Original Article/*Özgün Araştırma*

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A Comparative Study of the Effectiveness of Lumbar Steroid Injection in Kambin's Triangle Versus Conventional Transforaminal Approach for the Treatment of Lumbar Radicular Pain: A Prospective Randomised Study

Lomber Radiküler Ağrı Tedavisinde Kambin Üçgeni Yaklaşımı ile Uygulanan Steroid Enjeksiyonunun Etkinliğinin Konvansiyonel Transforaminal Yaklaşımla Karşılaştırılması: Prospektif Randomize Çalışma

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ABSTRACT

Objective: Low back pain is a very troublesome and common issue among patients irrespective of age and sex and is very difficult to manage with conservative management. It can lead to disability and mental issues.

Methods: After ethical committee approval, a prospective, randomised, double-blind comparative study on 40 patients aged 20-70 years, suffering from lumbar radicular pain was carried out by two different approaches i.e., conventional transforaminal and Kambin's triangle approach and epidural steroids were administered. Change in pain intensity using the Verbal Numerical Rating Scale was recorded as our primary outcome. Change in functional status using Oswestry Disability Index and Patient Satisfaction Score were our secondary outcomes. Any adverse event, complication, failure was also noted.

Results: Multiple logistic regression showed no difference in pain relief or improvement of functional status due to variable differences like the age, sex, disc level or the type of approach.

Conclusion: Both approaches of transforaminal epidural steroid injection were effective in reducing pain and increasing functional status significantly. There was no significant difference in their effectiveness and neither was superior to the other.

Keywords: Low back pain, transforaminal approach, Kambin's triangle approach

ÖZ

Amaç: Bel ağrısı, yaş ve cinsiyetten bağımsız olarak yaygın görülen bir problemdir. Hastalar için zahmetli bir süreç olan bu durumun konservatif olarak tedavisi çok zordur. Bu patoloji, hastalarda hareket kısıtlılığı ve mental problemlere yol açabilir.

Yöntem: Prospektif, randomize, çift-kör olarak planlanan çalışma etik kurul onayından sonra gerçekleştirildi. Lomber radiküler ağrısı olan 20-70 yaş arası 40 hasta konvansiyonel transforaminal ve Kambin üçgeni yaklaşımı olmak üzere iki farklı gruba ayrılarak epidural steroid uygulandı. Sözlü Sayısal Derecelendirme Ölçeği kullanılarak ağrı şiddetindeki değişiklik primer sonuç olarak kaydedildi. Oswestry Engellilik İndeksi ve Hasta Memnuniyet Skoru kullanılarak fonksiyonel durumdaki değişiklikler ikincil sonuç olarak kaydedildi. İşlem sırasında karşılaşılan advers olaylar, komplikasyonlar ve işlemin başarısız olduğu hastalar kaydedildi.

Bulgular: Yaş, cinsiyet, lezyonun lokalizasyonu ve yaklaşım yönteminde, ağrının giderilmesi ve fonksiyonel durumdaki iyileşme açısından gruplar arasında istatistiksel olarak anlamlı fark saptanmadı.

Sonuç: Transforaminal epidural steroid enjeksiyonu için kullanılan her iki yaklaşım da ağrıyı azaltmada ve fonksiyonel durumu düzeltmede anlamlı şekilde etkiliydi ve her iki yöntemin de etkinliği benzer bulundu. Etkililiklerinde önemli bir fark yoktu ve hiçbiri diğerinden üstün değildi.

Anahtar sözcükler: Bel ağrısı, transforaminal yaklaşım, Kambin üçgeni yaklaşımı

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INTRODUCTION

Low back pain (LBP) is a very common problem affecting populations of all geography and ages. Lumbar radicular pain is discretely localized, "band-like" in distribution, and shooting, or shocking in quality and can have a cutaneous component (1). The lumbar nerve root is compressed by a herniated disc or any other pathology resulting in inflammation of the injured nerve causing pain. Injury, inflammation or ischemia, anyone when present, can induce ectopic impulse in dorsal root ganglion resulting in radicular pain (2). The treatment strategy of LBP depends on the causal factor, severity, duration and other factors like age, and sex. There are various non-pharmacological or pharmacological treatments. Initial approach for lumbar radiculopathy includes a trial of conservative management, including patient education, staying active/exercise, manual therapy (such as McKenzie exercises), and non-steroidal anti-inflammatory drugs (NSAIDs) as first-line treatments (3-5). Options of interventional or surgical treatments are usually reserved for patients not responding to pharmacological treatment. Surgical treatment for lumbar radicular pain, like discectomy has been an option for ages. However, Spine Pain Outcome Research Trial (SPORT) comparing surgical treatment versus non-surgical conservative treatment shows statistically insignificant superiority of surgical treatment (6).

It is plausible to perform epidural steroid injections for treating lumbar radicular pain and preventing patients from undergoing undue surgical stress. The rationale for epidural steroid injection lies in the evidence that has demonstrated inflammatory mediators in the lumbar discs.

There are 3 common routes of accessing epidural space: The caudal route, interlaminar route and transforaminal route. The transforaminal route is unique and complex but injection is closer to diseased nerves. Also, injection through the transforaminal route can be performed by various approaches like the conventional (subpedicular), retrodiscal and posterolateral or preganglionic or Kambin's triangle approach. Though there are various studies about various routes for an epidural steroid injection, the literature lacks sufficient information regarding the superiority of one approach over another of Transforaminal Epidural Steroid Injection (TFESI). Most of them proposed Kambin's triangle approach as an alternative (7). To the best of our knowledge, no study had been done comparing conventional and Kambin's triangle approaches, especially in the Indian population. So, we hypothesize that Kambin's triangle approach of TFESI is superior in efficacy to the conventional approach of TFESI.

MATERIAL and METHODS

After approval from the Institute Ethical Committee, clinical research was done by the Ethical Principles for Medical Research Involving Human Subjects, outlined in the Helsinki Declaration of 1975 and the study got registered in the clinical trial registry (CTRI/2017/09/009711). After obtaining the informed written consent from patients, we conducted a prospective, randomized, double-blind comparative study on 40 patients aged 20-70 years, suffering from lumbar radicular pain in the Banaras Hindu University Hospital Department of Anaesthesiology.

Patients with lumbar radiculopathy, with nerve root compression in the paracentral or subarticular region at the level of supra-adjacent intervertebral disc based on an imaging study, patients with single-level TFESI ranging from L1 to S1 and with no prior therapeutic TFESI or any prior surgery were included in our study and were followed up for a period of 6 months. Whereas patients with generalized inflammatory diseases, previous use of anticoagulant agents, uncontrollable diabetes, known allergy from study drugs and/or contrast agents, current suspected or diagnosed infection, poor general health, cutaneous disorders around the injection site, patients with cognitive impairment, spinal canal stenosis and with cauda equina syndrome were excluded from the study.

Participants were randomly assigned to one of the following two groups using a computer-generated randomization table:

Group C patients received 2.5 mL of a solution containing 1.5 mL of 0.25% Bupivacaine (ANAWIN 0.25%, NEON laboratories, Thane, India) and 40 mg triamcinolone (KENACORT 40 mg, Abbott, Mumbai, India) by the conventional approach of TFESI.

Group K patients received 2.5 mL of a solution containing 1.5 mL of 0.25% Bupivacaine and 40 mg triamcinolone by Kambin's approach of TFESI.

Conventional transforaminal approach (Figure 1):

Patients were positioned prone with a pillow under the lower abdomen and above the iliac crest to reduce lumbar lordosis. After sterile preparation and draping of the skin at the injection site, the fluoroscope was positioned to obtain an anteroposterior (AP) view with the pedicle shadow bounding the upper aspect of the targeted foramen in the centre of the fluoroscope monitor. The cephalic caudal tilt of the image intensifier was used so that the vertebral endplate closest to the target is "squared," (i.e., the x-ray beam is parallel to the endplate which appeared as a solid line rather than an oval structure). An ipsilateral oblique projection was obtained so that the tip of the superior articular process (SAP) of the level below is positioned under the approximate "6 o'clock"

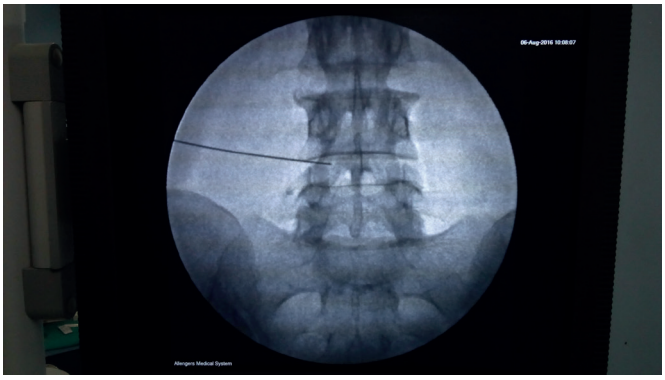

Figure 1. Lateral radiograph showing needle tip position in epidural space in the conventional procedure.

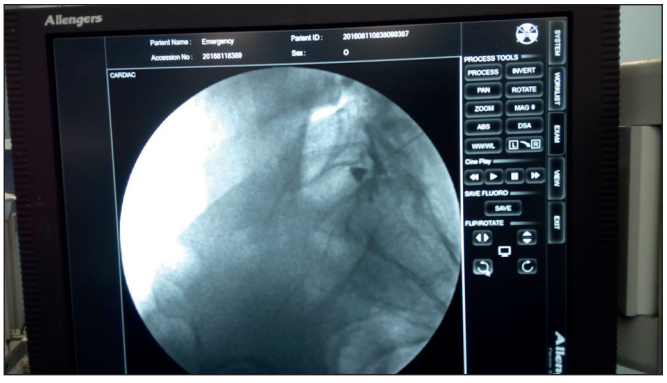

Figure 2. Lateral radiograph showing needle tip position in epidural space in the Kambin's procedure.

position of the pedicle. After creating a cutaneous wheel with a local anaesthetic, a 22G (BD spinal needle, Quincke type, New Delhi, India) procedure needle was advanced using a down-the-beam, "tunnel vision," technique toward the inferior aspect of the pedicle shadow. With help of an AP view, it was ensured that the needle has not been excessively advanced medially, past the 6 o'clock position of the pedicle. Lateral and AP views were saved to document the final needle position and provide a permanent record of the procedure. An AP view was then used for injection of contrast under active fluoroscopy because the structures that present danger, the medullary artery of Adamkiewicz or retrograde flow to the conus were perpendicular to the beam and were well visualised. When contrast was seen to flow medially through the foramen into the epidural space following the medial border of the pedicle spreading toward the intervertebral disc at the level above, 2.5 mL of the drug was injected and confirmation was done by visualisation of washing of contrast. The AP and lateral views were taken for record purposes (8).

Kambin's triangle approach (Figure 2)

Patients were positioned in a prone position with a pillow under the lower abdomen and above the iliac crest to reduce lumbar lordosis. After sterile preparation and draping of the skin at the injection site, the fluoroscope was positioned such that the endplate at the specific level was squared to the x-ray beam. An ipsilateral oblique view was then obtained so that the SAP of the level below was situated under the approximate midpoint of the inferior endplate of the level above. After the skin infiltrated with a local anaesthetic agent, a 22G procedure needle was advanced toward the intervertebral disc just lateral to the SAP. Resistance was encountered as the needle contacted the annulus where it was stopped, and a lateral view radiograph was taken to ensure needle depth. The needle was seen lying in the inferior aspect of the foramen adjacent to the intervertebral disc. An AP view was taken to ensure that the needle was within the foramen in a medial-lateral orientation. Two mL contrast was injected at this site. The contrast was noted to flow through the foramen and spread within the lateral epidural space both in a rostral and caudal direction. After the demonstration of an acceptable pattern of contrast distribution, 2.5 mL of the drug was injected and confirmation was done by visualization of washing of contrast (8).

All participants were evaluated by a single physician who was independent of the procedure. Our primary outcome was the assessment of pain relief using the Verbal Numerical Rating Scale (VNRS) whereas evaluation of functional status using the Oswestry Disability Index (ODI), Patient Satisfaction Score (PSS) and treatment failure were our secondary outcomes. Follow-up was done by a blinded physician at 1st, 3rd and 6th months. Verbal Numerical Rating Scale measured the pain experienced with 0 representing no pain and 10 representing the worst pain.

Oswestry Disability Index was used to assess improvement in functional status using a questionnaire. Patients were divided into 4 categories based on their improvement in pain and functional status as excellent (76-100%), good (51-75%), fair (26-50%) and poor (below 25%) improvement. Participants rating the improvement as "excellent" or "good" were considered as having successful treatment. Those rating the improvement as "fair" or "poor" were considered as having failed treatment. The PSS was also calculated once at 6th month follow up. Patient Satisfaction Score was calculated following a 7 points score based on questions asked according to Patient Satisfaction Questionnaire-18 (PSQ–18) (9). The 7 points were general satisfaction, technical quality, interpersonal manner, communication, financial aspects, time spent with doctors, and accessibility and convenience. All participants were also screened for any major or minor complications after a procedure like paresthesia and inadvertent intra vascular puncture. In case of intravascular puncture or any paresthesia, the needle was removed and

then, redirected under fluoroscopy guidance and the event was noted.

Statistical Analysis

Means of VNRS and ODI at 1st, 3rd and 6th months were compared by independent t-test. Repeated measure Analysis of Variance (ANOVA) with post hoc Bonferroni correction was also applied to see any difference between both approaches at different time levels. Multiple logistic regressions were performed to see the effect of other variables like age, sex, disc-level, and type of route. All collected data were analyzed with statistical software Statistical Analysis System (SAS) university edition and Statistical Package for the Social Sciences (SPSS) version 23.0. P values less than 0.05 were considered significant.

RESULTS

The demographic profiles of both groups were comparable (Table I). Out of 40 patients included, 25 patients showed improvement while treatment failed in 14 patients. One patient could not be followed up during the follow-up period after 25 days of injection due to unfortunate early death that was unrelated to the procedure, which later was tracked to Group C. Total of 39 patients were followed up and were analysed. Out of 25 improved participants, 11 patients were found to be of Group C. Fourteen patients were found to be of Group K. Repeated measures ANOVA showed that both approaches were effective in providing pain relief and improving functional status.

The pre procedural mean VNRS was 7.21±0.97 in Group C, whereas 7.3±0.97 in Group K. The mean VNRS in Group C are significantly lower (2.21, 3.32, 4.05 at 1st, 3rd and 6th months respectively) in the post procedural period. Similarly, there was significantly lower VNRS in group K (1.95, 2.85, 3.55 at 1st, 3rd and 6th months respectively) in the post procedural period. However, on intergroup comparison, it was statistically insignificant at all time intervals (Table II).

The pre procedural functional status using ODI scale showed the mean ODI score was 72.54±6.51 in Group C and 72.52±6.41 in Group K. In the post procedural period, it was significantly lower in both groups (26.8, 35.3 and 41.2 at 1st, 3rd and 6th months respectively in Group C, whereas 20.41, 29.86, 36.43 at 1st, 3rd and 6th months in Group K). However, it was insignificant on intergroup comparison (p>0.05) (Table III).

Table I. Patient Demographic Characteristics

Group Name (n)	Male:Female n:n	Age, years rounded mean (min-max)
Group C (19)	8:11	47 (23-68)
Group K (20)	8:12	48 (21-68)

n: Number of patients, **C:** Conventional, **K:** Kambin's triangle.

Table II. T-Test for Verbal Numerical Rating Scale at Follow up

T-Test for VNRS				
Follow up at	**Group**	**n**	**Mean±SD**	**p**
At 1st month	C	19	2.21±2.07	0.674
	K	20	1.95±1.76	
At 3rd months	C	19	3.31±2.42	0.557
	K	20	2.85±2.47	
At 6th months	C	19	4.05±2.75	0.566
	K	20	3.55±2.66	

VNRS: Verbal numerical rating scale, **n:** Number of patients, **SD:** Standard deviation, **C:** Conventional, **K:** Kambin's triangle.

Table III. T-Test for Oswestry Disability Index at Follow up

T-Test for ODI				
Follow up at	**Group**	**n**	**Mean±SD**	**p**
At 1st month	C	19	26.80±22.61	0.292
	K	20	20.41±13.95	
At 3rd months	C	19	35.32±25.02	0.483
	K	20	29.86±23.17	
At 6th months	C	19	41.27±28.45	0.580
	K	20	36.43±25.84	

n: Number of patients, **ODI:** Oswestry Disability Index, **SD:** Standard deviation, **C:** Conventional, **K:** Kambin's triangle.

The PSS was 75.10 and 74.70 in Group C and K which was statistically insignificant on intergroup comparison (p>0.05) (Table IV).

The patients were assessed for pain at the injection site. All patients complained of mild discomfort only, after injection. The pain did not persist in any patient for more than 24 hours and could be easily managed with simple analgesics. On performing Fisher's exact test, the difference in intravascular puncture was found to be insignificant (p>0.05). However, differences in numbers of patients complaining of paresthesia were found to be significantly less in Kambin's triangle approach (p<0.05) (Table V).

Table IV. T-Test for PSS

Group	n	Mean±SD	p
C	19	75.10±8.14	0.868
K	20	74.70±7.01	

n: Number of patients, **PSS:** Patient Satisfactory Score, **SD:** Standard deviation, **C:** Conventional, **K:** Kambin's triangle.

Table V. Fisher's Exact test for Complications of the Approaches

Group	Intravascular Puncture (Yes/No)		p
K	1	19	0.600
C	3	17	
Group	**Paresthesia (Yes/No)**		**p**
K	1	19	0.040*
C	7	13	
Group	**Treatment Failure (Yes/No)**		**p**
K	1	19	0.604
C	2	17	

*p <0.05 (statistically significant), **C:** Conventional, **K:** Kambin's triangle.

DISCUSSION

In our study, a significant difference was present between baseline VNRS and ODI scores and scores at 1st, 3rd and 6th months in both the groups. However, pain relief and improvement in functional status persisted in most of the patients. No significant difference was seen in declining effect over time in patients treated by either approach i.e., both groups had similar regression of effects with a p-value of 0.616 over 6 months (Figure 3 and 4). Multiple logistic regression performed showed no difference in pain relief, improvement of functional status and patient satisfaction between both groups as the p-value for all the variables was greater than 0.05.

Low Back Pain due to lumbar radiculopathy is debilitating; physically and psychologically. Psychological problems like depression may be the etiology or consequence in such patients negatively affecting their quality of life in either case. As reported in various literature, the pathogenesis of lumbar radicular pain lies in compression along with inflammation of nerves. Inflammation of nerve roots and their surrounding tissues is the presumed cause of sciatica associated with nerve root compression. However, it is common to have severe radiculopathy leading to paralysis without concomitant pain. On the other hand, many patients who have painful sciatica do not have demonstrable neurological deficits. Therefore, it appears that nerve root compression is not the only source of pain. The necessary ingredient is the

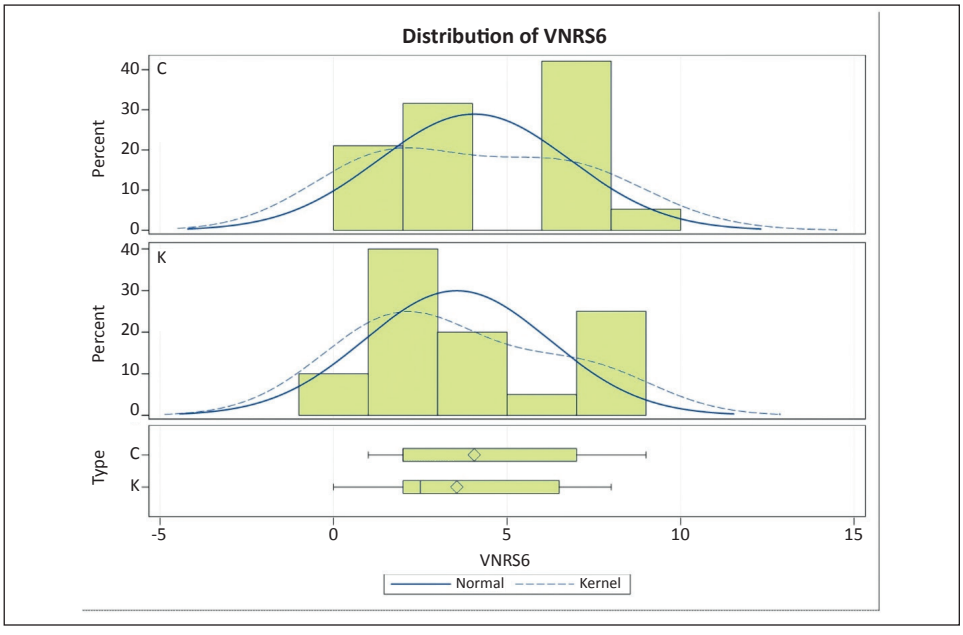

Figure 3. Graphical representation of Verbal Numerical Rating Scale at 6th month.

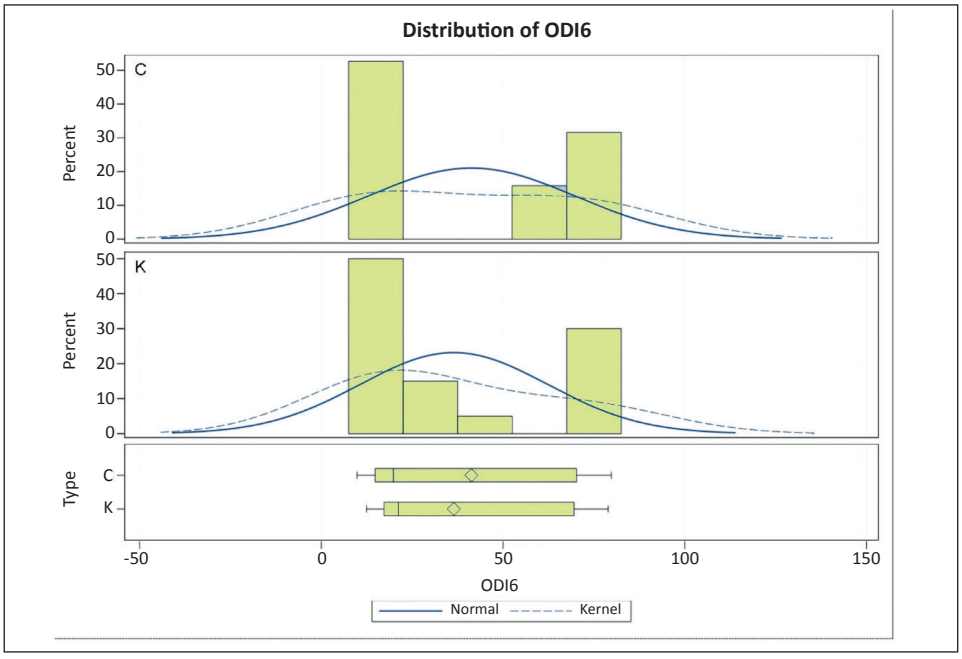

Figure 4. Graphical representation of Oswestry Disability Index at 6th month.

presence of inflammation that presumably irritated nerve endings in the dura mater and the perineural connective tissues. The rationale for injecting steroids in epidural space for lumbar radiculopathy is that steroid injected around nerves attenuates ongoing inflammation and improves the patient's quality of life by relieving pain and discomfort (10). In our study, TFESI was performed in patients with lumbar radiculopathy and pathology at a single disc level who did not benefit from pharmacological or non-pharmacological treatment. Transforaminal epidural steroid injection allows the needle to be positioned in epidural space near the nerve without provoking pain (11). We chose a transforaminal route to inject steroids in the epidural space because we believed that using this route, steroids will be instilled nearer to the pathological site than any other route. The alternate route, the interlaminar approach is easy to perform with a high success rate even when performed blindly. However, most of the time the injected steroid does not reach anterior epidural space and the volume of the drug to be used is also large. A common belief among pain physicians is that anterior epidural space is a more specific site to inject drugs because the source of inflammation i.e., prolapsed or ruptured intervertebral disc lies anteriorly to the nerve root. Inflammatory chemicals released from ruptured disc initiates inflammation in the nerve root leading to pain and steroids act by inhibiting these inflammatory mediators. It has been reported that the anterior and both dorsolateral compartments of the lumbar epidural space appear to communicate with each other and the filling of various compartments is asymmetric in several cases (12,13). Dorso-medial connective tissue in the posterior epidural space and deformation of the dural sac after epidural injection prevent the spread of injected local anaesthetic throughout the entire epidural space and results in a unilateral epidural block. Savolaine et al. showed that the posterior epidural space is divided by the plica mediana dorsalis and an additional transverse connective tissue plane (14). With fluoroscopic guidance chances of complications decrease significantly but still, a large volume of the drug must be given. Various routes of epidural steroid injection have been compared throughout the literature. However, very few studies have compared conventional or safe triangle approaches to Kambin's triangle approach. Theoretically, Kambin's triangle or preganglionic approach of TFESI is said to be more specific than the safe triangle or ganglionic approach because steroid injection given is closer to the nerve root in the former than the latter. However, practically what effect this apparently beneficial approach has in terms of outcome is debatable. Studies done till now have mixed results without clear evidence of the superiority of one approach over another. The conventional transforaminal approach uses a sub-pedicular route to inject the drug into the epidural space by placing a needle in a safe triangle. A safe triangle is a right triangle formed by the exiting nerve (hypotenuse), pedicle above (base) and lateral part of the upper vertebra (vertical plate). When injected through a safe triangle, drug must ascend rostrally to reach the pathological site of inflammation and exert its therapeutic effect. This phenomenon and placing the needle in a safe triangle is difficult when there is spinal stenosis, advanced disc degeneration, post-surgical scarring, and epidural fibrosis. Kambin's approach has the advantage of placing drugs closer to the nerve root. In difficult spines, Kambin's triangle approach has been shown equally successful

in drug placement. In our study, we found both routes of administration of steroids were significantly effective in treating low back pain due to lumbar radiculopathy, however, there was no significant difference between the groups. Our study is supported by Park et al.'s study comparing Kambin's triangle and conventional approaches for the treatment of spinal stenosis and found no significant difference (7). Although a greater percentage of patients who had relief was treated by Kambin's triangle approach in our study than the safe triangle approach, the difference was not statistically significant. Our study had a small sample size (n=39) which might have affected the result as similar with Park et al.'s study (7). Lee et al. compared the conventional approach with the posterolateral approach with a moderately large sample size of 108 patients and found no statistical difference in outcomes in their study (15). However, there was a significant reduction in pain sensation for the posterolateral approach. Contrary to these, Lee et al. in their retrospective study among 33 patients found a borderline (p=0.056) difference between conventional and preganglionic approaches (16). A prospective study on 239 patients by Jeong et al. comparing the ganglionic with preganglionic approach found a significant difference in terms of outcomes but this outcome was limited to 1st follow up after the procedure (17). However, there was no significance between the groups at 6 months follow up. They also included spinal stenosis patients in their study. Our study was focused on disc herniation patients only. Also, they did not exclude patients with acute LBP from their study as in our case. They also found that patients with a history of symptoms of shorter duration had better pain relief at mid-term follow-up. In our study, patients had symptoms for more than 6 months. The accidental intravascular puncture was found to be with both approaches. Although it was higher in Kambin's triangle than in conventional approaches but was statistically insignificant. Paresthesia was significantly more with the conventional approach than Kambin's triangle approach. Our results regarding complications matched with the results produced by Park et al. (7).

Our study had a few limitations. First, our follow-up was telephonic basis after 1 month which barred direct communication. Second, we did not consider the patient's psychological status which can affect all the variables studied in this study as all of them are subjective variables. Third, we did not classify the duration of the symptom and included all patients who had symptoms for more than 6 months in general. Fourth, the sample size was small to conclusively decide which method is superior. Hence, further studies with higher sample size and considering the other limitations are needed.

CONCLUSION

Low back pain is a major problem among the population with many possible etiologies. Low back pain associated with or without radiating pain to lower limb is most of the time caused by lumbar nerve root compression and inflammation. We conclude that TFESI is an acceptable short-term treatment for chronic LBP due to lumbar radiculopathy, which can result in cost-effectiveness and avoidance of surgery. Kambin's triangle approach could be an alternative treatment option depending on physician's familiarity with the approach and the patient's anatomy for chronic LBP over the conventional safe triangle approach.

AUTHOR CONTRIBUTIONS

Conception or design of the work: GS

Data collection: R

Data analysis and interpretation: AKP

Drafting the article: AR

Critical revision of the article: AR

All authors (GS, R, AKP, AR) reviewed the results and approved the final version of the manuscript.

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