Pain Physician 2019; 22:265-270 • ISSN 1533-3159

Randomized Trial

Comparison of Intravascular Injection Rate Between Blunt and Sharp Needles During Cervical Transforaminal Epidural Block

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Disclaimer: There was no external funding in the preparation of this manuscript.
Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 03-29-2018
Revised manuscript received: 10-14-2018
Accepted for publication: 10-18-2018

Free full manuscript: www.painphysicianjournal.com

Background: Cervical transforaminal epidural block (CTEB) is a useful option in the diagnosis and treatment of cervical radicular pain. However, inadvertent intravascular injection can lead to severe neurologic complications. Blunt needles are considered to displace instead of penetrate vessels because of their dull needle tip.

Objectives: To investigate whether there is a difference between blunt and sharp needles in intravascular injection rates during CTEB.

Study Design: Prospective, randomized, clinical trial.

Setting: A tertiary hospital in South Korea.

Methods: After institutional review board approval, 108 patients undergoing CTEB for treatment of radicular pain resulting from spinal stenosis and herniated nucleus pulposus were randomly assigned to one of 2 needle groups (blunt needle or sharp needle). The needle position was confirmed using biplanar fluoroscopy, and 2 mL of nonionic contrast medium was injected to detect intravascular injection. Intravascular injection was defined as the contrast medium spreading out through the vascular channel during injection under real-time fluoroscopy. This study was registered in ClinicalTrials.gov.

Results: The intravascular injection rate was not significantly different between the blunt needle and sharp needle groups (35.2% vs. 33.3%, $P > 0.05$). The procedure time was longer in the blunt needle group than in the sharp needle group (101.00 ± 12.4 seconds vs. 56.67 ± 8.3 seconds, $P < 0.001$).

Limitations: This was a single-center study. Additionally, the physicians could not be blinded to the type of needle used.

Conclusions: In the present study, use of a blunt needle did not reduce the rate of intravascular injection during CTEB compared to use of a sharp needle. In addition, procedure time significantly increased with blunt needle use compared to sharp needle use.

Key words: Analgesia, bleeding, blunt needle, cervical spine, clinical trials, complications, intravascular injection, radiculopathy, sharp needle, transforaminal epidural block

Pain Physician 2019: 22:265-270

Transforaminal epidural block (TEB) is a useful option in the diagnosis and treatment of radicular spinal pain (1-3). Notably, a retrospective study of 4,612 patients who underwent fluoroscopy-guided cervical TEB (CTEB) showed that this procedure is useful for cervical radicular pain (2). However, there are potential risks associated with TEB such as infection, dural puncture, bleeding, and intravascular injection. Although the risk is low, intravascular injection of particulate steroids can cause fatal neurologic deficits such as spinal infarction (4-6) and cerebral infarction (7,8), and therefore should be carefully monitored.

Blunt needles are considered to displace instead of penetrate vessels because of their dull needle tip (9,10). Therefore, to avoid intravascular injection of steroids during TEB, the use of blunt needles has been suggested (11,12). Animal studies have shown a reduction in incidence of arterial puncture and bleeding with the use of blunt needles compared to sharp needles (9,10). During lumbar TEB, several studies have found that the use of blunt needles could reduce intravascular injection and paresthesia compared to sharp needles (13-15). However, Smuck et al (16) failed to find any benefit of blunt needle during lumbosacral TEB compared to sharp needle.

The incidence of intravascular injection during TEB depends on the spine level. Previous studies using real-time fluoroscopy (RTF) revealed that the incidence of intravascular injection during TEB is higher in the cervical spine than in the lumbosacral spine (17-19). To date, no study has compared the incidence of intravascular injection between sharp needles and blunt needles during CTEB.

Therefore, in this study, we compared the incidence of intravascular injection between sharp needles and blunt needles during CTEB.

Methods

Patients

This was a prospective, randomized trial approved by the institutional review board of our hospital, and informed written consent was obtained from all patients. This study was registered in ClinicalTrials.gov.

From November 2016 to August 2017, we prospectively examined 108 patients who received CTEB. The inclusion criteria were patients >18 years of age with radicular pain caused by herniated nucleus pulposus and spinal stenosis. Exclusion criteria were pregnancy, allergy to contrast media, patient refusal, and persistent contraindication to nerve block such as coagulopathy and infection of the injection site.

Study Designs and Treatments

Two pain physicians were involved in this study. They had more than 10 years of working experience in the department of pain medicine. CTEB was performed by one and simultaneously observed by the other pain physician.

During the procedure, all patients were monitored using electrocardiography, pulse oximetry, and noninvasive blood pressure measurements. A 20-gauge cannula was inserted in the participant's forearm. The patients did not receive any sedation. Under fluoroscopic guidance, CTEBs were performed using a 22-gauge, 8.9-cm, sharp needle (Hakko Co., Chikuma-shi, Naganogen, Japan) or a 22-gauge, 7.6-cm, COUDE blunt nerve block needle (Epimed, Marlbourogh, England). The patient was placed in the supine position on a table with the head slightly extended. The fluoroscope was rotated obliquely to the ipsilateral side between 45° to 55° to supply the best view of the selected neural foramen. Before insertion of the sharp needle or blunt needle, skin infiltration with 1% lidocaine 1.5 mL was performed. In the sharp needle group, the needle was advanced to the superior articular process, at the division between the caudal and middle thirds. Then, the needle was advanced into the neural foramen, touching its posterior border to the halfway point between the medial and lateral borders of the articular pillars in an anteroposterior view. In the blunt needle group, a 18-gauge, 45-mm, blunt access cannula was advanced to the superior articular process, at the division between the caudal and middle thirds. After removing the stylet of the blunt access cannula, the needle was inserted to the sheath of the blunt access cannula. Then, the needle was advanced to the same target point as in the sharp needle group. After confirmation of final needle positioning using biplanar fluoroscopy, 2 mL of nonionic contrast medium (Omnipaque 300, GE Healthcare, Little Chalfont, Buckinghamshire, United Kingdom) was injected at the rate of 0.5 mL/s with RTF. Intravascular injection was defined as the spreading of the contrast medium through the vascular channel. If intravascular injection occurred, further injection of local anesthetics and steroids was aborted, and the needle positioning was changed. The procedure time was measured from insertion of the needle to end of administration of the contrast medium to confirm successful CTEB

Sample Size

Reduction in the incidence of intravascular injection by 50% was considered clinically important. The sample size was estimated with the requirement of type I and II errors < 0.05 and < 0.2, respectively. In the pilot study, the incidence of intravascular injection was 52%. Therefore, each group had to include at least 54 patients for the requirement of 50% reduction in the incidence of intravascular injection.

Statistical Analysis

Participant age, gender, diagnosis, spinal level of the procedure, and needling time were recorded. Continuous variables, such as age and needling time, were compared between the groups using independent t tests. Categorical variables, such as gender, injection side, and intravascular injection rate, were compared between the groups using the chi-square test (SPSS Version 20, IBM Corporation, Armonk, NY). A *P* value of < 0.05 was considered statistically significant.

Results

A total of 108 patients were included and 108 CTEBs were performed from C5 to C7 (Fig. 1). The characteristics of study patients are presented in Table 1. There were no significant differences in demographic and clinical characteristics between groups. The incidence of intravascular injection on each level is presented in Table 2. There was no significant difference in the rate of intravascular injection between the blunt needle and the sharp needle groups (35.2% vs. 33.3%, *P* > 0.05).

The procedure time was longer in the blunt needle group than in the sharp needle group (101 ± 12.4 sec-

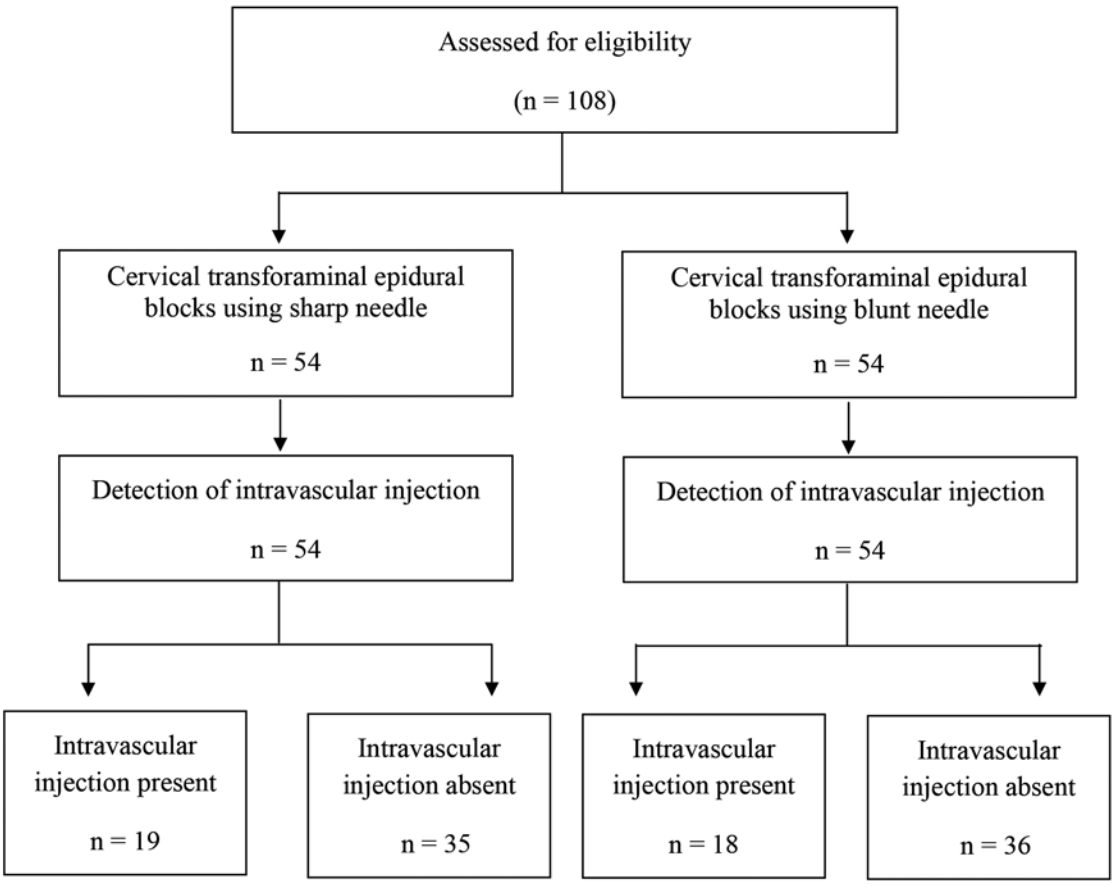

Fig. 1. *Flow diagram of the study design.*

Table 1. *Demographic and clinical characteristics of the study patients (N = 108).*

Variables	Value	
	Sharp Needle (n = 54)	Blunt Needle (n = 54)
Age (yrs)	54.8 ± 11.6	53.9 ± 12.6
Height (cm)	164.1 ± 8.1	163.7 ± 8.8
Weight (kg)	63.6 ± 10.7	62.7 ± 11.1
Male	28 (51.9%)	26 (48.1%)
Level		
C5	10	9
C6	25	23
C7	19	22

Table 2. *Incidence of intravascular injection during CTEB by level.*

Level	Sharp Needle		Blunt Needle	
	Number of injections	Number of intravascular injections (%)	Number of injections	Number of intravascular injections (%)
C5	10	3 (30.0)	9	3 (33.3)
C6	25	10 (40.0)	23	8 (34.8)
C7	19	6 (31.6)	22	7 (31.8)
Total	54	19 (35.2)	54	18 (33.3)

onds vs. 56.67 ± 8.3 seconds, $P < 0.001$). There were no serious complications such as spinal cord or cerebral infarction and infection.

Discussion

From our findings, there was no significant difference in intravascular injection during CTEB between the sharp needle and blunt needle groups. However, the procedure time was longer in the blunt needle group than in the sharp needle group.

In the cervical area, the vertebral artery gives rise to radicular and segmental medullary arteries, which can contribute to the supply of the central nervous system. Ascending and deep cervical arteries also form from those arteries and variably anastomose with the vertebral artery (20,21). The current cervical transforaminal approach, in which the target point is just anterior to the superior articular process, avoids the vertebral artery and its branches. However, radicular and segmental medullary arteries arising from the ascending and deep cervical arteries could be located in the posterior aspect of the intervertebral foramen, and the anatomy of the arteries in the cervical intervertebral foramina is variable. Consequently, penetration of these vessels may occur despite exact needle positioning (21). In addition, injected particulate steroids may act as emboli and incur infarction and neurologic sequelae (11). Therefore, in this study, dexamethasone, a nonparticulate steroid, was used.

It has been reported that the incidence of intravascular injection with a sharp needle in the cervical spine is 19.4% to 63.4% (17,18,22). In the present study, the incidence of intravascular injection with a sharp needle was 35.2%, which is in line with the findings of the previous studies (18).

It was reported that the incidence of intravascular injection during TEB is highest in the cervical spine (19). The intravascular injection rate has been reported to be 19.4% to 63.4% in CTEB (17,18,22) and 9.9% to 17.7% in lumbosacral TEB (17,23,24). In animal studies, blunt needles reduced blood vessel penetration compared to sharp needles (9,10). In clinical studies, it was shown that the blunt needle could better avoid intravascular penetration than the sharp needle during lumbosacral TEB (13,14). However, Smuck et al (16,25) reported that there were no differences in intravascular injection rate among Chiba, Quincke, pencil-point, and blunt tip needles during lumbosacral TEB. In the present study,

the blunt needle did not reduce intravascular injection compared to the sharp needle during CTEB. In addition, procedure time in the blunt needle group was longer than in the sharp needle group. For insertion of a blunt needle, an introducer is necessary. Therefore, an additional step is required to exchange the stylet for the blunt needle through the introducer. Because the blunt needle goes through the tissue by displacing instead of penetrating (16), steering and advancing were not easy to perform in CTEB. Therefore, manipulation of the blunt needle required more time, which could lead to an increase in discomfort during the procedure (26).

In the previous studies (17,19,27), it was not possible to define the vascular contrast medium spreading pattern as venous or arterial during TEBs because the patterns were ambiguous despite using RTF. Similarly, we could not differentiate between the 2 types of vascular pattern in this study.

Limitations

There were some limitations to the present study. First, the procedural pain physician could not be blinded to the type of needle used to perform CTEB. To minimize this confirmation bias and provide homogenous procedural conditions for CTEB, the same procedural pain physician performed all 108 injections. Additionally, the second pain physician simultaneously observed the incidence of intravascular injection and recorded the procedure time during CTEB. Following, the second pain physician also could not be blinded to the type of needle used to perform CTEB because of differences in the visible needle tip through the fluoroscopic image and procedure time. Third, this study was designed to compare the incidences of intravascular injection and procedure times between CTEB procedures using sharp needles and blunt needles. However, differences regarding any other adverse events, such as vasovagal symptoms, superficial bleeding, and patient discomfort, were not examined. Finally, this study was performed in a single center. Therefore, multicenter studies are needed to support our results.

Conclusions

Based on our findings, the blunt needle was not proven safer than the sharp needle for decreasing the rate of intravascular injection during CTEB. In addition, the use of the blunt needle increased procedure time compared to the sharp needle.

Acknowledgements

The authors would like to thank the editorial board of Pain Physician for review and criticism in improving the manuscript.

Author Contributions

All authors had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors designed the study protocol. JL and CP managed the literature searches and HS and KK provided summaries of previous related work. YJ wrote the first draft of the manuscript. SK provided revision for intellectual content and final approval of the manuscript.

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