



Corresponding Author:

Ji Hee Hong, MD, PhD
Department of Anesthesiology and Pain
Medicine, Keimyung University Dongsan
Hospital, 1035 Dalgubeol-daero, Dalseo-
gu, Daegu 42601, Korea
E-mail: swon13@hanmail.net

Comparison of Pain Relief and Spread Level Using Two Volumes of High Thoracic Erector Spinae Plane Block: A Prospective Randomized Study

Ji Hee Hong, Hyun Jae Kim, Jae Yun Lee

Department of Anesthesiology and Pain Medicine, Keimyung University Dongsan Hospital, Daegu, Korea

The erector spinae plane block (ESPB) is minimally invasive, safer, and technically easy procedure. Although the ESPB is considered an easier technique compared to the neuraxial block, its efficacy in patients with cervical radicular pain is uncertain. This study aimed to identify pain relief in patients with cervical radicular pain and spread level in the craniocaudal direction using fluoroscopic guidance. A total of 157 patients experiencing neck or arm pain caused by cervical spine disease or muscle related issues who underwent T2 ESPBs were included. The patients were injected with 10 mL (ESPB 10 mL group) or 20 mL (ESPB 20 mL group) of local anesthetic mixture containing a contrast medium. The degree of pain relief and disability was assessed using an 11-point numerical rating scale (NRS) and the neck disability index (NDI), respectively. Moreover, the spread level of ESPB in the craniocaudal direction was assessed. The number of patients who demonstrated excellent pain relief (NRS reduction > 50%) was 49 (62.8%) and 52 (65.8%) in the ESPB 10 mL and 20 mL groups, respectively. The total number of vertebral segments in the craniocaudal direction was significantly higher in the ESPB 20 mL group than in the ESPB 10 mL group (4.69 ± 1.31 vs. 5.96 ± 1.03 , $p < 0.001$). Both groups of ESPB demonstrated a significant reduction in NRS and NDI. The distribution of the contrast medium in the ESPB 20 mL group was more extensive than that in the ESPB 10 mL group.

Keywords: Craniocaudal direction, Erector spinae plane block, Neck disability index, Numerical rating scale, Pain relief, Spread level

Introduction

The erector spinae plane block (ESPB) is a minimally invasive, safer, and technically easy regional block, that provides favorable analgesia in acute and chronic neuropathic pain [1-4]. Although the initial application of ESPB involved the management of thoracic neuropathic pain [5], it is currently widely applied in various clinical situations such as thoracotomy, laparoscopic cholecystectomy, gastrectomy, mastectomy, and spinal surgery [6-9].

ESPB requires ultrasound guidance, which facilitates visualization of local anesthetic spread underneath the erector spinae (ES) muscles. The spinalis, longissimus thoracis, and iliocostalis muscles comprise the ES muscles, which run vertically along both sides of the vertebral column extending from the sacrum up to the skull base [1,10]. Furthermore, ESPB can be performed in the cervical, thoracic, and lumbar regions. Among them, upper or mid-thoracic ESPB has been used more widely compared to that in the cervical and lumbar regions [1].

Previous cadaveric studies on ESPB at the T5 level using computed tomogra-

phy (CT) reconstruction or direct dissection demonstrated the extensive craniocaudal distribution of methylene blue from T1 to T8 vertebral segments deep to the ES muscles with variable involvement of epidural, paravertebral, and intercostal spaces [10]. ESPB performed at the T2 level of the cadaver demonstrated an injected dye distribution ranging from C4 to T10. Furthermore, 36% of the cadavers showed the spread of an injected dye to the ventral ramus, dorsal ramus, paravertebral space, and even the contralateral side [11]. Although the exact action mechanism of ESPB remains unclear, the analgesic effect is thought to be achieved by blocking the ventral and dorsal rami of the spinal nerves. When T2 ESPB is performed in patients with cervical radicular pain, blocking the cervical ventral and dorsal rami may potentially provide pain relief. In accordance with this finding, a previous case report demonstrated that high thoracic ESPB performed at the T3 level was effective in pain relief of cervical radiculopathy in a 13-week pregnant woman [12]. However, no clinical study has proven the analgesic efficacy of T2 ESPB in patients with cervical radiculopathy except for one case report [12].

We hypothesized that ESPB 10 mL group has a similar effect in pain relief and spread level as that of ESPB 20 mL group. The primary endpoint of this study was to compare the effect of pain relief and spread level in patients with cervical degenerative spine disease using 10 mL or 20 mL of local anesthetics in ESPB at the T2 level.

Methods

This prospective and randomized study was approved by our Institutional Review Board (2022-01-026-02). All study participants provided written informed consent to participate in this study. A total of 177 patients aged between 20 and 80 years who received T2 ESPB with either 10 mL or 20 mL of local anesthetics were enrolled. Of these, 157 patients completed this study (February 21, 2022 to October 30, 2022) (Fig. 1).

Patient selection

The inclusion criteria were as follows: (1) patients with sub-acute or chronic neck pain with or without arm pain originating from cervical intervertebral disc herniation, facet arthropathy, foraminal stenosis, and cervical spondylolisthesis, confirmed via cervical (CT) or magnetic resonance imaging (MRI); (2) a score of more than 4 on an 11-point numerical rating scale (NRS) [13] within the week preceding the screening day; (3) neck disability index (NDI) of more than 15 [14];

(4) duration of pain of greater than 1 month; and (5) patients who could fully understand all items described in the NDI. The exclusion criteria were as follows: (1) patients with a history of allergic reactions to local anesthetics and contrast medium; (2) pregnancy; (3) spine deformity; (4) prior history of cervical spine surgery; (5) no previous cervical MRI or CT; (6) coagulation abnormality; and (7) history of receiving another neuraxial block within 1 month before the study.

Group allocation

Patients were injected with 10 or 20 mL of local anesthetic mixture and the spread level of ESPB between the two groups was compared. The local anesthetic mixture of 0.1% ropivacaine in the ESPB 10 mL group was prepared by mixing 5 mL of 0.2% ropivacaine with 5 mL contrast medium (Bonorex, 300 mg I/mL). For the ESPB 20 mL group, 10 mL of 0.2% ropivacaine mixed with 10 mL of the contrast medium was used to prepare 20 mL of the 0.1% ropivacaine mixture. Patients were assigned randomly to be in one of two groups receiving different injection volumes. According to a computer-generated randomization table, patients in two groups re-

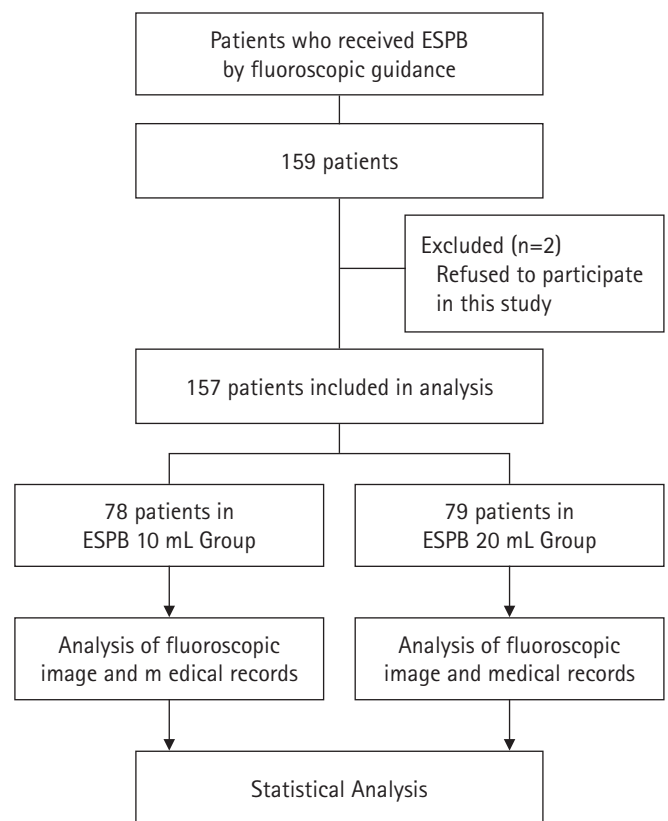


Fig. 1. Consort diagram. ESPB, erector spinae plane block.

ceived 10 mL of the 0.1% ropivacaine mixture (the ESPB 10 mL group) or 20 mL of the 0.1% ropivacaine mixture (the ESPB 20 mL group).

Assessment of clinical outcome

The severity of neck and arm pain was evaluated using the 11-point NRS [13] (0, no pain; 10 worst pain imaginable) before administering the ESPB, and 2, 4, and 6 weeks after the procedure. The NDI, (0-4, no disability; 5-14, mild disability; 15-24, moderate disability; 25-34, severe disability; > 35, complete disability) [14], was assessed before administering the ESPB and 6 weeks after the procedure. The NRS and NDI were assessed by a physician who was blinded to the assigned patient groups. The NRS was obtained by asking "What was your average pain score over the past 24 hours?"

The NDI, introduced in 1991, is a simple, short, and self-reporting questionnaire consisting of 10 items that evaluates the patient's ability to perform physical activities [15]. The NDI is easy to apply in both clinical and research settings and it includes strong psychometric characteristics [15]. Validity assessment and cross-cultural adaptation of the Korean version of NDI have been performed previously [14].

Excellent relief in pain and disability was defined as more than 50% and 30% reduction in the NRS and NDI, respectively. Moderate relief in pain and disability was defined as less than 50% and 30% reduction in the NRS and NDI, respectively. No change in pain and disability was considered indicative of poor relief in pain and disability.

During the 6 weeks of the study period, all patients received 10 mL or 20 mL ESPB 3 times at 0, 2, and 4 weeks after first visit of pain clinic, irrespective of their pain relief. Injected patients were strictly counseled not to receive any other injection therapy. They were given an acetaminophen (325 mg) and tridol (37.5 mg) combination, and aceclofenac 100 mg for medication during 6 weeks of the study period.

T2 ESPB by fluoroscopy after ultrasound guidance

One physician who had experiences of fluoroscopic and ultrasound guided injections more than 5 years performed T2 ESPB. Right or left sided ESPB was performed depending on the location of the neck and radiating arm pain. If a patient received both sides of ESPB, only one side of the injection was included in the analysis. Patients were laid in a prone position for the performance of ESPB. Using a linear high-frequency probe (Logiq S8; GE Healthcare) in the longitudinal position enveloped in a sterile polyvinyl sheath containing ultrasound gel, the spinous process, the lamina, and the T2 transverse

process was confirmed by serially moving a probe from the midline to the lateral side of an upper thoracic spine. Once identified, a 100 mm, 23-gauge needle was inserted in the plane from the caudal to cranial direction. A local anesthetic mixture was injected subsequent to the contact of transverse process. We confirmed the linear spread of the local anesthetic mixture beneath the ES muscle. After confirming a successful linear interfascial plane spreading under ultrasound guidance, the fluoroscopic examination was performed for the final evaluation of the craniocaudal spread level.

Analysis of the craniocaudal spread level

The spread level of T2 ESPB was assessed using the saved fluoroscopic images in the Picture Archiving and Communication System (M6; INFINTT Healthcare). One of the authors who was not involved in fluoroscopy and ultrasound guided T2 ESPB and blinded to the patient group analyzed the spread level. That physician had more than 10 years of clinical experience in ultrasound and fluoroscopic guided injections.

The extent of the craniocaudal spread was assessed using anteroposterior images. After identifying the highest cranial and lowest caudal ESPB levels, final craniocaudal spread level was assessed by counting all segments covered by the contrast medium. Since all ESPBs were performed at the T2 transverse process in both groups, 1 segment of cranial spreads from T2 was defined when the contrast medium was detected until the upper endplate or more than the upper half of the T1 body. One segment of caudal spreads from T2 was defined when the contrast medium was detected until the lower endplate or more than the lower half of the T2 body (Fig. 2).

Statistics

A preliminary study for sample size calculation was performed. Assuming the mean differences in spread level between the ESPB 10 mL and 20 mL groups as 0.5 ± 0.9 and an α error level of 0.05, a β error level of 0.2, and a dropout rate of 15%, 63 patients were required in each group with 80% power and significance level of 5%.

Kolmogorov-Smirnov test was used to examine the normal distribution. If it showed normal distribution, an independent Student's t-test was used to compare the continuous variables (mean \pm standard deviation). Categorical variables were reported as the number of patients (%) and compared using Pearson's Chi square test. A repeated measure of ANOVA was used to analyze the changes in NRS at multiple time points between the ESPB 10 mL and ESPB 20 mL groups.

Differences in the mean vertebral segment covered with

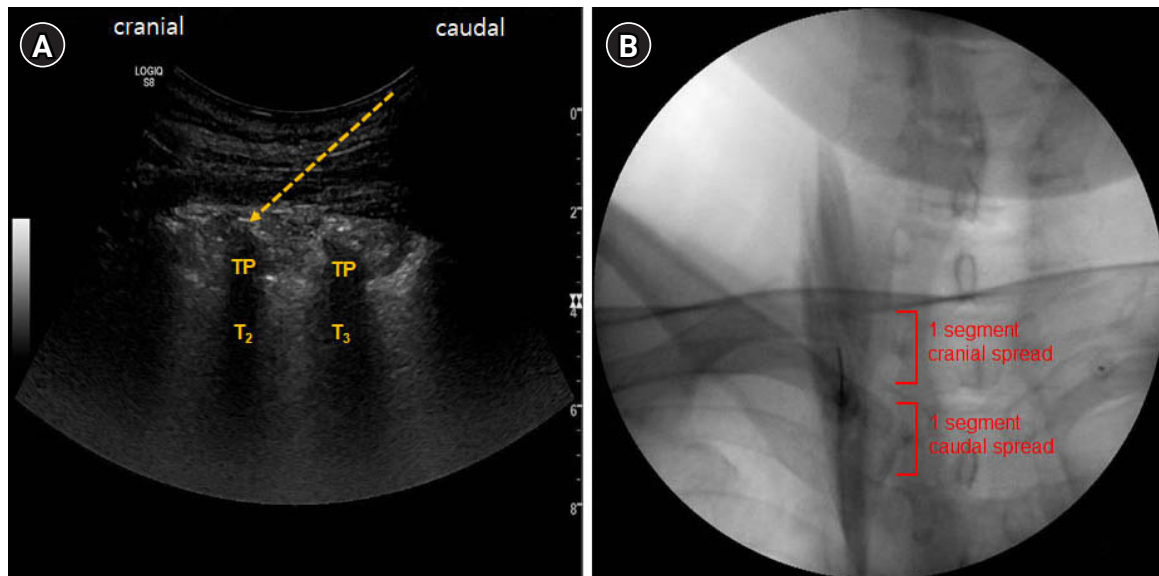


Fig. 2. Ultrasound image showing the passage of needle for T2 erector spinae plane block (A) and anteroposterior image showing 1 segment cranial and caudal spreads (B). TP, transverse process.

Table 1. Demographic data of participants

	ESPB 10 mL group (n = 78)	ESPB 20 mL group (n = 79)	p value
Age (yr)	57.1 ± 11.6	54.6 ± 12.4	0.213
Sex (M/F)	52 (66.7)/26 (33.3)	49 (62.0)/30 (38.0)	0.618
Body mass index (kg/m ²)	24.3 ± 2.8	24.2 ± 2.5	0.150
Side of injection (right/left)	37 (47.4)/41 (52.6)	40 (50.6)/39 (49.4)	0.750
Diagnosis			0.795
Cervical facet joint arthrosis	21 (26.9)	26 (32.9)	
Cervical foraminal stenosis	26 (33.3)	26 (32.9)	
Cervical herniated intervertebral disc	20 (25.6)	19 (24.1)	
Cervical spondylolisthesis	11 (14.1)	8 (10.1)	

Values are presented as mean ± standard deviation or number of injections (%). ESPB, erector spinae plane block.

contrast medium between the ESPB 10 mL and ESPB 20 mL groups were compared using an unpaired t-test (IBM SPSS version 20, IBM Corp., Armonk, NY, USA). A *p*-value of < 0.05 was considered statistically significant.

Results

The 10 mL and 20 mL groups included 78 and 79 patients, respectively (Fig. 1).

Neither group displayed any significant differences in age, sex, body mass index, side of injection, and diagnosis of neck and arm pain (Table 1).

The number of patients who showed an excellent pain relief (more than 50% reduction in the NRS) was 49 (62.8%) and 52

(65.8%) in the ESPB 10 mL and 20 mL groups, respectively (Table 2). NRS changes did not show any significant effects for the group, and the time and group interaction (Fig. 3A).

The number of patients who showed an excellent improvement in disability (more than 30% reduction in the NDI) was 35 (44.8%) and 38 (48.1%) in the ESPB 10 mL and 20 mL groups, respectively (Table 3). A significant reduction in NDI was found at 6 weeks compared to before procedure in both groups (17.1 ± 6.1 vs. 12.3 ± 5.6 in the ESPB 10 mL group, 18.9 ± 6.5 vs. 13.2 ± 7.0 in the ESPB 20 mL group, $p < 0.001$; Fig. 3B).

The total number of vertebral segments in the craniocaudal direction was significantly higher in the ESPB 20 mL group than the number in the ESPB 10 mL group (4.69 ± 1.31 vs.

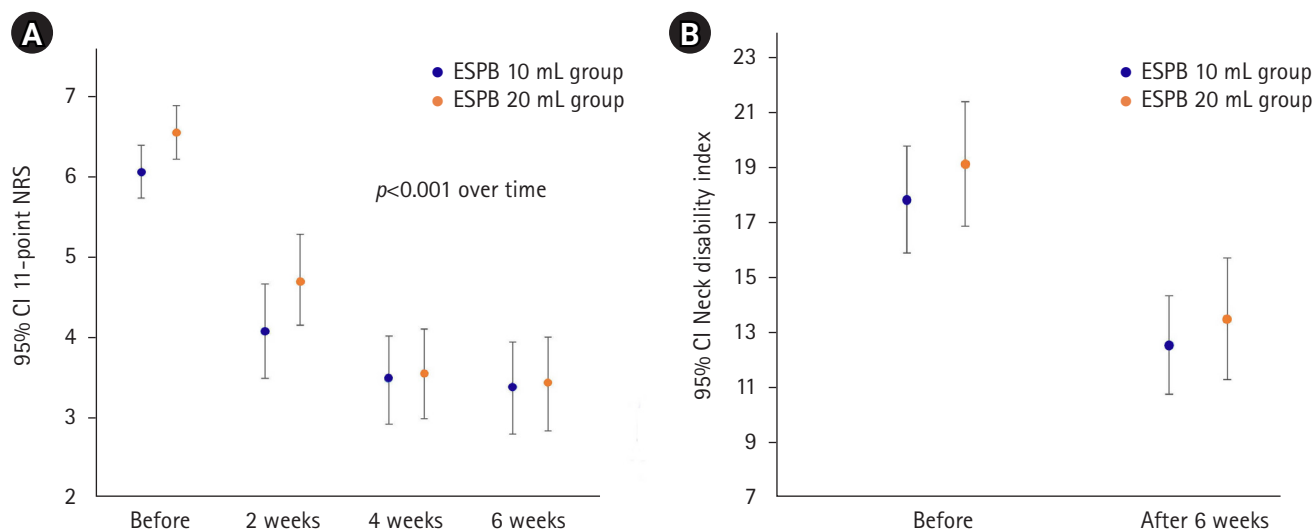


Fig. 3. Comparison of changes in the 11-point NRS (A) and neck disability index (B) before ESPB and at 6 weeks after ESPB in the 10 mL or 20 mL ESPB group. NRS, numerical rating scale; ESPB, erector spinae plane block; CI, confidence interval.

Table 2. The number of patients showing pain relief according to an 11-point numerical rating scale (NRS) between the 10 mL and 20 mL ESPB groups

	ESPB 10 mL group (n = 78)	ESPB 20 mL group (n = 79)	p value
Excellent (> 50% reduction)	49 (62.8)	52 (65.8)	0.828
Moderate (< 50% reduction)	20 (25.6)	17 (21.5)	
Poor (no reduction)	9 (11.5)	10 (12.6)	

Values are presented as number of patients (%). Excellent, more than 50% reduction in the 11-point NRS; Moderate, less than 50% reduction in the 11-point NRS; Poor, no reduction in the 11-point NRS.

Table 3. The number of patients showing improvement in disability according to the neck disability index (NDI) between the 10 mL and 20 mL ESPB groups

	ESPB 10 mL group (n = 78)	ESPB 20 mL group (n = 79)	p value
Excellent (> 30% increase)	35 (44.8)	38 (48.1)	0.752
Moderate (< 30% increase)	25 (32.0)	21 (26.5)	
Poor (no increase)	18 (23.0)	20 (25.3)	

Values are presented as number of patients (%). Excellent, more than 30% reduction in NDI; Moderate, less than 30% reduction in NDI; Poor, no reduction in NDI.

Table 4. The mean vertebral segment covered with contrast medium of T2 erector spinae plane block (ESPB)

	ESPB 10 mL group (n = 78)	ESPB 20 mL group (n = 79)	p value
Number of segments with cranial spread	2.72 ± 1.22	3.52 ± 1.07	< 0.001
Number of segments with caudal spread	2.06 ± 0.97	2.46 ± 0.75	< 0.001
Total number of segments	4.69 ± 1.31	5.96 ± 1.03	< 0.001

Values are presented as mean ± standard deviation.

5.96 ± 1.03, $p < 0.001$; Table 4). The cranial spread was more extensive than the caudal spread in both groups (2.72 ± 1.22 vs. 2.06 ± 0.97 in the ESPB 10 mL group, 3.52 ± 1.07 vs. 2.46 ± 0.75 in the ESPB 20 mL group, $p < 0.001$; Table 4, Fig. 4).

In both groups of ESPB, contrast medium spread up to C6 was observed in the cranial direction (28/78, 35.8% vs. 30/79, 37.9%; Fig. 5A). Two patients in the ESPB 10 mL group

demonstrated contrast medium spread up to C3 level (Fig. 5A). The most common contrast medium spread level in the caudal direction was up to T3 in both groups of ESPB (31/78, 39.7% vs. 36/79, 45.5%; Fig. 5B).

No major complications were reported in any of the patients after T2 ESPB.

Discussion

Both groups of high thoracic ESPB performed at the T2 level demonstrated a significant reduction in NRS and NDI 6 weeks after the procedure. The number of patients showing excellent pain relief was as high as 60% in both groups. The relief in neck and arm pain was also consistent with the improvement in disability, which was demonstrated by significant decrease in NDI 6 weeks after ESPB.

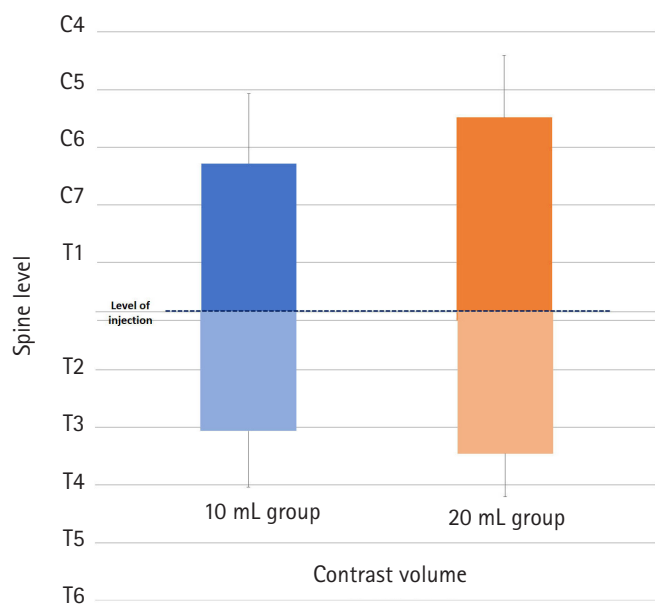


Fig. 4. The extent of craniocaudal spread of T2 in the 10 mL and 20 mL erector spinae plane block groups.

The total number of cervicothoracic vertebral segments, from cranial to caudal was 4.7 and 6 segments in the ESPB 10 mL and 20 mL groups, respectively. When the injected volume was doubled, a significant increase in the extent of contrast medium spread was observed. Although the spread level of ESPB 20 mL was significantly more extensive than that of the ESPB 10 mL group, the analgesic efficacy was similar between the two groups.

The cranial spread was more extensive than the caudal spread in both groups and this phenomenon may be attributed to the anatomical features of ES muscles. The 3 separate cervical ES muscles, semispinalis cervicis, longissimus cervicis, and iliocostalis cervicis, insert into the transverse processes of the C2-C6 vertebrae and provide a pathway for the cranial spread of the injected medication [16]. One advantage of ESPB is its phrenic nerve-sparing effect. A high thoracic ESPB resulting in local anesthetic spread up to the C3 level, poses a theoretical risk of phrenic nerve block, which leads to respiratory difficulty [16]. In this study, only 2 patients in the ESPB 10 mL group showed contrast medium spread up to the C3 level. The most common cranial and caudal spread levels observed in both groups of ESPB were C6 and T3, respectively. The cranial spread up to C6 would be sufficient to reach the pathological level given that the most commonly involved cervical spine levels with degenerative changes arise in the C5-6 or C6-7 levels [17]. A previous study also demonstrated that the sensory block level in the high thoracic ESPB group distributed from the C4-C5 level to the T3-T4 with the sparing of the C3 branch [18]. However, highly variable extent of

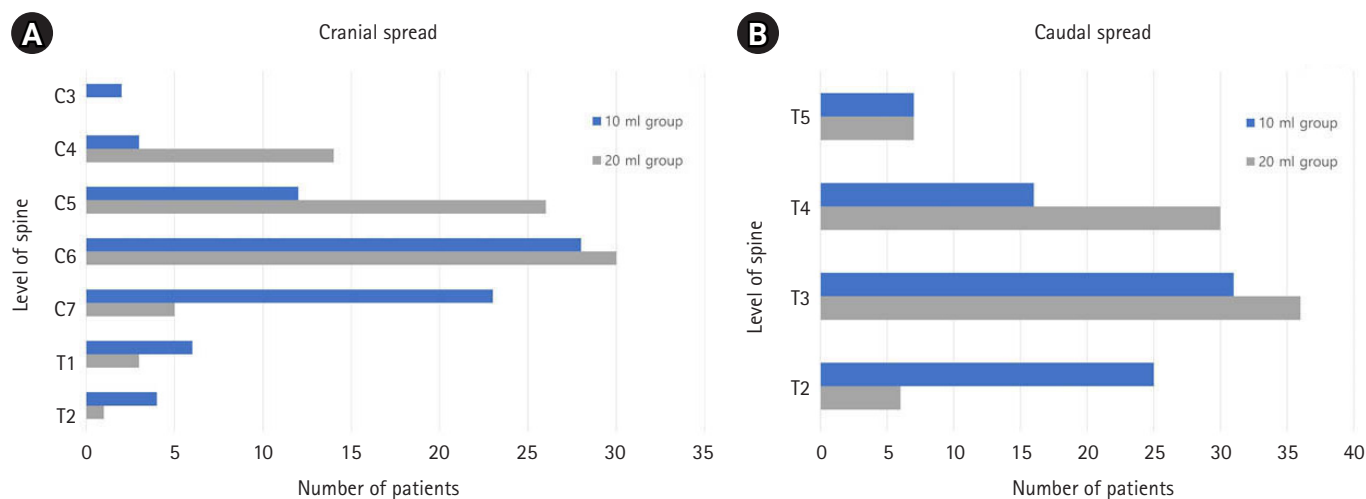


Fig. 5. Number of patients showing contrast medium spread to highest cranial (A) and lowest caudal (B) directions.

contrast dye spread and the level of sensory block have been reported previously [11,19]. When 20 mL diluted contrast dye was injected at the T2 level transverse process, it showed variable distribution of craniocaudal spread ranging from 4 to 14 vertebral segments. When ESPB was performed at the T8 level, this variability increased, ranging from 9 to 20 vertebral segments [11]. In contrast to this finding, this study revealed a more consistent range of craniocaudal spread, which remained from 3 to 8 vertebral segments when 20 mL of local anesthetics was injected. However, direct comparisons of contrast medium spread levels between cadavers and living patients have some limitations. Although the injection volume used in the cadaver study [11] was the same as that used in the present study, the injected solution (methylene blue) was different. In contrast to methylene blue, the contrast medium mixed with local anesthetics in this study has distinct characteristics due to its unique osmolality and viscosity [20]. Therefore, such differences associated with the characteristics of the injected material may lead to diverse and variable craniocaudal spread. In addition, the spread of the contrast dye in a cadaveric model might have some differences due to the reduced tissue tension and elasticity in the cadaver.

Originally, the ESPB at the T5 transverse process was introduced to manage thoracic pain [5]. The analgesic effect of ESPB depends on the craniocaudal spread of local anesthetics extending several vertebral levels in the fascial plane deep to the ES muscle. When local anesthetics are injected into this space, they diffuse anteriorly into the adjacent neural foraminal and intercostal spaces, where they act on the spinal nerves [5,16]. CT also demonstrates that the injected material diffuses anteriorly to approach the area of the cervical neural foramen and adjacent dorsal ramus, where the injected local anesthetics exert their effect. This phenomenon might explain the analgesic effect and the level of sensory block [16].

This study included patients with neck pain and radiating arm and shoulder pain due to cervical facet joint arthrosis, foraminal stenosis, herniated intervertebral disc, and spondylolisthesis. However, thoracic ESPB has been used widely for the purpose of postoperative pain management rather than painful degenerative spine disease [3,18,21-24].

Given that the analgesic effect of T2 ESPB is achieved through anterior diffusion, reaching the region of the cervical neural foramen [5] as well as the ventral and dorsal rami, it is hypothesized that this technique could be effective in managing degenerative cervical spine disease, a common condition encountered in pain clinics. Previous studies also demonstrated favorable treatment outcomes of high thoracic ESPB in ra-

dicular arm pain [12,16].

Previous study confirmed the spread of radiocontrast agents using MRI or CT 1 to 2 hours after the injection [16]. However, we confirmed the spread of the contrast medium immediately after the prepared medication was administered. Such differences in time duration in assessing the location of the contrast medium may result in discrepancies in the spread level.

This study has several limitations. First, we evaluated the analgesic efficacy of high thoracic ESPB with only short term outcomes. However, we could effectively regulate other possible factors that might have affected the clinical result of this study due to the short study period. Second, the confirmation of the location of injected medication was performed just after the injection was done. The assessment of contrast medium distribution should be conducted at least 1 to 2 hours after the injection, to allow sufficient time to for it to diffuse into the anterior or another space.

In conclusion, both groups of ESPB demonstrated significant reductions in the NRS and NDI. The ESPB 20 mL group showed a more extensive distribution of the contrast medium than that observe in the ESPB 10 mL group.

Acknowledgements

None.

Ethics approval

This prospective and randomized study was approved by the Institutional Review Board of Keimyung University Dongsan Hospital (2022-01-026-02). All study participants provided written informed consent to participate in this study.

Conflict of interest

The authors have nothing to disclose.

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ORCID

Ji Hee Hong, <https://orcid.org/0000-0002-6679-3088>

Hyun Jae Kim, <https://orcid.org/0009-0001-6332-0138>

Jae Yun Lee, <https://orcid.org/0000-0003-0976-2573>

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