlo)/*Post hoc* test: Dunn's Test - Med.: Median - Max.: Maximum - Min.: Minimum; VAS: Visual analog scale

Table 4: Patient outcomes at the end of 12 months

	CSS *n* (%)	FS *n* (%)	LDH *n* (%)	TOTAL *n* (%)	*P*
Non-respondents	46 (82.1)[b]	25 (41)	46 (76.7)[b]	117 (66.1)	<0.001
Respondents	10 (17.9)	36 (59)[ac]	14 (23.3)	60 (33.9)	

Fisher–Freeman–Halton (Monte Carlo)/Pearson Chi-square test (Monte Carlo)/a: Significant compared with CSS group; b: Significant compared with FS group; c: Significant compared with LDH group

Table 5: The distribution of patients foraminas corresponding to 50% reduction in visuel analog scale pain ratings at the end of 6th and 12th month

Foramina	VAS RESPOND 6th month		VAS RESPOND 12th month		*P*
	nonresponder *n* (%)	responder *n* (%)	nonresponder *n* (%)	responder *n* (%)	
L2-3	3 (3.0)	5 (6.4)	4 (3.7)	4 (5.8)	0.999
L3-4	28 (28.3)	15 (19.2)	29 (26.9)	14 (20.3)	0.999
L4-5	44 (44.4)	41 (52.6)	51 (47.2)	34 (49.3)	0.065
L5-S1	24 (24.2)	17 (21.8)	24 (22.2)	17 (24.6)	0.999
P	0.367		0.717		

Fisher Freeman Halton (Monte Carlo), McNemar Test (exact). VAS: Visuel analog scale

Discussion

Transforaminal epidural steroid injection has been applied in many different spinal pathologies until now. However, there is a lack of publications about the efficacy of this intervention in different spinal pathologies. To our knowledge, there is no other literature reporting the results of TFESI in different spinal pathologies except the study performed by Kanayama *et al*.[7] Our study is different in terms of inclusion of one year follow-up results of patients who had received one session of TFESI. In the previous studies, pain and functional life scales were limited to short-terms (1-3 months), considering that the efficacy of the combination of steroid and local anesthetics is often short. Nevertheless, we gathered the one year results of the patients and compared the clinical results in different spinal pathologies in the present study.

Spinal stenosis is one of the most common degenerative spinal pathologies after 60 years of age. Spinal stenosis is characterized by narrowing of the central spinal canal, compression of the lateral recess and neuroforamen. It is widely known the main complainment in patients with CSS is neurologic cladication. The radicular pain that patients suffer in CSS group was associated with accompanying lateral recess stenosis and it has been reported in many previous studies that lateral recess stenosis is one of the most important causes of radicular pain in patients with spinal stenosis.[12-14] In our study, patients with central canal stenosis and accompanying lateral recess stenosis were studied. In our severity classification, grade 3 axial planar spinal canal narrowing and lateral recess stenosis were detected at a ratio of 71.2% of our cases. Different outcomes have been reported in many studies which report the results of spinal stenosis cases in the literature.[15-18] In the randomized prospective study of Davis *et al*. patients with spinal stenosis were divided into 3 groups (mixed, foraminal and lateral recess stenosis) and avoidance of surgery was evaluated as a success criterion.[19] In the study group, only 40% of the patients with lateral recess stenosis recovered after the procedure, 37% were operated, 14% had second TFESI procedure and 7% applied to the algology departments. Lutz *et al*. also reported that in patients with lateral recess stenosis, TFESI had worse outcome.[20]

In the present study, the 1-year results were good only in 10 patients (17.9%) in CSS + LRS group. When FS group was compared to CSS + LRS group, statistically significant difference was found at the end of 12 months. The results of our patients with central stenosis showed slightly difference from the literature. One of the reasons for this was the number of our patients with lateral recess stenosis was higher than the other studies. Besides unlike the other studies, TFESI procedure was performed only once in our study. In the studies reporting long-term outcomes, recurrent TFESI procedures were applied to patients with persisting complaints.[16-19] As another reason, the parameters we used as outcome measure were more strict than other studies (both 50% decrease in VAS and 40% decrease in ODI). There is only one similar study which was performed by Botwin *et al*. in the literature.[18]

The good outcomes of foraminal stenosis is because of the slow and chronic pathogenesis of the disease. Injection made directly to the inflamation area ensures that the process is effective.[21] In the patients with foraminal stenosis, perineural adhesions in the intervertebral foramen cause the injection to be trapped in the foramen.[22] We think that the trapped injection in this region has a longer efficiency unlike the other pathologies. In accordance with this hypothesis, the rate of patients who responded to treatment at the end of the first year in the foraminal injection group was found to be 59% in the present study. Kabatas *et al*. also reported good one year results at a ratio of 55%.[23]

Lomber disc herniations are one of the most common spinal pathologies. TFESI is usually applied in lomber disc herniations as one of the nonsurgical methods in cases that do not respond to drug treatment. Different results have been reported in many studies about TFESI application in

the literature. In the study performed by Ghahreman *et al*., treatment was successful in 26% of lomber disc herniation patients with high grade nerve root compression.[24] Kanayama *et al*. defined the rate of obviating surgery as a success criterion and the results were good in %42 of the patients.[7] Karppinen *et al*. also found that short-term results were good for lomber disc herniations, but long-term efficacy was absent.[25] Cohen *et al*. reported that short-term (3 months) results of epidural steroid application was satisfactory (50%) in lomber disc herniations but this rate decreased to 29% by 6 months.[26]

In the present study, we identified 1-year success rate as 23.3%. The reason we could not provide satisfactory results in the lomber disc herniation group may be that 71.7% of patients had grade 3 nerve root compression. Another reason is that the nerve is always exposed to the repetitive and irritative compression from the same point and this effect is usually due to the median side of the root. Besides that, the intervention is frequently performed one level distally to the affected root and the medication is taking a long epidural route to reach the pathology area, reducing the efficacy of the drug.

The strength of our study is to assess the long term results of a single TFESI procedure with reliable outcome measures in different spinal pathologies. If we did not use these outcome measure parameters, we could not understand whether TFESI was really effective both in the meaning of pain control and function improvement.

There are limitations in our study. One of them is the retrospective design. Secondly, patients who respond well to injections at the end of one year with a single TFESI procedure might had additional benefits from drug therapy or pyhsical therapy. However, the effects of these treatments would be very limited because patients who were refractory to these treatments were enrolled in the study as we mentioned in the inclusion criteria.

Conclusion

TFESI is a treatment modality with long-term efficacy in patients with isolated foraminal stenosis. It should be kept in mind as an important alternative treatment method in patients with advanced age and high surgical morbidity. Although this procedure gives good short-term results in patients with disc herniations and central spinal stenosis, it seems to provide inadequate long-term results. We think that randomised controlled trials in larger groups of patients will provide more accurate and informative results.

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the declaration of Helsinki. All participants provided informed consent.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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