Randomized Trial

Contrast Medium Volume Needed to Reach Anterior Epidural Space via the Kambin Triangle or Subpedicular Approach for Transforaminal Epidural Injection

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Background: Transforaminal (TF) lumbar injection is a commonly used minimally invasive intervention for management of chronic low back pain. TF injection can be performed using various approaches to inject the drug to the anterior epidural space (AES).

Objectives: To identify the volumes of contrast medium needed to reach the AES and other landmarks in the Kambin triangle (KB) and subpedicular (SP) approach of TF injection in patients with lumbosacral radicular pain.

Study Design: Randomized controlled trial.

Setting: Pain clinic and operating room of a tertiary care hospital.

Methods: Seventy-five eligible patients were randomized to receive TF epidural injection either by SP (SP group; n = 38) or the KB (KB group; n = 37) approach under fluoroscopic guidance. After confirming the appropriate needle position, contrast medium was injected at 0.5 mL increments up to 2 mL under intermittent fluoroscopy. Contrast medium volumes needed to reach specific landmarks, that is, AES, medial to superior pedicle, medial to inferior pedicle, medial aspect of both the superior, and neural spread, were recorded. Following this, 4 mL of the drug (0.5% lidocaine 1 mL + methylprednisolone 80 mg + 1 mL normal saline solution) was injected. Patients were evaluated for Visual Analog Scale (VAS) and modified Oswestry Disability Questionnaire (MODQ) scores after epidural injections at 2 weeks, 1 month, and 2 months.

Results: Average volume of contrast medium needed to reach AES was 1.10 ± 0.46 mL in the KB approach and 1.10 ± 0.38 mL in the SP approach. Contrast medium volume needed to reach other landmarks showed comparable results in both groups. AES was seen in 27.02% (10/37) patients in the KB group and 23.6% (9/38) patients in the SP group with 0.5 mL of contrast medium. This increased to 56.76% (21/37) and 77.7% (28/38) with 1 mL of contrast medium ($P = 0.03$, chi-square test). No anterior spread was seen even after 2 mL of contrast medium in 4 patients in the KB group and 2 patients in the SP group. Neural spread was seen in 100% of patients in the KB group after 0.5 mL of contrast medium, but in 34 (89.4%) patients in the SP group ($P = 0.03$, chi-square test). We did not note any contralateral spread. Short-term effectiveness in pain relief in terms of VAS for back pain and functional improvement in terms of MODQ score over time showed similar results in both groups. Intravascular needle puncture and needle paresthesia was comparable in both groups.

Limitations: Small follow-up duration is one the limitations of this study. Future studies will be needed to assess any long-term differences in outcome between approach methods. Also, use of intermittent fluoroscopy might have limited detection of intravascular injections of the contrast medium in comparison to the continuous fluoroscopy.

Conclusions: To conclude, our study revealed that average volume of contrast medium needed to reach AES and other landmarks were comparable with both approaches of TF injection.

Key words: Transforaminal injection, subpedicular approach, Kambin triangle approach, contrast medium spread, anterior epidural spread

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Low back pain with lumbosacral radicular pain (LSRP) is an important health problem and a leading cause of disability worldwide (1). The most common etiology for LSRP is intervertebral disc herniation. Management options include conservative approach, minimally invasive intervention, and surgery. Minimally invasive interventions are preferred in patients not responding to conservative treatment in the wake of unsatisfactory surgical outcome (2,3)

Transforaminal (TF) lumbar injection is a commonly used minimally invasive intervention for management of chronic low back pain (4,5). TF injection can be performed using various approaches. Currently, subpedicular (SP) TF approach is more commonly used. In this technique, the injecting needle is progressed under the inferior part of the pedicle into the safe triangle located in the superolateral part of the symptom-associated spinal level (6,7). Needle placement in this region may avoid nerve root trauma as exiting nerve root usually traverses inferior to the safe triangle. This approach and location is preferred, as the drug can be injected into the anterior epidural space (AES), the site of inflammation between the herniated disc and anterior nerve root sleeve (6). However, it becomes difficult to place the injection needle into the desired space and injection of the drug into the supraadjacent preganglionic and epidural space, which can occur in cases of foraminal stenosis (8,9). Further, the artery of Adamkiewicz (AKA) could be located in the safe triangle approximately 97% of the time (10). Delivering the drug into the AKA accidently using this approach can lead to vascular trauma and paraplegia (10,11). The AKA and radiculomedullary arteries are reported to be mostly located in the upper one-third of the foramen (12,13). Hence there is a search for alternate approaches through which the drug can be delivered into the AES (11).

Kambin defined the posterolateral approach, defining a triangular working zone (Kambin triangle [KB]), which is a right angle triangle over the dorsolateral disc as a site of approach for intervertebral disc (13,14). The hypotenuse is formed by the exiting nerve root, the base is formed by the superior border of caudal vertebra, and the height is formed by the dura/traversing nerve root. Using this triangle for TF injection, the risk of injecting the agent into the AKA and vessel damage may be reduced.

Few authors have reported the volume of contrast medium needed to reach specific landmarks using one of the various approaches of TF epidural injection (15,16). Park et al (15) compared the effectiveness of the SP and KB approaches in patients with lumbar canal stenosis and reported the diffusion scope of contrast medium of these 2 approaches using 1 mL contrast medium bolus as one of the outcomes of the study. The authors reported comparable contrast medium diffusion and similar efficacy over the short term between the 2 approaches (15). In another study, Park et al (16) reported 100% spread to the AES with the KB approach after injecting 2 mL of contrast medium.

To the best of our knowledge, no study has been conducted to define the volume of contrast medium needed to reach the AES using the KB approach and compared it with the SP approach. Aim of this study was to determine the volume of contrast medium needed to reach the AES via the KB and SP approaches in patients with LSRP.

Methods

After approval of the institute ethics committee, this study was conducted at a tertiary care institute in northern India. The study is registered with the clinical trial registry of India with registration number CTRI/2018/01/011168. In this randomized double-blind trial, 75 patients of either gender between ages 18 and 65 years, with unilateral radicular lumbar pain and/or low back pain ≥ 3 months having Visual Analog Scale (VAS) score > 5 were enrolled. Patients allergic to contrast medium, previous history of surgery on the spine, history of TF epidural injection in the past, generalized inflammatory disorder, patient on anticoagulant therapy, those having cutaneous disorder around the injection site, cauda equina syndrome, mentally retarded, and pregnant patients were excluded.

Patients were evaluated by taking history, physical examination, and underwent magnetic resonance imaging and coagulation profile testing.

Randomization and Blinding

Patients were randomized to 1 of the 2 groups: the KB group (received TF injection through the KB approach), or the SP group (received TF injection through the SP approach) using computer-generated randomization (software Randomizer with block of 6 [Offered by "Social Psychology Network" Wesleyan University, CT]) sequences. These random numbers were kept in an opaque sealed envelope and were opened just before the procedure. None of the investigators had access to the randomization sequence.

All procedures were performed by a single investigator (BG) and followed by other investigators (JKM/AS). Study cases were kept in-between clinical nonstudy cases during the procedure, as well as for follow-up. This was done to enhance the blinding and allocation concealment. Both patients and the investigator assessing the patient were unaware of the group allocation.

Procedure

All procedures were performed in the prone position under fluoroscopic guidance using standard American Society of Anesthesiologists monitors. To minimize lumbar lordosis, a pillow of 10 cm height was kept under the lower abdomen. The intervertebral level and the side for drug administration were determined according to the clinical examination and the results of diagnostic imaging studies. Fluoroscopic biplanar imaging was used in anteroposterior (AP) and lateral views. After patient positioning, x-ray was taken and epiphyseal plate of the upper and lower vertebral body was focused by moving the cephalocaudal angle of the C-arm. Then C-arm was rotated obliquely by 15 to 30 degrees toward the site of injection so that the superior articular process was seen at the middle of intervertebral disc.

Kambin Approach (KB Group)

At that location, a Spinocan 3.5-inch 22-gauge spinal needle (B. Braun, Melsungen, Germany) was inserted into the skin after infiltration with local anesthetic toward the lateral lower part and in front of the superior articular process and parallel to the x-ray projection path. In the final position, the needle was located medially in the 5 o'clock direction of the upper pedicle at the AP view and the posteroinferior part of the foramen in the lateral view.

SP Approach (SP Group)

The spinal needle was inserted and advanced below the pedicle after infiltration with local anesthetic. The needle was progressed until the inferolateral border of the pedicle was parallel to the x-ray projection path, then the C-arm was adjusted to the lateral view, and the needle was slowly advanced toward the anterosuperior aspect of the intervertebral foramen.

Contrast Medium Spread

After final location of the needle, an aspiration test was done to check for blood in the syringe, and contrast medium was injected at 0.5 mL increments until 2 mL under intermittent fluoroscopy with AP and lateral views. After each 0.5 mL increment, the spread to the AES and other landmarks, such as neural spread, medial to inferior pedicle (MIP), medial to superior pedicle (MSP) of corresponding level of injection, medial to both inferior and superior pedicle (MISP) on same side and spread to other side, were noted. An independent observer blinded to group allocation interpreted the degree of contrast medium spread on fluoroscopic images.

Drug Administration

After checking dye diffusion, 4 mL of the drug (2% lidocaine 1 mL + methylprednisolone 80 mg (2 mL) + 1 mL normal saline solution) was injected. All patients in either group were observed for at least 60 minutes in the postanesthesia recovery room.

Evaluation and Follow-Up

Patients in both groups were evaluated for pain using the VAS and disability using the modified Oswestry Disability Questionnaire (MODQ) section 1 to 10 at baseline, 2 weeks, 1 month, and 2 months after TF injection.

The primary outcome of the study was to determine the volume of contrast medium needed to reach the AES. Secondary outcomes recorded contrast medium spread to other landmarks, that is, neural spread, MIP of the corresponding level, MSP of the corresponding level, both MISP on same side, and spread to other side. Other secondary outcomes were VAS and MODQ scores over time.

Statistical Analyses

The statistical analyses were carried out using the Statistical Package for Social Sciences version 20.0 for Windows (IBM Corporation, Armonk, NY). Normality of data were checked by measures of the Kolmogorov–Smirnov test. For normally distributed data, the means of the 2 groups were compared using the t-test. For skewed data, the Mann–Whitney U test was applied. Qualitative variables were described as frequencies and proportions. Proportions were compared using the chi-square test. To analyze the VAS and MODQ scores over time, 2-way repeated-measure analysis of variance (ANOVA) was used within and in-between groups. The Greenhouse–Geisser test was used with adjustment for time × factor, time × group interaction, and between-patient effects for VAS and MODQ scores, followed by the Bonferroni correction for multiple comparisons. Significance level of P was set ≤ 0.05.

Sample Size Calculation

Sample size was calculated based on the previous study (17). To achieve an effect size of 0.47 and 80% power with a type 1 error of 0.05, total sample size of 70 was required. Effect size was calculated under the assumption that 50% of the patients in either group will have anterior epidural spread with 1 mL of contrast medium. To allow for a 15% dropout rate, the final sample size was 35 patients per group (17).

Results

Figure 1 shows the flow of patients. Ninety-six patients were assessed for eligibility; 85 met inclusion criteria, and 4 patients refused consent. Study protocol

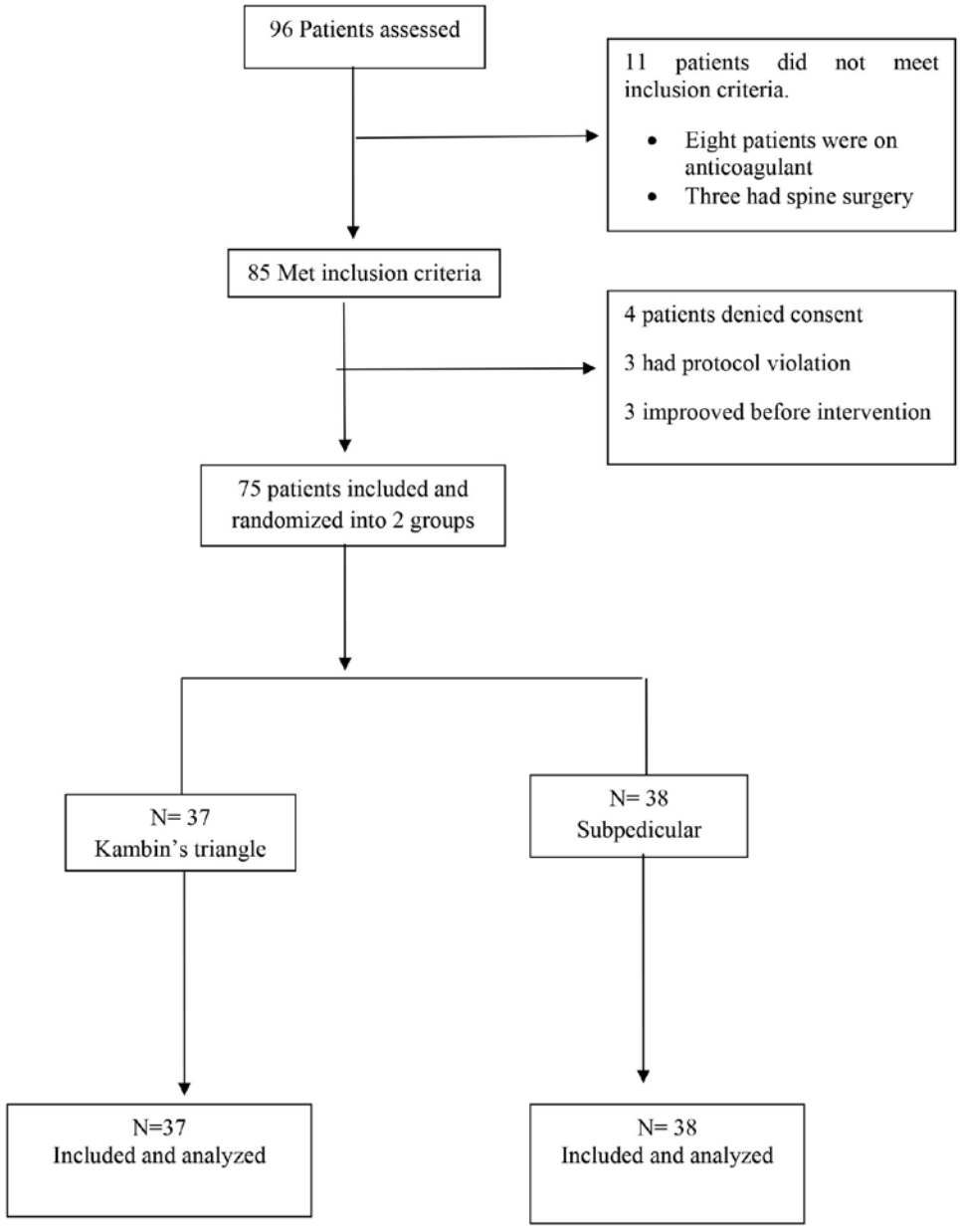

Fig. 1. *Flow diagram showing patient participation.*

could not be followed in 3 patients. Intervention was not performed in 3 patients, as they improved on the day of intervention. A total of 75 patients were included and randomized into 2 groups (n = 37 in the KB group and n = 38 in the SP group). Demographic data were comparable between both groups (Table 1).

Mean volume needed to reach the AES was comparable in both groups (1.10 ± 0.46 mL in the KB group; 1.10 ± 0.38 mL in the SP group; $P = 0.07$, t-test). Table 2 shows the mean value of contrast medium need to reach various landmarks in both groups, which was comparable, except for neural spread. Significantly less mean volume was required for neural spread in the KB group.

With 0.5 mL contrast medium, the AES was seen in 27.02% (10/37) of patients in the KB group, and 23.6% (9/38) of patients in the SP group. This increased to 56.76% (21/37) and 73.7% (28/38) with 1 mL of contrast medium in the KB and SP groups, respectively ($P = 0.03$, chi-square test). After 2 mL of contrast medium, the AES was observed in 89.2% (33/37) and 94.7% (36/38) and was still absent in 4/37 (10.8%) and 2/38 (5.3%) of patients in the KB and SP groups, respectively. Table 3 shows the incidence of patients achieving various landmarks at different incremental volumes of contrast medium.

Neural spread was seen in 100% of patients in the KB group after 0.5 mL of contrast medium, but in 34 (89.4%) patients in the SP group ($P = 0.03$, chi-square test). After 1 mL of contrast medium, 37 (97.4%) patients out of 38 showed neural spread in the SP group. After 1.5 mL, 100% neural spread was also seen in the SP group.

Back, Leg Pain, and MODQ Over Time

Repeated-measure ANOVA showed time × factor interaction ($P < 0.01$) for VAS score of back pain, leg pain, and MODQ, but no time × group interaction ($P > 0.05$) in both groups. Effect was not comparable between groups ($P > 0.05$), except for leg pain over various follow-up times. Pairwise analysis within group showed that VAS score for back pain, leg pain, and MODQ measured at various follow-up times decreased significantly compared with baseline scores in both groups ($P < 0.001$). Between-group analysis revealed that VAS score for back pain and MODQ was comparable in the 2 groups at

Table 1. *Baseline and demographic data.*

Baseline Characteristics	KB Group (n = 37)	SP Group (n = 38)	*P* Value
Age (yrs)	44.35 ± 14.0	42.21 ± 13.19	0.51
Gender* Male Female	 21 (56.7%) 16 (43.2%)	 24 (63.1%) 14 (36.8%)	0.527
Weight (in kg)	67.95 ± 8.7	67.24 ± 10.36	0.28
Baseline VAS back	7.81 ± 1.24	7.47 ± 1.1	0.84
Baseline VAS leg	7.46 ± 1.36	7.21 ± 1.14	0.653
Baseline MODQ	54.08 ± 6.51	52.18 ± 6.9	0.75

Data are expressed as mean ± SD and analyzed using the t-test.
*Data are expressed in frequency (%) and analyzed using the chi-square test, *P* value < 0.05 is significant.

Table 2. *Mean ± SD volume of contrast medium needed to reach different landmarks.*

Different Landmark	KB Group (mL)	SP Group (mL)	*P* Value
AES	1.10 ± 0.46	1.10 ± 0.38	0.07
MIP	1.25 ± 0.35	1.45 ± 0.46	0.19
MSP	1.17 ± 0.33	1.32 ± 0.40	0.09
Neural spread	0.50 ± 0.00	0.56 ± 0.21	0.00

Table 3. *Various incremental volumes of contrast medium with incidence of patient achieving AES, MIP, and MSP.*

Volume (mL)	AES			MIP			MSP		
	KB % (n)	SP % (n)	P	KB % (n)	SP % (n)	P	KB % (n)	SP % (n)	P
0.5	27.02% (10/37)	23.6% (9/38)	0.80	2% (1/37)	2% (1/38)	0.95	2% (1/37)	2/38 5.2%	1.00
1.0	56.76% (21/37)	73.7% (28/38)	0.03	35% (13/37)	9/38 23.6%	0.27	45.9% (17/37)	44.7% (17/38)	1.00
1.5	81% (30/37)	94% (35/37)	0.16	62.1% (23/37)	16/38 42.1%	0.08	62.1% (23/37)	42.1% (16/38)	0.44
2.0	89.2% (33/37)	94.7% (36/38)	0.36	67.5% (25/37)	63.1% (24/38)	0.16	92.5% (25/37)	85.7% (24/38)	0.92

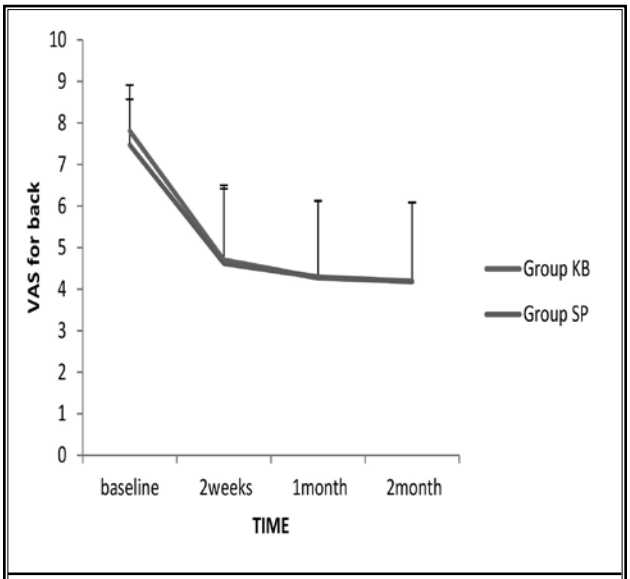

Fig. 2. *VAS for back pain at various intervals in the 2 groups over different times.*

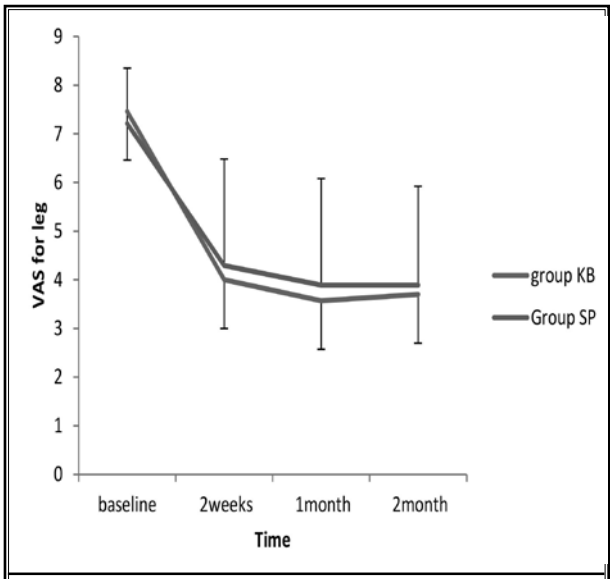

Fig. 3. *VAS for leg pain at various intervals in the 2 groups over different times.*

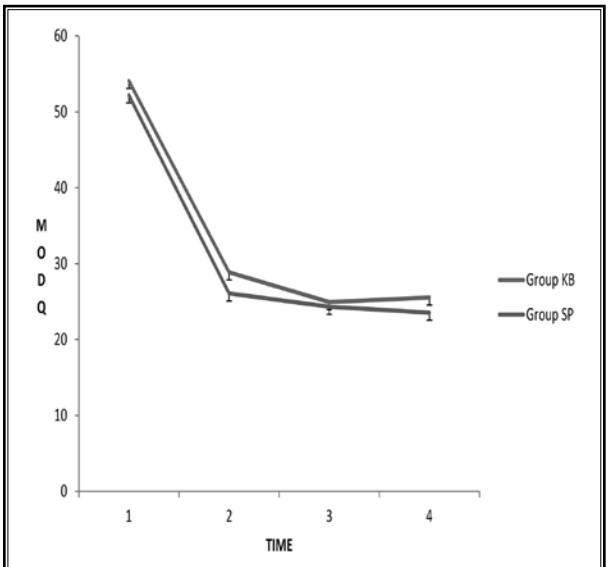

Fig. 4. *MODQ index at various intervals in the 2 groups over different times.*

various time intervals. However, there was a significant reduction in mean VAS for leg pain in the KB group compared to the SP group at follow-ups (Figs. 2–4).

Fluoroscopic Time

The mean fluoroscopy time was 20.41 seconds (standard deviation [SD] = 6.10 seconds) in the KB group, and 18.92 seconds (SD = 5.42) in the SP group, which was comparable in the 2 groups ($P = 0.51$).

Complications

We did not encounter any intrathecal, intradiscal, or subdural placement of contrast medium. Intravascular needle puncture was encountered in 7/37 (18.9%) patients in the KB group, and 4/38 (10.5%) patients in the SP group ($P = 0.3$). Needle relocation was done in these cases. Seven (18.9%) patients in the KB group and 6 (15.7%) patients in the SP group reported needle paresthesia ($P = 0.7$). The needle was slightly withdrawn in these cases. No patient complained of any swelling, redness, or persistent pain at the site of injection.

Discussion

Results of this study showed no difference in the volume of contrast medium needed to reach the AES via the KB and SP approaches of TF injection in patients presenting with LSRP with documented prolapsed intervertebral disc (PIVD). Spread to other landmarks were also comparable between both groups, except for neural spread. At 0.5 mL of contrast medium, a significantly greater number of patients in the KB group showed neural spread as compared with the SP group. Significant improvement was observed with both approaches of TF injection in pain (VAS back and leg) and functional disability (MODQ) during the 2 months

follow-up. There was no difference in VAS scores for back pain between the 2 groups. However, mean VAS for leg in the KB group were significantly lower than the SP group at follow-ups.

To best of our knowledge, only one randomized control trial is available in which the contrast medium spread pattern has been compared using the KB and SP approaches of TF injection as a head-to-head comparison as secondary outcome. Park et al (15) compared the KB with the SP approach of TF injection. They studied contrast medium spread pattern after 1 mL of a contrast medium single bolus in the KB and SP approach as secondary outcomes in 42 patients with spinal stenosis. They noted comparable results in contrast medium diffusion between the 2 approaches. In the SP group, contrast medium spread to the AES was found in 95.4% of patients (only AES spread in 18 [81.8%] patients and anterior and posterior epidural spread in 3 [13.6%] patients), and in 100% in the KB group. However, our results showed difference in the AES after 1 mL of contrast medium. AES spread was seen in 56.76% (21/37) in the KB group, and 73.7% (28/38) in the SP group after 1 mL contrast medium in our study. This variation in results could be due to differences in study patient demographic, clinical/ethnic characteristics, as well as study methodology. The mean age of patients selected by Park et al (15) was 69.23 ± 7.98 years in the KB group, and 66.95 ± 7.70 years in the SP group, versus 45.20 ± 13.82 years and 39.70 ± 13.78 years in our study, and they included patients with canal stenosis, whereas we included patients presenting with radicular pain and PIVD. Also, they used a single 1 mL bolus of contrast medium, whereas we used incremental doses of 0.5 mL up to 2 mL.

Few other authors have studied contrast medium spread pattern using either the KB, SP, or retroneural approach alone of TF injections in various observational studies (16,18).

Park et al (16) reported the contrast medium spread pattern in the KB approach in 44 patients. They injected a total of 5 mL of contrast medium in 0.5 mL increments and calculated the average dose of contrast medium reaching different landmarks (16). The average dose of contrast medium reaching the AES was 1.18 ± 0.53 mL, which is comparable to our study in the KB group (1.06 ± 0.44 mL). AES spread was observed in 100% after injecting 2 mL of contrast medium. Similarly, we noted spread around the AES in 90% after 2 mL contrast medium in the KB group.

Furman et al (19) studied the injectate volume required to reach specific landmarks in lumbar TF epidural injection using the SP approach in 60 patients. Their landmarks were MSP of the corresponding level of injection, superior aspect of the superior IV disc, inferior aspect of inferior IV disc, and both the superior and inferior aspect of IV disc of the corresponding level of injections. They slowly injected 5 mL of contrast medium under continuous flow and noted down-spread to different landmarks. The average contrast medium volume needed to extend to the medial aspect of the superior pedicle of the corresponding level of injection was 0.33 ± 0.196 mL, however, we noted a higher volume of contrast medium (1.17 ± 0.33 mL) needed to reach the MSP. This variation in results could be due to differences in methodology of study. Furman et al studied the contrast medium spread under continuous fluoroscopy, whereas we used 0.5 mL increments. There was no mention of contrast medium reaching the AES by Furman et al (19).

Furman et al (20), in another observational study, observed contrast medium flow selectivity using the SP approach of TF injection in 30 patients using total volume of 4 mL contrast medium injected slowly at 0.5 mL increments. They noted the average volume of contrast medium needed to reach the superior and inferior level was 1.16 mL, and to reach the contralateral side was 2.67 mL. However, they did not mention the volume of contrast medium needed to reach the AES.

Botwin et al (21) studied the contrast medium spread pattern via the SP group of TF injection in 20 patients. They administered a 2 mL bolus of contrast medium and noted unilateral, bilateral, ventral, and dorsal spread. Anterior epidural spread was seen in 100% of patients. Spread was unilateral in all patients. Our study also revealed similar results with respect to anterior epidural spread (95%) and unilateral spread (100%). Other landmarks used were different. They have also noted vascular needle placement in 10% of patients (similar to ours, 10% in the SP group).

Manchikanti et al (6) evaluated contrast medium flow pattern and intravascular needle placement via the SP approach of TF injections in 100 patients. They used 0.5 to 2 mL of contrast medium. They found ventral filling in 88% of patients and nerve root filling in 97% of patients, with intravascular needle placement in 22% of patients, and mean fluoroscopy time of 14.4 ± 9.8 seconds. Our study showed similar results with respect to AES spread and nerve root filling. However, we noted a lower incidence of intravascular needle placement (10%) in the SP group.

The KB approach is thought to provide reduced therapeutic effects because the agent is injected into the lateral epidural space, but in our study, better leg pain relief was found with this approach. Few authors have reported the therapeutic effects with the use of the KB approach. In a retrospective study, Crall et al (22) reported no statistical difference in the immediate treatment effects from injections using the preganglionic KB approach in this area. Similarly, Park et al (15) found no statistical difference in treatment effect between the 2 methods. However, both these studies enrolled patients with lumbar canal stenosis. However, the preganglionic approach was superior to the SP approach in treatment effects after 4 weeks in a study conducted by Jeong et al (23), a result that may be attributed to the fact that their group had more patients with herniated intervertebral disc than patients with spinal stenosis. Preganglionic KB approach may be more effective for patients with herniated intervertebral disc because the needle can be placed closer to the nerve root compressed by the herniated intervertebral disc. This is probably why we observed better leg pain relief in the KB group.

In our previously published study, fluoroscopy time reported with TF injection was 16.21 ± 5.44 seconds (24). The slightly higher fluoroscopy time (21.35 seconds [SD = 6.706] in the KB group, and 20.25 seconds [SD = 5.581] in the SP group) in the present study may be due to differences in methodology. In the present study, we took AP and lateral images at every 0.5 mL of contrast medium injection up to 2 mL over 4 times.

There was no difference in intravascular placement of the needle in-between the KB and SP groups in our study (10% in each group). Park et al (16) also noted comparable incidence of intravascular placement (18% in SP and 15% KB group).

We used methylprednisolone in our study, as our experience in clinical practice (unpublished data) is that particulate lumbar steroids have better outcome compared with nonparticulate steroids. Recently, the Benelux Work Group reviewed the literature on complications of epidural steroids and provided updated safety recommendations (25). One of the conclusions of the guidelines is that both particulate corticosteroids and dexamethasone can be used for lumbar TF injections at L3 or lower (25). Further, there are insufficient data regarding equivalence and long-term safety regarding dexamethasone, and hence dexamethasone cannot be made obligatory at present for lumbar TF injections at L3 or lower (25).

Our study has a few limitations. Only one observer interpreted the degree of contrast medium spread on fluoroscopic images; hence interobserver reliability could not be calculated. However, this was an independent observer blinded to group allocation. Second, as contrast medium and local anaesthetic with steroid injectate solution have different viscosities, the epidural flow characteristics may differ. With injectate solution being less viscous, it is anticipated that it would flow at least to the same landmarks as of contrast medium if not beyond it. Third, our study had a small follow-up duration of only 2 months; therefore future studies will be needed to assess any long-term differences in outcome between approach methods. Finally, the use of intermittent fluoroscopy might have limited detection of intravascular injections of the contrast medium in comparison to the continuous fluoroscopy (26).

Conclusions

Our study revealed that the average volume of contrast medium needed to reach the AES was 1.06 ± 0.44 mL in the KB approach, and 0.97 ± 0.34 mL in the SP approach. We did not find any difference in contrast medium volume needed to reach the AES in both approaches. Our study suggests that we could use a lower volume of drugs to target the AES in single-level involvement.

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