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COMPARISON OF THE EFFECTIVENESS OF TRANSFORAMINAL EPIDURAL STEROID INJECTION ALONE WITH THAT OF COMBINED TRANSFORAMINAL AND CAUDAL EPIDURAL STEROID INJECTION IN MULTI-LEVEL LUMBAR DISC DISEASE

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ABSTRACT

Objective: This study compared the effectiveness of transforaminal epidural steroid injection (TFESI) alone with that of combined transforaminal and caudal epidural steroid injection (CESI) in multi-level lumbar disc disease, which does not require surgery and does not respond to conservative treatment.

Materials and Methods: A total of 99 patients, who were administered TFESI alone or in combination with CESI for radicular pain between November 2018 and August 2019, were analysed retrospectively.

Results: The visual analogue scale (VAS) and the Oswestry Disability index (ODI) scores of the patients were evaluated in the pre-injection and post-injection periods in the 3rd week, 3rd month and 6th month. Both the ODI and VAS scores were significantly lower in the early and late post-injection periods than in the pre-injection period in both groups. Combined TFESI and CESI for multi-level lumbar disc disease provided significant improvement in pain management and functional capacity compared with TFESI alone.

Conclusion: Combined transforaminal and CESIs should be considered in patients with multi-level lumbar disc disease, which is difficult to manage.

Keywords: Multi-level disc disease, lumbar, transforaminal, caudal, epidural steroid injection

INTRODUCTION

Intervertebral disc disease is the most common cause of lumbosacral radiculopathy. Approximately 10-15% lumbar disc diseases require surgical treatment[1,2]. Radiculopathy is treated by conservative treatment options, such as bed rest, medical treatment and physical therapy[3-5]. Multi-level lumbar disc disease is a common clinical entity and can occur at any age; however it is common in the elderly[6]. The treatment of multi-level lumbar disc disease is controversial. Most agree that conservative treatment should be the first option, unless surgical indications are absolute[7].

Epidural steroid injection (ESI) is a minimally invasive treatment for patients who do not benefit from conservative treatments and do not require surgery[8]. ESI can be performed through the pre- or post-ganglionic transforaminal, interlaminar or caudal route. The choice of method depends on the aetiology and location of pain[9-13].

This study aims to compare the effectiveness of transforaminal epidural steroid injection (TFESI) alone with that of combined transforaminal and caudal epidural steroid injection (CESI) in multi-level lumbar disc disease that does not require surgery or respond to conservative treatment.

MATERIALS AND METHODS

Since it is a retrospective data analysis, ethics committee approval is not required. Informed consent was obtained from the patients.

Patient Inclusion and Exclusion Criteria

The medical records of patients, referred to our clinic between November 2018 and August 2019, with unilateral or bilateral radicular leg pain or multi-level lumbar disc disease (bulging and/or protrusion) detected by magnetic resonance imaging (MRI) (Figure 1A-C), with no neurological deficits, for whom symptoms were not relieved by conservative treatment, who were not candidates for surgery, and did not undergo TFESI alone

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or combined TFESI and CESI, were analysed retrospectively. Patients who had single-level lumbar disc herniation; lumbar spinal stenosis or spondylolisthesis; previous lumbar surgery or injection; psychiatric, oncologic and infective disease and spinal trauma history; extruded or sequestered disc herniation visible on the lumbar MRI scan; radicular leg pain for no longer than three months; been getting conservative treatment currently; undergone TFESI or combined TFESI and CESI but had restricted relief with medical or physical therapy; and not been to follow-up examinations were excluded from this study.

Intervention (TFESI and CESI) Procedure

TFESI and CESI were performed in the operating room by the same surgical team on the prone patient. All patients had intravenous access. Blood pressure, electrocardiogram, pulse and oxygen saturation were monitored. If necessary, sedation was performed with midazolam and fentanyl.

TFESI Procedure: The vertebral level was determined in the prone position with anterior-posterior (A-P) positioning of the C-arm fluoroscope following skin antisepsis and draping. The C-arm fluoroscope was placed in an oblique position at 15°, and an appropriate view was provided for the intervertebral foramen. Local anaesthetic (1 mg, 1% lidocaine) was applied to the skin and subcutaneous tissue. TFESI was performed using the preganglionic approach described by Lee et al.[14,15] After the skin and subcutaneous tissue were passed, a 21-gauge 90 mm spinal needle (Egemen International, İzmir, Turkey) was directed toward the intervertebral foramen under the guidance of C-arm fluoroscopy. After correct positioning was achieved, the C-arm fluoroscope was placed in the A-P position and 1 mL of contrast solution (Omnipaque 300; iohexol, 300 mg iodine/mL, Amsterdam Health, Princeton, NJ, USA) was injected to control epidural flow (Figure 1D). After the location of the spinal needle was confirmed, aspiration was performed to check for blood or cerebrospinal fluid. Subsequently, 40 mg methylprednisolone acetate (Depo-Medrol, Pfizer İlaç Ltd. Şti., Lüleburgaz, Kırklareli, Turkey) and 10 mg bupivacaine hydrochloride (Marcaine 0.5%, Astra Zeneca, İstanbul, Turkey) were slowly injected for an average of 2 min. The process was repeated for each level.

CESI Procedure: In the prone position, local anaesthetic (1 mg, 1% lidocaine) was applied to the skin and subcutaneous tissue on the upper part of the natal cleft, following skin antisepsis and draping. The 21-gauge, 90 mm spinal needle (Egemen International, İzmir, Turkey) was advanced along the sacrococcygeal ligament under the control of a laterally positioned C-arm fluoroscope and then advanced 1-2 cm into the caudal canal, passing through the sacral hiatus palpated in the middle of both sacral horns (Figure 1E). The level of the spinal needle did not exceed the S2 level in any case. After the aspiration test resulted negative, the position of the spinal needle was confirmed by injecting contrast medium (Omnipaque 300; iohexol, 300 mg iodine/mL, Amsterdam Health, Princeton, NJ, USA). In addition to 40 mg methylprednisolone acetate (Depo-Medrol, Pfizer İlaç Ltd. Co., Lüleburgaz, Kırklareli, Turkey) and 10 mg bupivacaine hydrochloride (Marcaine 0.5%, Astra Zeneca, İstanbul, Turkey), 20 cc of 0.9% sodium chloride was slowly injected. Thereafter, the patients were kept under observation for 2-4 h and discharged. The patients were not given non-steroidal anti-inflammatory drugs except paracetamol.

Pre- and Post-intervention Assessment and Follow-up

The pain scores of the patients were evaluated using the visual analogue scale (VAS), where 0 and 10 indicate the absence of pain and severe pain, respectively. The restriction of the patients' routine activities was evaluated using the Oswestry Disability index (ODI). The VAS and ODI scores of the patients were recorded during the pre-injection period in the 3rd week, 3rd month and 6th month of outpatient clinic visits.

Statistical Analysis

Statistical analyses were performed using the SPSS software version 21 (SPSS, Chicago, IL, USA). The numerical variables were investigated using visual (histograms and probability plots) and analytical methods (Kolmogorov-Smirnov or Shapiro-Wilk test) to determine normal distribution. Mean and standard deviation were used for normally distributed variables, and median and minimum-maximum were used for non-normally distributed variables. The chi-square test or Fisher's exact test were used to compare proportions in different groups. As age was normally distributed, Student's t-test was used to compare between groups. As follow-up time was non-normally

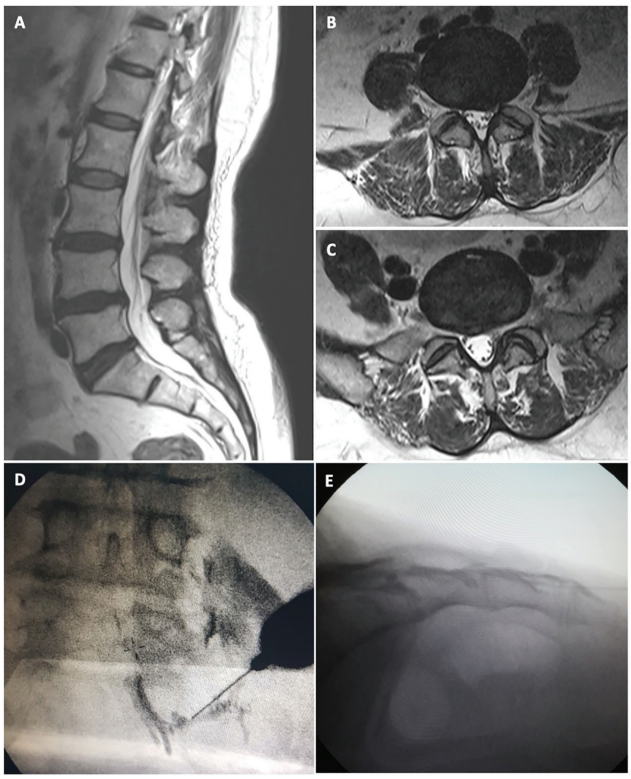

Figure 1. A-C) Pre-injection magnetic resonance imaging. Axial and sagittal sections show multi-level lumbar disc disease. **D)** Transforaminal epidural steroid injection. **E)** Caudal epidural steroid injection

distributed, the Mann-Whitney U test was used for comparison. Repeated measures ANOVA was used to compare VAS and ODI among patients according to the presence or absence of caudal injection. A p value less than 0.05 was considered statistically significant.

RESULTS

Of 99 patients included in the study, 48 were administered TFESI alone, whereas 51 were co-administered TFESI and CESI. The average age of the TFESI group was 47.0±11.2 years and that of the TFESI + CESI group was 45.3±9.2 years. The TFESI group comprised 19 (39.6%) men and 29 (60.4%) women, whereas the TFESI + CESI group comprised 20 (39.2%) mean and 31 (60.8%) women. In the TFESI group, 12 (25%) patients had disc hernias at L3-L4 and L4-L5 and 36 (75%) patients had disc hernias at L4-L5 and L5-S1. In the TFESI + CESI group, seven (13.7%) patients had disc herniation at L3-L4 and L4-L5 and 44 (86.3%) patients had disc hernias at L4-L5 and L5-S1. The median follow-up was determined for 18 months in the TFESI group and 17 months in the TFESI + CESI group. No significant difference was found between the groups in terms of demographics and clinical features (Table 1).

The VAS and ODI scores of the patients were evaluated in the pre- and post-injection periods in the 3rd week, 3rd month and 6th month. The mean VAS score of the patients was 8.29±1.03 in the pre-injection period, 3.51±1.57 in the 3rd week, 4.18±1.50 in the 3rd month, and 6.83±1.18 in the 6th month. Regression in the VAS score was statistically significant in the early, mid, and late periods (p<0.001). In the TFESI group, the mean VAS score was 8.44±0.80 in the pre-injection period, 4.69±1.11 in the 3rd week, 5.17±1.21 in the 3rd month, and 7.44±0.85 in the 6th month. In the TFESI + CESI group, the mean pre-injection VAS score was 8.16±1.21, 2.39±1.04 in the 3rd week, 3.25±1.11 in the 3rd month, and 6.25±1.16 in the 6th month. The VAS scores of the TFESI + CESI group were significantly lower than those of the TFESI group in the 3rd week, 3rd month and 6th month post-injection (p<0.001) (Table 2, Figure 2). The mean ODI score of the patients was 57.37±6.75 in the pre-injection period, 29.96±6.33 in the 3rd week, 31.78±6.43 in the 3rd month, and 53.70±7.23 in the 6th month. Regression in the ODI score was statistically significant in the early, mid, and late periods (p<0.001). In the TFESI group, the mean ODI score was 57.46±5.86 in the pre-injection period, 32.96±6.60 in the 3rd week, 34.46±6.64 in the 3rd month, and 56.38±6.00 in the 6th month. In the TFESI + CESI group, the mean ODI score was 57.29±7.55 in the pre-injection period, 27.14±4.57 in the 3rd week, 29.25±5.12 in the 3rd month, and 51.18±7.43 in the 6th month. The ODI scores of the TFESI + CESI group were significantly lower than those of the TFESI group in the 3rd week, 3rd month and 6th month post-injection (p<0.001) (Table 2, Figure 3).

Table 1. Demographics and clinical characteristics of the study population

	TFESI + CESI (n=51)	TFESI (n=48)	p
Age, years	45.3±9.2	47.0±11.2	>0.05
Gender, n (%)	20 males (39.2) 31 females (60.8)	19 males (39.6) 29 females (60.4)	>0.05
Level			>0.05
L3-L4 + L4-L5, n (%)	7 (13.7)	12 (25)	-
L4-L5 + L5-S1, n (%)	44 (86.3)	36 (75)	-
Follow up, median (min-max)	17 (7-31)	18 (7-32)	>0.05

TFESI: Transforaminal epidural steroid injection, CESI: Caudal epidural steroid injection, min: Minimum, max: Maximum, n: Number

Table 2. Comparison of the results of TFESI alone with combined TFESI and CESI

	Pre-injection	3th week	3th month	6th month	p
VAS					
Total	8.29±1.03	3.51±1.57	4.18±1.50	6.83±1.18	<0.001
TFESI + CESI	8.16±1.21	2.39±1.04	3.25±1.11	6.25±1.16	<0.001
TFESI	8.44±0.80	4.69±1.11	5.17±1.21	7.44±0.85	<0.001
ODI					
Total	57.37±6.75	29.96±6.33	31.78±6.43	53.70±7.23	<0.001
TFESI + CESI	57.29±7.55	27.14±4.57	29.25±5.12	51.18±7.43	<0.001
TFESI	57.46±5.86	32.96±6.60	34.46±6.64	56.38±6.00	<0.001

TFESI: Transforaminal epidural steroid injection, CESI: Caudal epidural steroid injection, VAS: Visual analog scale, ODI: Ostwestry Disability index

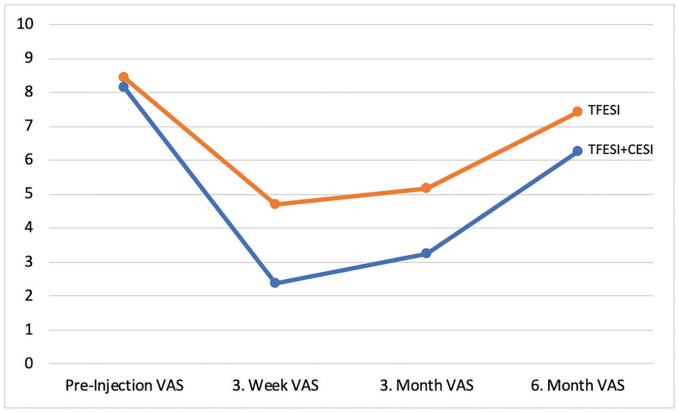

Figure 2. Changes in visual analogue scale (VAS) score of the transforaminal epidural steroid injection (TFESI) alone and TFESI + caudal epidural steroid injection (CESI) groups

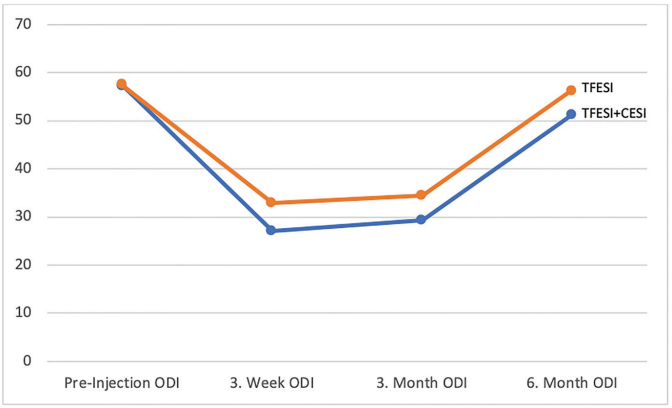

Figure 3. Changes in the Oswestry Disability index (ODI) score of the transforaminal epidural steroid injection (TFESI) alone and TFESI + caudal epidural steroid injection (CESI) groups

DISCUSSION

Although medical therapy, physiotherapy, ESI, and surgery are good options for lumbar disc herniation treatment, presence of cauda equina syndrome and severe paresis are absolute indications for surgery[16]. Pain unrelieved by medical and/or conservative treatment, greater than 3/5 muscle strength, pain longer than six weeks, and recurrent pain are relative indications for surgery[16]. The rate of postoperative reoperation can increase up to 26% in lumbar disc disease[17]. Complications related to lumbar microdiscectomy decrease success rate. Notably, complications due to surgery or recurrence are greater in multi-level lumbar disc disease. The fact that conservative or minimally invasive treatment modalities are the first choice in multi-level lumbar disc disease, which is seen in the elderly and the treatment of which is controversial,[18] can have more satisfying results for the patient and the surgeon.

ESI is a minimally invasive, non-surgical treatment option. ESI can be applied via three routes: transforaminal ESI (TFESI), interlaminar ESI (IESI), and caudal ESI (CESI)[9-12]. TFESI has several advantages over the other methods. It is applied directly to the pathologic region, it can reach the anterior epidural space, and it requires a lower volume of drugs[19,20]. CESI has a lower complication ratio because it reaches the epidural space easily; however, it requires more drugs volumetricalls[21]. IESI is minimally invasive and non-specific as injected drugs can migrate caudally, cranially and anteriorly[22]. In all three methods, steroids injected into the epidural space suppress ischaemia and inflammation caused by the migrating leukocytes and several neuropeptides, which are released when the nucleus pulposus occupies the epidural space[23].

Many studies have analysed the effectiveness of TFESI and CESI for radicular pain caused by lumbar disc disease and found TFESI to be most effective[14,24,25]. Several reviews have indicated that TFESI is effective for lumbosacral radicular pain[20,26]. CESI is also effective against lumbosacral radicular pain[27-30]. The two methods were compared by Kircelli et al.[31], who found that combined treatment was more effective than TFESI alone.

Although many studies have analysed the effectiveness of TFESI and CESI, few studies have been conducted on multi-level lumbar disc disease. Manchikanti et al.[32] examined the effectiveness of TFESI, IESI and CESI in radicular pain caused by lumbar disc disease. The effectiveness of TFESI, IESI and CESI was similar in the two-year follow-up; however, the effectiveness of ESI in multi-level lumbar disc disease was not analysed. Ökmen and Ökmen[33] applied IESI to 120 patients with multi-level lumbar disc disease and found that the VAS and ODI scores decreased significantly after the procedure compared with that in the preoperative period. Singh et al.[34] found significant improvement in radicular pain in patients who underwent two levels of TFESI.

Although TFESI and CESI are minimally invasive treatment modalities, many complications, such as death, paraplegia, spondylodiscitis, nerve damage, spinal cord infarction, headache, dizziness, nausea and vomiting, can develop[35-40]. In our patient group, no serious complications were observed; however, four patients complained of dizziness.

In our study, the medical records of patients with multi-level lumbar disc disease with radicular pain and ESI were retrospectively analysed. The 99 patients were divided into two groups: TFESI was administered to 48 patients, whereas TFESI and CESI were co-administered to 51 patients. Statistical analysis of the changes in the VAS and ODI scores showed that combined therapy was more effective in improving pain management and functional capacity. Our results showed that the need for surgical treatment can be reduced by combining TFESI and CESI for multi-level lumbar disc disease, which is difficult to manage. As the number of surgeries decreases, the incidence of complications secondary to surgery decreases. Therefore, it will be possible to obtain more satisfactory results for the patient and the surgeon.

Study Limitations

This study has two main limitations: the retrospective nature of the study and the analgesic treatments used by the patients during the post-injection period not being followed up.

CONCLUSION

Co-administration of CESI with TFESI in multi-level lumbar disc disease showed significant improvement in pain management and functional capacity. Combined TFESI and CESI should be considered in patients with multi-level lumbar disc disease, which is difficult to manage.

Ethics

Ethics Committee Approval: Since it is a retrospective data analysis, ethics committee approval is not required.
Informed Consent: Informed consent was obtained from the patients.
Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Concept: O.B., Design: O.B., Data Collection or Processing: Ş.E., Analysis or Interpretation: O.B., Literature Search: O.B., Ş.E., Writing: O.B.
Conflict of Interest: The authors declare no competing financial interests and no sources of funding and support, including any for equipment and medications.
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