Prospective Study

Comparison of Caudal Versus Transforaminal Epidural Steroid Injection in Post Lumbar Surgery Syndrome After Single-level Discectomy: A Prospective, Randomized Trial

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Background: Epidural fibrosis (EF) is one of the leading causes of post lumbar surgery syndrome (PLSS). Although there are studies in the literature suggesting that lumbar epidural steroid injections are an effective method in the pain management of PLSS caused by EF, no study is available comparing the effectiveness and safety of caudal and transforaminal approaches.

Objectives: To investigate the efficacy of caudal epidural steroid injection (CESI) versus transforaminal epidural steroid injection (TFESI) in patients with PLSS.

Study Design: A prospective, randomized, assessor-blind study.

Setting: Interventional pain management center at a tertiary care center.

Methods: Patients with low back and radicular pain related to EF following single-level lumbar discectomy were included. The patients were randomly divided into 2 groups: a CESI group and a TFESI group. All patients were assessed before the procedure (baseline) and at one hour, 3 weeks, and 3 months after the procedure using the Numeric Rating Scale (NRS-11) and at baseline, 3 weeks, and 3 months using the modified Oswestry Disability Index (mODI). Treatment success was defined as a ≥ 50% decrease in the NRS-11 scores compared to baseline.

Results: A total of 56 patients (n = 26 CESI group; n = 30 TFESI group) were included. NRS-11 and mODI scores showed a significant decline in both groups at all follow-ups ($P < 0.001$). At 3 weeks, the improvement in the mODI scores was significantly higher in the TFESI group ($P = 0.020$). In all follow-ups, the NRS-11 scores were similar between the groups. At 3 weeks, the rates of patients with a ≥ 50% decrease in NRS-11 scores were 53.8% and 60% in the CESI group and TFESI group, respectively, while these rates were 30% and 26.7%, respectively, at 3 months.

Limitations: This study had no placebo-control group and a relatively short follow-up.

Conclusion: Both CESI and TFESI are effective and safe methods in the treatment of PLSS caused by EF following lumbar discectomy. These methods can reduce pain and disability. Although both methods have similar treatment success rates, TFESI seems to be a more effective treatment method in reducing disability at 3-week follow-up.

Keywords: Post lumbar surgery syndrome, failed back surgery syndrome, post laminectomy syndrome, epidural fibrosis, epidural steroid injections, transforaminal, caudal, radiculopathy, back pain

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Lumbar disc herniation (LDH) is one of the most frequent indications for lumbar spine surgery. Surgical discectomy is an effective method in the treatment of lumbosacral radicular pain in patients who are refractory to noninvasive treatments (1). However, it is not always a solution for pain relief (2). In the majority of patients (90%), favorable results can be achieved with surgical treatment, while 10% may experience chronic low back pain and/or radicular pain (3). Post lumbar surgery syndrome (PLSS) is a term to describe persistent or recurring pain of unknown origin after spine surgeries. It has been thought that epidural fibrosis (EF), perineural scars, acquired stenosis, recurrent disc herniation, or sacroiliac/facet joint pain play a role in the etiology of PLSS (4). Among them, EF is one of the leading causes of PLSS, accounting for about 8% to 60% of the cases (5,6).

Revision surgery aiming at adhesiolysis and scar resection is challenging and ineffective in the treatment of PLSS with high complication rates (7,8). Considering the high failure rate of reoperations, minimally invasive interventional procedures should be considered for pain management in these patients (9). Although the use of epidural steroid injections (ESIs) has decreased in the treatment of chronic pain in recent years, these injections are still widely utilized, particularly transforaminal ESIs (TFESIs) (10-12). Several studies have shown that caudal ESI (CESI) is an effective method in patients with PLSS who are unresponsive to conservative pain-relieving therapies (13-18). TFESI and interlaminar ESI are the other outpatient procedures. However, TFESI is more widely used and is a target-specific option with better drug delivery into the ventral epidural space where pathological alterations occur (19). The interlaminar approach lacks target specificity and distribution of the injectate into the dorsal space; the risk of dural puncture particularly increases due to adhesions at the laminectomy site (7).

Although there are studies in the literature suggesting that ESI is an effective method for pain management in PLSS, no study is available comparing the effectiveness of different ESI methods. In the present study, therefore, we aimed to investigate the efficacy of CESI versus TFESI in patients with PLSS and to provide a contribution to the body of knowledge on this topic in the literature.

Methods

Study Design and Study Population

This single-center, assessor-blinded, prospective, randomized study was conducted at Marmara University, Faculty of Medicine, Department of Pain Medicine. Prior to study, all patients were informed about the nature of the study and a written informed consent was obtained. The study was approved by the Marmara University, Faculty of Medicine, Ethics Committee with the approval number 09.2014.0085. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patients who were admitted with radiating pain to the low back and lower limbs and diagnosed with EF-related PLSS based on physical examination and contrast medium-enhanced spinal magnetic resonance imaging (MRI) findings were included. Inclusion criteria were as follows: age between 18 and 65 years; previous single-level, open, nonfusion discectomy for L4-5 or L5-S1 LDH within the past 6 months; having EF involving the L4, L5 or S1 nerve root seen on MRI; having low back and leg pain for at least 6 months and unresponsive to conservative therapies; a Numeric Rating Scale (NRS-11) score of ≥ 4; and having a single-level EF in the operated level and side as assessed by contrast medium-enhanced spinal MRI (20). Exclusion criteria were as follows: having a multilevel EF; previous surgery for mulilevel disc herniation; previous lumbar fusion surgery; having recurrent disc hernia; having sacroiliac/facet joint pain; having lumbar spinal stenosis, spondylolysis, spondylolisthesis, or scoliosis; a history of ESI within the past 6 months; having bleeding diathesis; presence of systemic or local infections; pregnancy; and known hypersensitivity to the injectates to be administered.

Randomization

Randomization was performed using computer-generated random numbers. The patients were divided into 2 groups: the CESI (n = 31) group and the TFESI (n = 31) group (Fig. 1). In the TFESI group, the spinal nerve root compressed by EF as assessed by physical examination and MRI findings was identified and a single-level TFESI was applied.

Data Collection and Assessment

Demographic and clinical characteristics of the patients including age, gender, body weight, operation level, and duration of pain were recorded. The pain severity was evaluated using the NRS-11 before the procedure (baseline) and at one hour, 3 weeks, and 3 months after the procedure. Functional results were assessed using the modified Oswestry Disability Index (mODI) at baseline, 3 weeks, and 3 months after the

procedure. Demographic data, preprocedural and postprocedural data, follow-up results, and treatment outcomes were documented by a physiatrist who was blind to the group allocation.

All procedures were performed under the guidance of fluoroscopy by a pain medicine specialist with a minimum of 10 years experience in ESI application. The specialist interpreted physical examination and MRI findings and decided the level of injection in the TFESI group. The initiation of analgesics was not allowed throughout the study and no adjustment was made for patients receiving analgesics prior to the study.

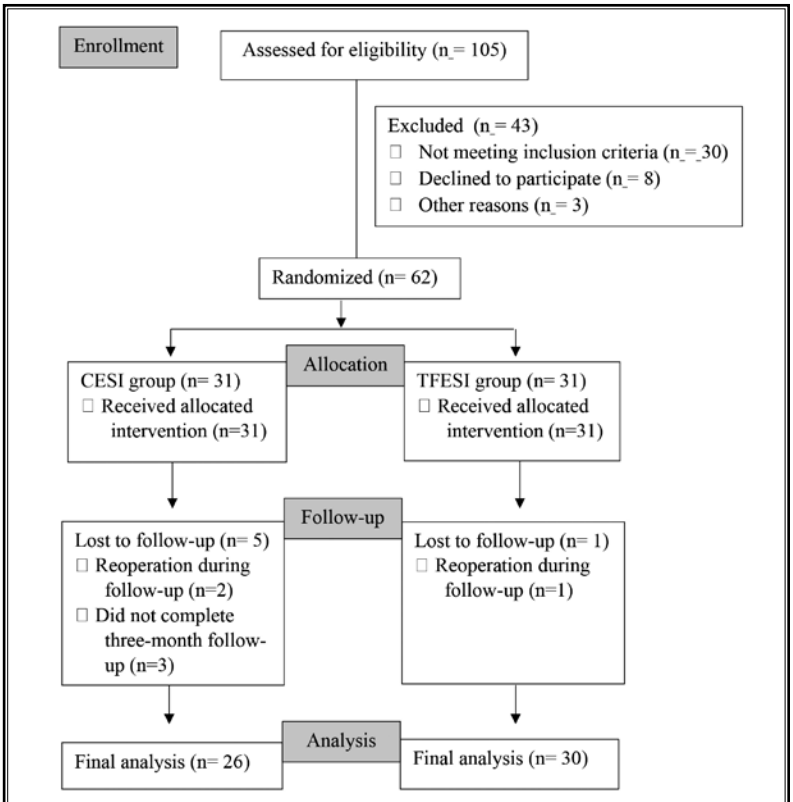


Fig 1. *Patient flow diagram.*

Treatment Protocols

In the TFESI group, all patients were positioned prone. The injection site was cleaned with povidone-iodine 3 times and a sterile drape was applied. The arm of the fluoroscope was rotated 0° to 30° oblique position and 0° to 15° cranial angulation and the foramen was visualized. Short-acting local anesthesia (3 mL of 2% prilocaine) was applied to the skin and subcutaneous tissue. A 3.5-inch, 22-gauge spinal needle was inserted just below the pedicle. It was advanced into the subpedicular space using the coaxial technique under the intermittent guidance of fluoroscopy. The needle position was confirmed through a lateral view. Using lateral views, the needle was placed at the posterior one-third of the foramen. Using the anteroposterior view, one to 2 mL of the contrast agent (300 mg/50 mL iohexol) was given and the distribution pattern was visualized. Once the epidural distribution of the contrast agent was confirmed without vascular flow, a mixture of 40 mg (one mL) of triamcinolone acetonide, 2 mL of physiological saline, and 2 mL (0.5%) of bupivacaine was injected.

In the CESI group, the sacral hiatus was visualized from the lateral view under the guidance of fluoroscopy. Short-acting local anesthesia (3 mL of 2% prilocaine) was applied to the skin and subcutaneous tissue. A 3.5-inch, 22-gauge spinal needle was inserted to the caudal epidural space under the intermittent guidance of fluoroscopy. Using the anteroposterior view, the needle was confirmed not to surpass the S3 foramen level. One to 2 mL of the contrast agent (300 mg/50 mL iohexol) was given and the distribution pattern was visualized, which showed bilateral L5-S3 distribution without vascular flow. A mixture of 40 mg (one mL) of triamcinolone acetonide, 7 mL of physiological saline, and 2 mL (0.5%) of bupivacaine was injected. A total mixture of 10 mL was used for CESI (21).

All patients were followed for one hour after the procedure and evaluated at one hour. The patients without any procedural complications were discharged.

Statistical Analysis

Statistical analysis was performed using SPSS for Windows version 24.0 software (IBM Corp) Descriptive data were expressed in mean ± standard deviation (SD) or median (interquartile range [IQR] 25th-75th) or number and frequency, where applicable. The normality of the distribution of continuous variables was tested using the Shapiro-Wilk test. The Mann–Whitney U test or Student's t-test or was performed to compare quantitative variables. The Friedman test was carried out to analyze median NRS-11 and mODI scores after CESI and TFESI procedure during follow-up. The χ^2test

or Fisher's exact test was used to analyze categorical variables. A *P* value of < 0.05 was considered statistically significant.

Results

The evaluation included 105 patients. As a result of the exclusion criteria, 62 patients were included in the analysis and randomized from January 2016 through January 2020, out of whom 3 were excluded from the study, as they did not complete their 3-month follow-up and 3 patients were excluded due to reoperation during follow-up. A total of 56 patients were included in the final analysis (n = 26 in the CESI group and n = 30 in the TFESI group) (Fig. 1).

The mean age was 53.4 ± 11.2 years in the CESI group and 51.8 ± 12.6 years in the TFESI group. The median duration of symptoms in the CESI and TFESI groups was 23 and 26 months, respectively. Baseline demographic and clinical characteristics of the patients are shown in Table 1.

Both groups showed a statistically significant improvement in the median NRS-11 scores in all time points (*P* < 0.001). Although baseline NRS-11 scores were similar, median NRS-11 scores at 3 weeks were lower in the TFESI group, although it did not reach statistical significance (*P* = 0.190). However, median NRS-11 scores were similar between the groups at 3 months (*P* = 0.590) (Table 2, Fig. 2). At 3 weeks, the rates of patients with a ≥ 50% decrease in NRS-11 scores were 53.8% and 60% in the CESI group and TFESI group, respectively, while these rates were 30% and 26.7%, respectively at 3 months (Table 2).

Both groups showed a statistically significant improvement in median mODI scores in all time points (*P* < 0.001). In the TFESI group, median mODI scores were significantly lower at 3 weeks (*P* < 0.050) (Fig. 3). However, similar mODI scores were achieved in both groups at 3 months.

During the procedure, the needle was repositioned in 5 patients due to an intravascular contrast filling pattern (n = 4 in the TFESI group and n = one in the CESI group). After the procedure, hypotension due to vasovagal reactions was seen in 4 patients (n = 2 in the TFESI group and n = 2 in the CESI group). Temporary motor block was observed in the lower extremity in 7 patients (n = 5 in the TFESI group and n = 2 in the CESI group). Procedure-related side effects were transient and completely resolved after a short time.

Table 1. *Baseline demographic and clinical characteristics of patients.*

Variable	CESI (n = 26)	TFESI (n = 30)	*P* value
Gender, n (%)			
Men	17 (65.4%)	21 (70%)	0.700
Women	9 (34.6%)	9 (30%)	
Age, years (mean ± SD)	53.4 (±11.2)	51.8 (±12.6)	0.470
BMI, kg/m^2, median (IQR)	29.6 (27.2-32.6)	28.2 (24.7-32.5)	0.620
Symptom duration, months (IQR)	23 (16.5-51)	26 (12-52)	0.910
Medication, n (%)			
NSAID use, n (%)	12 (46.2%)	8 (26.7%)	0.200
Pregabalin	9 (34.6%))	9 (30%)	
Gabapentin	4 (15.4%)	7 (23.3%)	
Amitriptyline	1 (3.8%)	4 (6.7%)	
Duloxetine	0	2 (13.3%)	

Data are given in mean ± SD, median (IQR) or n (%), unless otherwise stated. CESI: caudal epidural steroid injection, TFESI: transforaminal epidural steroid injection, BMI: body mass index; NSAID: nonsteroidal anti-inflammatory drug; SD: standard deviation; IQR: interquartile range.

Discussion

In the present study, we compared the efficacy of CESI versus TFESI in patients with PLSS who underwent discectomy for LDH. Our study results showed that both methods yielded favorable results for pain and disability at all time points in both groups. However, the improvement in mODI scores was statistically significantly higher at 3 weeks in the TFESI group than the CESI group. Although not statistically significant, the improvement in the NRS-11 scores at 3 weeks was greater in the TFESI group than the CESI group. At the 3 month follow-up, the rates of patients with ≥ 50% decrease in NRS-11 scores were 30% and 26.7%, in the TFESI and CESI groups, respectively.

Previous studies have shown that ESI has a relatively low efficacy in fixed lesions such as EF leading to spinal nerve root compression, compared to disc herniation (15). However, there is a limited number of studies investigating the efficacy of ESI in PLSS patients in the literature. In a study, Rosenberg et al (22) assessed the effectiveness of TFESI in patients who underwent surgical treatment for radiculopathic back pain and found that TFESI provided no significant improvement in pain at any timepoints up to one year. In this study, the type of low back surgery and the origin of pain were not clarified and, therefore, these results can be attributed

Table 2. *Comparison of NRS and mODI scores according to treatment method.*

Variable	CESI (n = 26)			TFESI (n = 30)			*P* value
NRS-11, median (IQR)	**median**	**IQR**	**%**	**median**	**IQR**	**%**	
Baseline	7	6-9		8	7-9		0.290
After the injection (one h)	0	0-3.25	100	0	0-1.25	100	0.480
Third week	5	2-6.25	50	2.5	1-6	63.3	0.190
Third month	5.5	3-8	12.7	6	3.5-7.25	26.8	0.590
P value	<0.001			<0.001			
mODI							
Baseline	56	48-72		52	44-63		0.300
Third week	41	31.5-55.5	13.9	29	17.5-44	40.4	0.020
Third month	51	31.5-62	3.6	46	30-54	15.2	0.180
P value	<0.001			<0.001			
Patients with ≥ 50% decrease in NRS-11, n (%)							
Third week	14 (53.8%)			18 (60%)			0.600
Third month	8 (%30.8)			8 (26.7%)			0.700

Data are given in median (IQR) or n (%), unless otherwise stated. CESI: caudal epidural steroid injection, TFESI: transforaminal epidural steroid injection, NRS-11: Numeric Rating Scale; mODI: modified Oswestry Disability Index; IQR: interquartile range.

Fig 2. *Comparison of median NRS-11 scores.* NRS-11: Numeric Rating Scale. CESI: caudal epidural steroid injection. TESI: transforaminal epidural steroid injection.

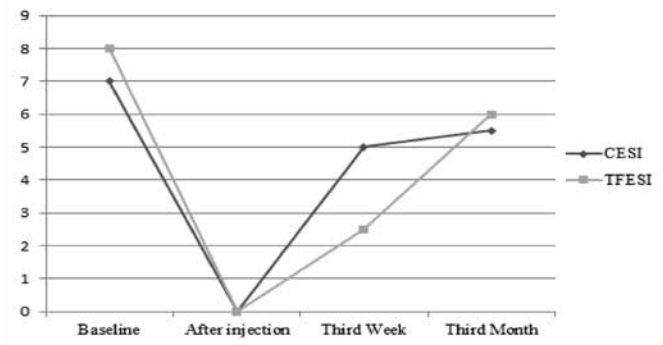
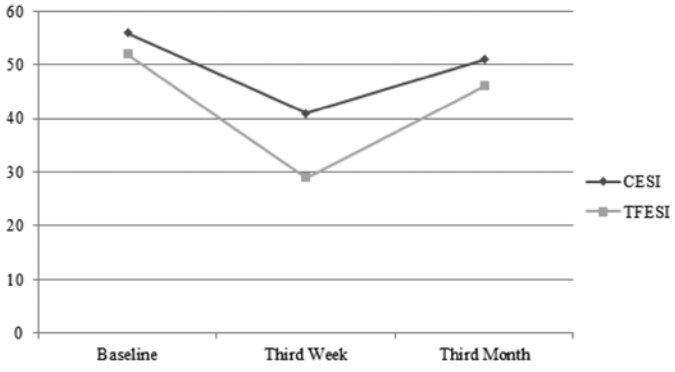


Fig. 3. *Comparison of the median mODI scores.* mODI: Modified Oswestry Disability Index. CESI: caudal epidural steroid injection. TESI: transforaminal epidural steroid injection.



to the heterogeneous study population. In another study, Lee et al (4) compared the clinical effectiveness of percutaneous adhesiolysis versus TFESI in patients with PLSS and found the treatment success to be 33.9% in the TFESI group at 6 months (4). In our study, the treatment success rate was 26.7% at 3 months and comparable between the groups.

In a double-blind, randomized control study, Manchikanti et al (14) investigated the effectiveness of fluoroscopically directed, repeat caudal epidural injections with or without steroids in the treatment of chronic low back pain and lower extremity pain after PLSS. The patients were divided into 2 groups: Group I received 0.5% lidocaine and Group II received 9 mL of 0.5% lidocaine mixed with one mL of 6 mg of nonparticulate beta-

methasone. At one-year follow-up, the improvement rates with decreased pain and disability scores were 53% and 47% in Group I and Group 2, respectively. At 2 years, these rates were 59% and 58% in Group I and Group 2, respectively.

In our study, the lower treatment success rate at 3 months can be attributed to the lack of repeated injections. In the study by Akkaya et al(17), ultrasound versus fluoroscopy-guided CESIs were compared in patients with PLSS. The authors found a significant decrease in both pain and ODI scores in both groups during a 3-month follow-up period and concluded that CESI was an effective analgesic method in the treatment of PLSS. These results are consistent with our study findings. However, significantly lower mODI scores and remarkably lower NRS-11 scores at 3 weeks in the TFESI group in our study can be attributed to the fact that the TFESI injectate could be delivered effectively into the ventral epidural space where pathological alterations occur.

In the present study, the treatment success rates were relatively low in both groups. This can be explained by several factors. As mentioned above, EF, perineural scars, acquired stenosis, recurrent disc herniation, or sacroiliac/facet joint pain may be implicated in the etiology of PLSS (4). In one study, PLSS was secondary to facet joint pain in 16% of patients and a lumbar facet joint nerve block plays a key role in the diagnosis at a moderate to strong recommendation level (23,24). Some authors also have suggested that sacroiliac joint pain is common after lumbar decompressive surgery without instrumentation (25).

Although sacroiliac/facet joint-related pain can be misdiagnosed as radicular pain, axial low back pain is a predominant symptom in sacroiliac/facet joint-related pain (26). In our study, we included patients with low back pain and radicular pain and carried out a meticulous patient selection process. However, we were unable to assess sacroiliac/facet joint-related pain through diagnostic block testing. Therefore, all PLSS-related factors could not have been eliminated in this study. Additionally, EF may prevent drug delivery into the affected site (7). This can be recognized based on the presence of a filling defect following contrast agent administration during the procedure. In patients with EF-related filling defect, percutaneous adhesiolysis could be a more appropriate treatment method that has been shown to be effective in EF (27).

In our study, we confirmed epidural distribution of the contrast agent without intravascular flow; however, we did not evaluate the distribution pattern of the contrast agent. Furthermore, Ghahreman et al (28) examined clinical and radiological characteristics predictive of a favorable response to TFESI by grading the spinal nerve root compression related to LDH and found that it was effective in patients without significant compression of the nerve root. We performed no subgroup analysis by grading the spinal nerve root compression related to EF and, thus, relatively low treatment success rates in the TFESI group can be attributed to the presence of high-grade compression of the nerve root in these patients that deserves further investigation.

EF following spinal surgery is a natural formation of excessive scar tissue at the surgical site characterized by epidural fat replaced by fibrotic tissues (29). It may cause lateral spinal stenosis, leading to an entrapped nerve root, nerve root irritation, and even epidural blockade. Collagen fibers surrounding the nerve tissue may lead to arterial tissue perfusion and decreased venous return. Compression and fixation result in inflammation and edema of the nerve root. Fixation can be seen in the dorsal or ventral epidural space (30).

Although the mechanism of action of ESIs in pain relief is still unclear, several theories have been proposed. One of the most widely accepted theories is that steroid injection exerts anti-inflammatory effects through the inhibition of phospholipase A2, an inflammatory enzyme, and proinflammatory cytokines (9). In addition, steroids and local anesthetics have been thought to inhibit pain by interfering with the conduction of the ectopic discharge and normal nonmyelinating C fibers in the spinal nerve root compressed through the effect of neural membrane stabilization. Local anesthetics may increase the blood flow of an ischemic spinal nerve root (19). They may also exert their effects by removing inflammatory cytokines due to the washout effect of the injection material and adhesiolysis of the scar tissue (17).

CESI has been shown to be the most safe and simple ESI with a low complication rate, including dural puncture and other adverse effects compared to other methods of injections (31). It has been also applied to patients with coagulation disorder and coagulopathy, as it is a safer method than interlaminar ESI and TFESI (32). In addition, CESI has superior advantages, as it exerts its effect on a broad field with high-dose administration in a single session in patients with PLSS who usually have multiple pain sites (33). In their study, Mohamed et al (34) applied caudal epidural injection to patients with different levels (L4-5 and L5-S1) of disc

pathologies (34). They found no significant difference in the disability, pain relief, and patient satisfaction between the groups. In light of these data, we also included patients with different levels (L4-5 and L5-S1) of spinal nerve root compression.

Intravascular penetration and vasovagal reactions are the most frequent complications of TFESI (31,35). In our study, both were the most common complications, consistent with the literature. None of the patients experienced serious complications during or after the procedure.

On the other hand, conus infarction following TFESI has been reported in the literature, although it is limited to case reports (36-38). This catastrophic complication is more common in patients who have had previous lumbar spine surgery (37). This can be attributed to neovascularization in the scar tissue in these patients (39). Direct arterial injury and consequent thrombus formation, and occlusion caused by vasospasm and particulate steroids, have been implicated in the etiology of conus infarction (32,36). Although extremely rare, so-called red flag symptoms may occur, such as lower limb paralysis and difficulty in urination and bowel movement; therefore, special care should be paid to patients undergoing TFESI.

The selection of particulate versus nonparticulate steroids is also of utmost importance in ESI. Recent studies have shown a similar efficacy profile for particulate and nonparticulate steroids and, currently, there is a growing trend to adopt nonparticulate steroids in clinical practice, particularly to avoid particulate steroid-related neurological complications such as conus infarction (32). In a study including Spine Intervention Society physicians, Clements et al (40) reported that 41% of the physicians used a particulate steroid in lumbar TFESI with a substantial variability in particulate and nonparticulate steroid choice for ESI in practice. In another study, Chatterjee et al (41) showed that methylprednisolone, a particulate steroid, yielded a significant longer term pain relief than dexamethasone following TFESI (41). In the literature, no consensus has yet to be reached upon this subject. Additionally, particulate steroids have been utilized in many studies in recent years (42-44). However, due to the serious concerns regarding the safety profile of particulate steroids, nonparticulate steroids could have been used in our study. Also, repeated injections are associated with increased effectiveness in patients with radiculopathy having short-term pain relief and/or who are unresponsive to ESI (45). In our study, the low treatment success rates can be attributed to the lack of repeated injections.

Nonetheless, there are some limitations to the present study. Small sample size, short-term follow-up, using particulate steroid, and the lack of repeat injections and a control group are the main limitations. However, our study cohort is homogeneous, as those with PLSS related to EF were only included. The main strength of this study is that, to the best of our knowledge, it is the first study to compare the efficacy of CESI versus TFESI in patients with PLSS and to provide a contribution to the body of knowledge on this topic in the literature.

Conclusion

Both CESI and TFESI are effective and safe methods in the treatment of PLSS caused by EF following lumbar discectomy. These methods can reduce pain and disability. Although both methods have similar treatment success rates, TFESI seems to be a more effective treatment method in reducing disability at 3-week follow-up. Further large-scale, long-term, prospective, randomized control studies are needed to gain a better understanding of these methods in the treatment of PLSS.

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