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Comparison of Whitacre needle and Chiba needle on the incidence of intravascular injection during caudal epidural injections

A single-blind, randomized clinical consort study

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Abstract

Caudal epidural injection (CEI) is effective for lumbar spinal pain. However, accidental intravascular injection reduces therapeutic efficacy of CEI and leads to fatal complications such as hematoma, and neurologic deficit. Whitacre needle has been reported to be effective for reducing intravascular injection during transforaminal epidural injection, compared with Quincke needle. The bevel of Chiba needle is shorter than that of Quincke needle. In this study we compared Whitacre needle and Chiba needle on incidence of intravascular injection during CEI.

This was a single-blind, randomized clinical consort study. After institutional Review Board approval, a total of 164 patients underwent CEI were randomly allocated to one of 2 group (Whitacre needle or Chiba needle group). Intravascular injection was assessed with real-time fluoroscopy. In addition, total procedure time was measured. Data were compared between groups, and $P < .05$ was consideredstatistically significant.

There were no differences between groups in terms of patient demographic and clinical characteristics. There was no significant difference on incidence of intravascular injection between Whitacre and Chiba needle group (11% vs 19.5%, $P = .192$). However, the procedure time is significantly longer in the Whitacre than Chiba needle group (172.8 ± 53.8 sec vs 147.1 ± 61.1 sec, $P = .005$).

Based on current study, our results indicated that Whitacre needle was not effective to decrease the incidence of intravascular injection during CEI, compared to Chiba needle.

Abbreviations: CEI = caudal epidural injection, TFEI = transforaminal epidural injection.

Keywords: caudal epidural injection, Chiba needle, complication, fluoroscopy, intravascular injection, Quincke needle, Whitacre needle

1. Introduction

Caudal epidural injection (CEI) is useful for treatment of lower back pain and/or radiculopathy.[1,2] It is performed by inserting a needle through the sacral hiatus to deliver drugs to epidural space. It is suggested that CEI is ideally performed with fluoroscopic guidance for accurate needle placement.[3,4] However, in CEI inadvertent intravascular injection can occur up to about 40%.[5–7] It can be attributed to complications from failure of procedure to fatal side effects such as paraplegia, spinal cord infarction and epidural hematoma.[8–10]

The different needle type can affect the incidence of intravascular injection during transforaminal epidural injection (TFEI).[11–13] Whitacre type needle has a pencil point needle tip with side hole. It is reported that Whitacre needle is effective to decrease the incidence of intravascular injection during TFEI, compared with Quincke needle.[11–13] Quincke needles and Chiba needles have a sharp cutting tip with different angle of bevel. Quincke needle (20° bevel angle) is a long bevel needle whilst Chiba needle (35° bevel angle) is a short bevel needle. It was suggested that the short bevel needle potentially can decrease tissue injury, compared with long bevel needle while providing the steering and tissue penetration advantage of long bevel needle.[14] Up to date, there are no studies about the comparison of Whitacre needle and Chiba needle on the incidence of vascular penetration during CEI. Therefore, in the

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present study we compared Whitacre needle and Chiba needle on the incidence of intravascular injection in patients underwent CEI using real time fluoroscopy.

2. Methods

2.1. Patients and setting

This single-blind, randomized clinical consort study was approved by institution review board of our hospital and written informed consent was obtained from all patients. This study was registered in the Clinicaltrail.GOV (NCT04204720). The patients who received CEI were enrolled. Inclusion criteria were patients with low back pain and/or leg radicular pain caused by disc herniation or spinal stenosis. Exclusion criteria included allergy to local anesthetics or contrast medium, coagulopathy, local at the injection site, and patient refusal.

A total of 164 patients were enrolled and randomly allocated to one of 2 groups using computer-generated randomization; Group Whitacre (n = 82) received CEI using 25-gauge, Whitacre needle (BD, New Jersey, USA) and group Chiba (n = 82) received the procedure using 25-gauge, Chiba needle (Hakko Co., Naganogen, Japan).

Two pain physicians with more than 10 years of working experience in the pain management department were involved in this study. The same pain physician performed caudal block using a single technique, which was simultaneously observed by the other pain physician.

2.2. Intervention and outcome measurement

All patients were monitored with electrocardiography, pulse oximetry, and noninvasive blood pressure measurements. All procedures were performed under fluoroscopic guidance. Patients were prone-positioned with their feet rotated internally and pillow under lower abdomen and hip. Sacral hiatus was identified by palpating sacral cornua and anteroposterior and lateral view were obtained with fluoroscopy to verify the midline of the sacral hiatus. After aseptic preparation, skin was infiltrated with 1% lidocaine 2 ml and needle was inserted at 50–60° angle into the sacrococcygeal ligament midway between the cornua. After passing sacrococcygeal ligament, the needle was lowered to 20–30° angle and advanced 5 mm into the sacral canal under fluoroscopic guidance. After confirmation of final needle positioning using biplanar fluoroscopy, 5 ml of nonionic contrast medium (Omnipaque 300, GE Healthcare, Buckinghamshire, United Kingdom) was injected at the rate of 1 ml/second under real-time fluoroscopy (Fig. 1 A). Intravascular injection was defined as a characteristic fleeting pattern of contrast media that immediately disappeared (Fig. 1 B). If intravascular injection occurred, the needle was repositioned. After confirmation of caudal injection without any inadvertent intravascular spread, 5 ml of injectate (0.25% lidocaine with 5 mg dexamethasone disodium) was administered. The procedure time from insertion of the needle to end of administration of the contrast medium to confirm successful CEI was measured using a stop watch (Dretec, Saitama, Japan).

2.3. Sample size and data analysis

In the previous study the incidence of intravascular injection was approximately 40% during CEI.[7] It is considered clinically important to detect 50% reduction in the incidence of vascular injection (from 40% to 20%). Calculation of sample size with the α error at 0.05 (two-sided) and the β errors at 0.02 (power = 0.8) revealed that 82 patients were required in each group for the requirement of 50% reduction in the incidence of vascular injection. Student *t* test for analysis of continuous variables, and Chi Squared test with Yates correction or Fisher test for analysis of categorial variables were respectively (SPSS version 20, Chicago, IL, USA). $P < .05$ was considered statistically significant.

3. Results

A total of 164 patients who underwent CEI were analyzed (Fig. 2). Patients characteristics were presented in Table 1. There were no significant differences between 2 groups in terms of

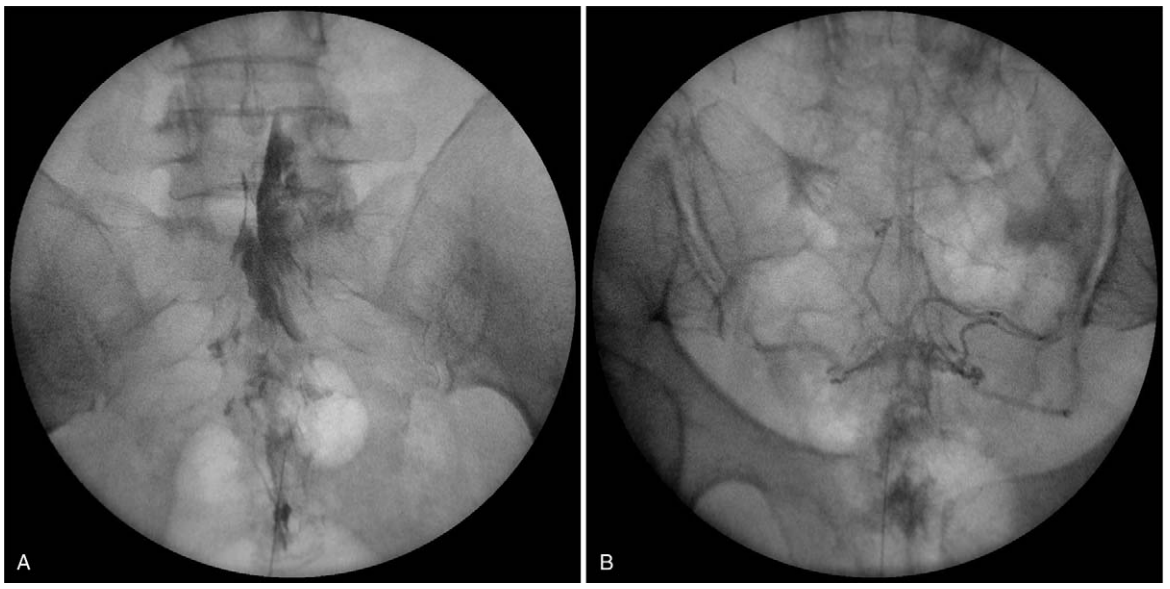

Figure 1. The caudal epidural block under real time fluoroscopy. A. Epidural injection of contrast media. B. Intravascular injection of contrast media.

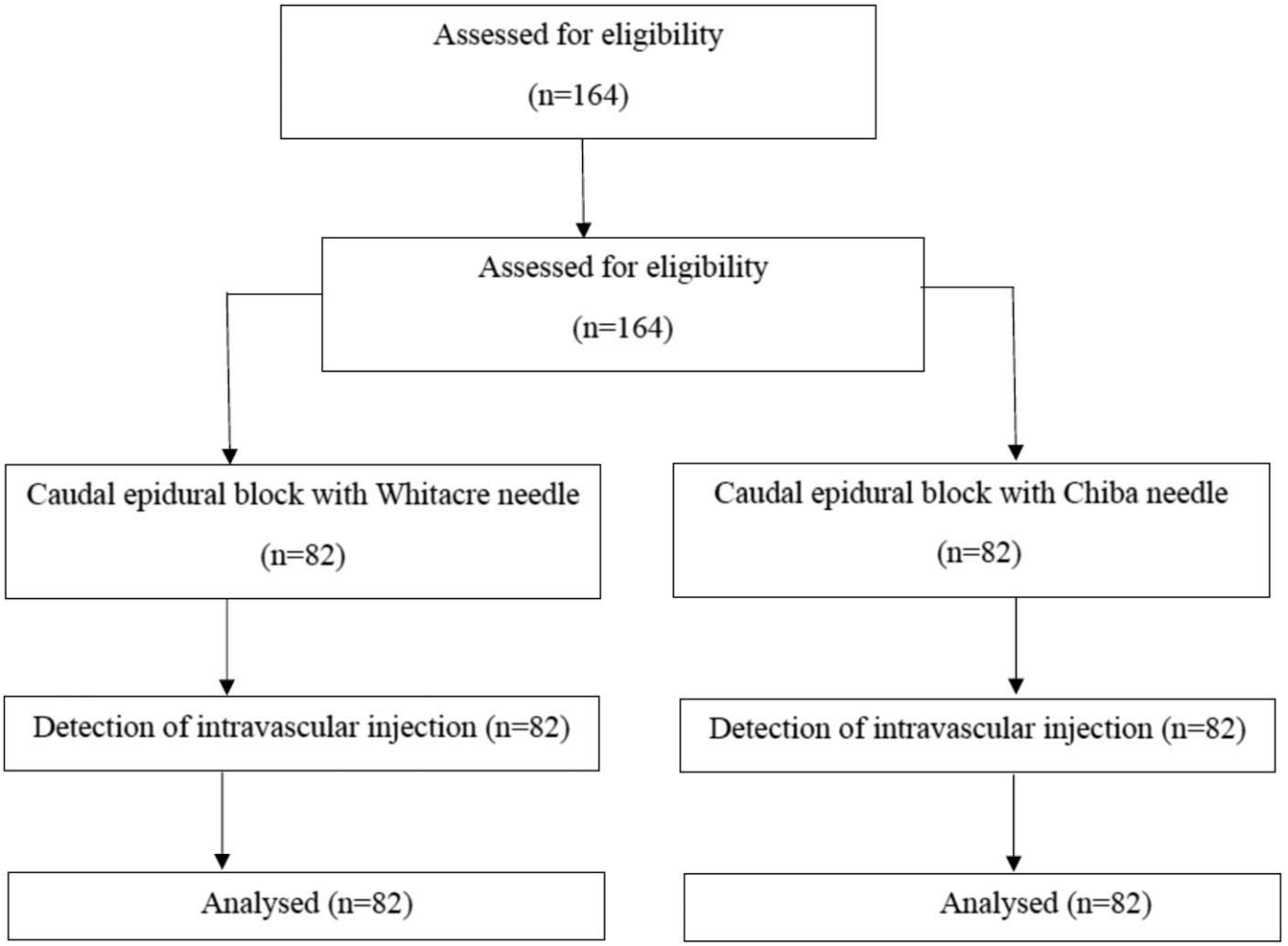

Figure 2. Flow diagram of the study.

demographic data and clinical characteristics. The incidence of intravascular injection was 11% (9/82) for Whitacre needle and 19.5% (16/82) for Chiba needle group, respectively (Table 2). There was no significant difference in the incidence of intravascular injection between 2 group ($P = .192$). The procedure time is longer in Whitacre needle than Chiba needle group (172.8 ± 53.8 second vs 147.1 ± 61.1 second, $P = .005$) (Table 2.). There were no neurological complication and epidural hematoma associated with the intervention in 2 groups.

Table 1

Demographics and clinical characteristics of the study patients (N = 164).

Demographics	Whitacre (n = 82)	Chiba (n = 82)
Sex (M/F)	31/51	25/57
Age (year)	66.5 ± 9.2	65.5 ± 10.8
Height (cm)	160.6 ± 7.6	160.4 ± 7.5
Weight (kg)	64 ± 9.5	63.1 ± 10.8
Herniation of nucleus pulposus	18	15
Spinal stenosis	64	67

Data are presented as mean ± standard deviation or number.

4. Discussion

Our results show that Whitacre needle is not effective to reduce the incidence of intravascular injection, compared with Chiba needle. However, procedure time significantly increased in the Whitacre needle than the Chiba needle group.

CEI is a commonly used for the treatment of lower back pain and/or radiculopathy.[1,2] The safety and effectiveness of CEI rely on reliable needle placement in the epidural space. In CEI

Table 2

Incidence of intravascular injection and procedure time during caudal epidural injection (n = 164).

	Group Whitacre (n = 82)	Group Chiba (n = 82)	*P* value
Intravascular injection n (%)			
Man	5 (6%)	9 (11%)	.402
Woman	4 (5%)	7 (8.5%)	.535
Total	9 (11%)	16 (19.5%)	.192
Procedure time (second)	172.8 ± 53.8	147.1 ± 61.1	.005

Data are presented as number (percentage). Group Whitacre = Patients who received caudal epidural injection using Whitacre needle; Group Chiba = Patients who received caudal epidural injection using Chiba needle.

inadvertent vascular injection decreases the effectiveness of the intervention and increases fatal side effects such as paraplegia, spinal cord infarction, and epidural hematoma.[8–10,15] Inadvertent arterial needle penetration can cause dissection, vasospasm, or occlusion, leading to ischemic damage in the distal area. In addition, injected particulate corticosteroids may act as emboli, which can increase the risk of infarction of spine cord.[10,15,16] Therefore, in the present study dexamethasone, a nonparticulate corticosteroid, is used.

Several methods to detect to intravascular injection during epidural injection are used such as aspiration test, real time fluoroscopy and digital subtraction angiography. The sacral venous plexus has thin vascular wall and low pressure system, which can lead to rapid collapse of vein upon aspiration.[17] Therefore, the accuracy for evaluation of intravascular injection with aspiration test significantly decreases, compared with real time fluoroscopy.[3,18] In addition, the previous studies demonstrated that real time fluoroscopy provides similar efficacy to digital subtraction angiography for detecting intravascular injection during epidural block.[19,20] Digital subtraction angiography has several disadvantages such as increase of radiation exposure to patients and physicians and high cost of new and upgraded fluoroscopic device.[20] In the present study, real time fluoroscopy is used for detecting intravascular injection.

The needle type can influence the incidence of intravascular injection during TFEI. In the previous studies, blunt tip needle and pencil type needle have benefits in reducing the incidence of vascular injection during lumbar TFEI, compared with Quincke needle.[11–13] Whitacre needle and blunt tip needle have similar risk of intravascular injection during lumbar TEFI.[21] Whitacre needle has a tapering pencil-point tip and side hole, which can slide by the vessel without penetration. Even if vessels are punctured with Whitacre needle, intravascular injection of the contrast media may not occur because of side port of the needle.[11] It was shown that the incidence of intravascular injection was significantly lower in Whitacre needle, compared with Quincke needle during lumbar TEFI (5.4% vs 16.2%).[13] However, it is not clear that which type of needle is better to reduce intravascular injection. It was reported that blunt needle is more beneficial than sharp needle during TEFI (2.4% vs 13.3%).[22]. But a recent study showed sharp and blunt needle have comparable risk of intravascular injection during cervical TEFI (35.2% vs 33.3%).[23] In the present study, there is no difference of incidence of intravascular injection between Whitacre and Chiba needle during CEI.

The previous study showed that procedure time of lumbar TEFI was significantly longer in Whitacre needle group than the Quincke needle group, which consequently increased the amount of radiation exposure.[12]Quincke and Chiba needles have a sharp cutting tip. However, Whitacre needle has a tapering pencil-point tip, which can require more force to puncture tissues such as skin, muscles and ligament and lack the steering ability, which consequently increases procedure time and leads to infrequent use of the needle for spinal intervention.[12] In the present study, interventional time significantly also increases in the Whitacre needle group, compared with Chiba needle group.

There are several limitations in this study. First, the pain physician was impossible to be blinded to the type of needle for CEI. To reduce the bias and provide homogenous procedural condition, the same pain physician performed caudal block using a single technique, which was simultaneously observed by the other pain physician. Second, this study was done in a single center and sample size was relatively small, which limited the ability to extrapolate the results beyond the selected patients. Therefore, further studies in the multi center, involving large number of patients are required to support our study.

5. Conclusions

Based on current study, our results indicated that Whitacre needle is not proven safer than the Chiba needle for decreasing incidence of intravascular injection during CEI. In addition, procedure time with Whitacre significantly increases, compared with the Chiba needle.

Author contributions

Data curation: Saeyoung Kim, Sungsick Park, Sioh Kim.
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Writing – original draft: Jungwon Lee.
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