Randomized Controlled Trial

A Comparison of Anesthetic Quality between Single and Septum-based Double Injection for Ultrasound-Guided Costoclavicular Block: A Randomized Controlled Trial

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Background: In a costoclavicular (CC) approach of an ultrasound (US)-guided infraclavicular brachial plexus block (BPB), a septum between the lateral and the medial/posterior cords can result in an incomplete block. We hypothesized that double injections in each compartment between the septum would result in a higher success rate of BPB than a single injection in the center of the CC space.

Objectives: This study was conducted to confirm the superiority of block quality achieved by septum-based double injections (experimental group; group E) over single injection in the center of the CC space (control group; group C).

Study Design: A randomized, controlled trial

Setting: Department of Anesthesiology and Pain Medicine, Korea University College of Medicine, Anam Hospital.

Methods: Sixty-eight patients who underwent upper extremity surgery randomly received a single (SI group, n = 34) or a septum-based double injection (DI group, n = 34) using the CC approach. Ten milliliters of 2% lidocaine, 10 mL of 0.75% ropivacaine, and 5 mL of normal saline were used for BPB in each group (total 25 mL). Sensory-motor blockade of the ipsilateral median, radial, ulnar, and musculocutaneous nerves was assessed by a blinded observer at 5-minute intervals for 30 minutes immediately after local anesthesia administration. The assessed variables were the success rate, the rate of all 4 nerves blockade, and onset time.

Results: Thirty minutes after the block, the success rate was significantly higher in the DI group than in the SI group (64.7% in the SI group vs 91.2% in the DI group, $P = 0.009$), and the rate of all 4 nerves blockade also significantly increased in the DI group compared to the SI group (44.1% in the SI group vs 91.2% in the DI group, $P = 0$). The onset time was significantly shortened in the DI group compared with the SI group (26.3 ± 5.6 min in the SI group vs 21.3 ± 6.2 min in the DI group, $P = 0.010$).

Limitations: We considered that the location of the septum was always between the lateral cord superficially and the medial/posterior cords below it. In some patients in whom the septum was not visible, a superficial lateral cord was injected first, and then deep medial and posterior cords were injected, assuming that the 2 compartments were divided by the septum.

Conclusions: Compared with the SI, the septum-based DI of CC approach increased the success rate and the rate of all 4 nerves blockade and shortened the onset time.

Key words: Brachial plexus block, costoclavicular approach, infraclavicular block, double injection, ultrasound

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Recently, a costoclavicular (CC) approach has been considered for ultrasound (US)-guided infraclavicular brachial plexus block (BPB) based on its efficiency and safety over a conventional paracoracoid approach (1,2). In the CC approach, the 3 cords are more superficially clustered lateral to the axillary artery; hence, it is more accessible (1). However, a single injection to the center of the cluster formed by the 3 cords could result in an incomplete and uneven distribution of the local anesthetic (LA) to all 3 cords (1).

In our previous study, using the CC approach, we demonstrated that the injections to each of the 3 cords resulted in an increased rate of blockage of all 4 nerves compared to a single injection in the center of the 3 cords using 25 mL of LA (3). However, these triple injections required a greater amount of technical proficiency and more needle passes (3).

In a cadaveric study, Brenner et al identified a septum in 60% of the cases that received a single injection of a dye and confirmed that the septum impeded the spread of the dye (4). Monzó and Hadzic observed a hyperechoic linear septum in 92.5% of patients and described that the presence of the septum between the lateral cord and the medial/posterior cords could be a cause of incomplete LA distribution in a single injection (1). They recommended that more than one injection is necessary to block all 3 cords equally (1).

Therefore, we hypothesized that septum-based double injections (one is targeted to the lateral cord, which comprises the upper compartment of the septum, and the other is targeted to the medial and the posterior cord, which comprises the lower compartments of the septum) would increase the success rate compared to a single injection CC approach without targeting all 3 cords.

Methods

Study Population

Written informed consent was obtained from all the patients after the study protocols were approved by the Korea University's institutional ethics committee (IRB No. 2021AN0150), and the trial was registered in the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN000043880). This study was performed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 checklist.

A total of 68 patients scheduled for surgery of the forearm and hand were enrolled in the study. The patients were aged 19-80 y and had an American Society of Anesthesiologists (ASA) physical status of I-III. The exclusion criteria included chronic obstructive pulmonary disease or respiratory failure, pregnancy, breastfeeding, body mass index $\geq$ 35 kg/m^2, preexisting neuropathy in the operated limb, coagulation disorders, known allergy to LA, local injection at the puncture site, failure to cooperate, and refusal to participate. We conducted a randomized, controlled, parallel-group study (Fig. 1).

The patients were randomly assigned to either the single injection group (SI group, n = 34) or the septum-based double injection group (DI group, n = 34) using a random integer set generator (http://www.random.org/). The ratio of allocation was 1:1. A researcher who was not involved in performing the block generated the randomization set and enrolled the participants. All the procedures were conducted at Anam Hospital, Korea University College of Medicine, Seoul, Korea, from April 2021 to June 2021.

Procedures

All infraclavicular BPBs were performed in the anesthesia procedure room approximately one hour before the scheduled surgery. On arrival, supplemental oxygen delivery and standard monitoring (electrocardiogram, noninvasive blood pressure, and pulse-oximetry) were conducted, and a time-out procedure was performed. Intravenous premedication (50 μg fentanyl and 1 mg midazolam) was administered to all the patients. All the blocks were performed by an experienced anesthesiologist (HJ Shin). We have applied the same methodology in our previous study of a single vs triple injection costoclavicular approach (3).

The patients were placed in the supine position with their ipsilateral arm abducted to 90° and palms facing the ceiling. The patient's head was turned slightly to the contralateral side for the BPB.

The BPBs were performed under US guidance, and strict aseptic precautions were followed. A 22-gauge, 80-mm nerve-stimulating needle (Uniplex, Pajunk GmbH Medizintechnologie, Geisingen, Germany) with a high-frequency (L 4-12 MHz) linear array transducer was used for the BPB in both groups. A nerve stimulator was used to evoke the motor response of the forearm by the 3 cords stimulation and to avoid nerve injury along the needling pathway. The transducer was positioned immediately below the midpoint of the clavicle and over the medial infraclavicular fossa. The transducer was also tilted slightly cephalad to direct the US beam toward the CC space. In the CC space, the axillary artery was identified beneath the subclavius

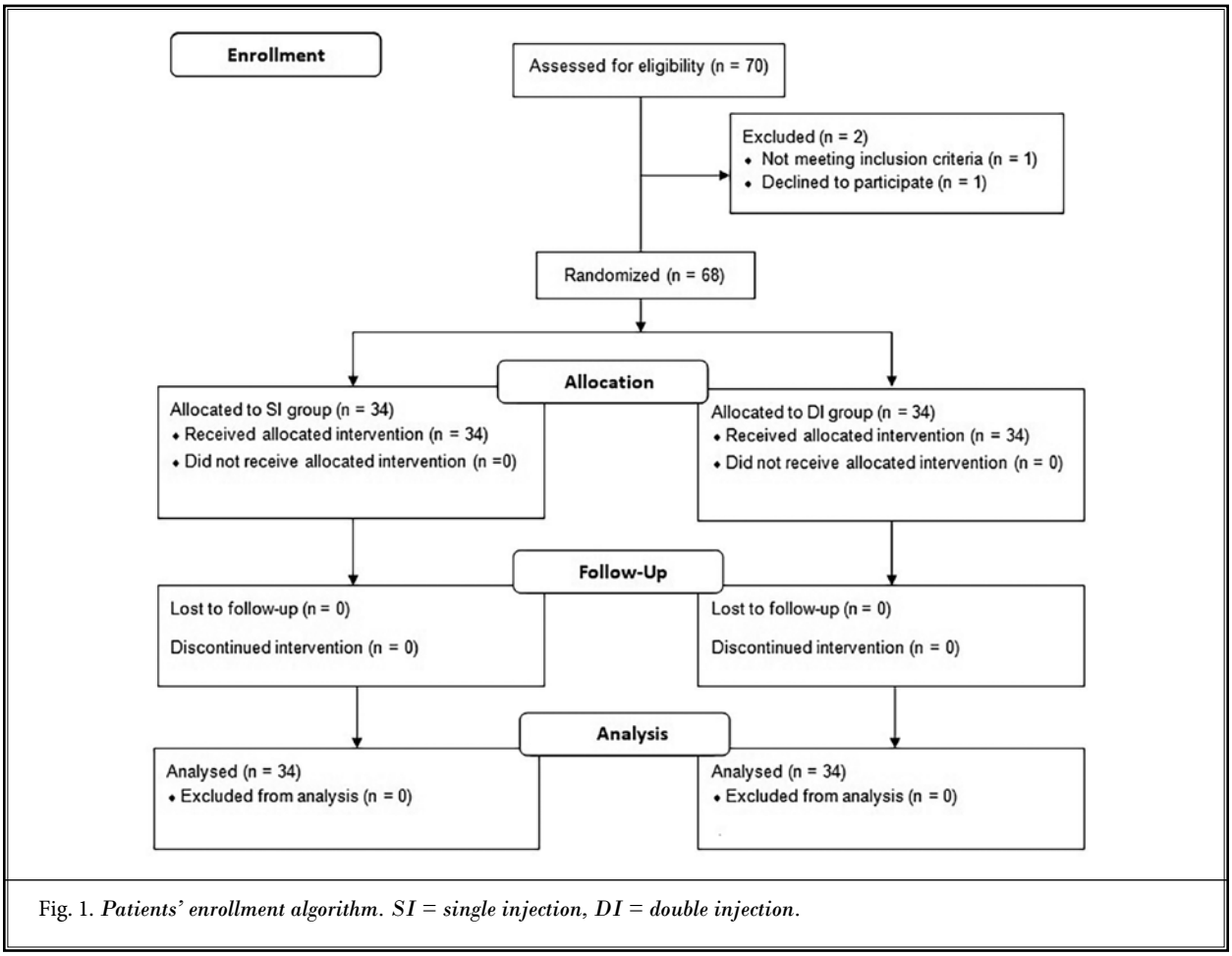

Fig. 1. *Patients' enrollment algorithm. SI = single injection, DI = double injection.*

muscle. Before all the procedures, we searched for the intra-compartmental hyperechoic linear line that could represent the septum and recorded whether it was present or absent.

All the blocks were performed under LA infiltration (2 mL of 1% lidocaine). The block needle was inserted in-plane and from a lateral-to-medial direction. The total volume of the LA mixture was 25 mL (10 mL of 2% lidocaine mixed with 10 mL of 0.75% ropivacaine and 5 mL of normal saline) in each group (3). The LA was injected in 2 - 3 mL increments following intermittent negative aspiration under direct US visualization of the LA distribution. If paresthesia was induced during the procedure, the needle was withdrawn by 2 - 3 mm. The anesthesiologist then ensured that paresthesia was not induced before injecting the LA. The needle tip, as always, was visualized before the LA injection. The US screen was positioned such that it was not visible to the patients in either group.

In the SI group, following the skin puncture, the block needle was advanced to the brachial plexus sheath. After the sheath was penetrated, a small amount (0.5 - 1 mL) of 0.9% normal saline was incrementally injected to 'open' the perineural space until the needle tip was positioned at the center of the cord cluster (3,5). A nerve stimulator (0.3 - 0.5 mA) was used to check and record the motor responses of the 3 cords. After the correct needle tip position was confirmed, 25 mL of the LA was injected gradually.

In the DI group, following the skin puncture, the block needle was advanced to the lateral cord, the most superficial nerve component; the needle tip was placed close to it, and the nerve stimulator (0.3 - 0.5 mA) was used to confirm precise needle placement (we checked the motor response from the lateral cord stimulation: biceps brachii contraction or pronation of the forearm). One-half of the LA volume was then injected into the lateral cord. After that, the needle

was advanced deeply on breaking through the septum to the gap between the medial and posterior cords, which were considered below the septum. The needle tip was placed close to them, and the nerve stimulator (0.3 - 0.5 mA) was applied to confirm the motor response from the medial and posterior cord stimulation (finger or wrist flexion or extension), and the rest of the LA volume was then injected to the medial and posterior cords (Fig. 2).

Evaluations

Imaging time was defined as the time interval between the contact of the US transducer with the patient and the acquisition of a satisfactory image and the needling time was defined as the time interval between the advancement of the needle to the skin and the termination of the LA injection through the block needle; the needling time was applied following 1-2 minutes from the LA skin wheal were recorded. Thus, the performance time was defined as the sum of the imaging and needling times (3).

In both groups, identification of the septum in the US view before the procedure, pop-off feeling of the septum, and motor responses of the 3 cords during the procedure were recorded.

Subsequently, BPB was evaluated immediately after the LA injection and every 5 minutes for up to 30 minutes by a single blinded observer. The sensory block was evaluated using an alcohol swab on the dermatomes of the ulnar (fifth finger), median (palmar aspect of the second finger), radial (dorsum of the hand between the thumb and second finger), and musculocutaneous (lateral aspect of the forearm) nerves (5). The patients quantified the level of the sensory block using an 11-point scale (10 = normal sensation, 0 = no sensation to cold). A complete sensory block was defined by a score of 0 in each nerve dermatome. The motor block was evaluated using a 3-point scale (2 = no block, 1 = paresis; reduced force compared with the contralateral arm, 0 = paralysis; incapacity to overcome gravity), which was applied to the entire arm (5). Accordingly, a complete motor block was defined by a score of 0. The onset time was defined as the time required to obtain full sensory and motor block of the median, ulnar, radial, and musculocutaneous nerves (6). The cases where even one nerve was missed were excluded from the calculation of the onset time. After completing this evaluation, the patient was moved to the operating room for the surgery.

When a patient requested sedation during the surgery, Precedex 0.5 µg/kg/h was infused based on the decision of the anesthesiologist, who was blinded to the group allocations.

At the end of the surgery, the anesthetic grade was assessed using a 3-point scale, where excellent, surgery was completed with only BPB required; insufficient, surgery was completed but required IV medication (≤ 100 µg fentanyl and ≤ 5 mg midazolam with propofol infusion [25 - 50 µg/kg/min]) or an additional local injection at the corresponding incision site; and failure, general anesthesia or additional nerve block was required to complete the surgery (6). Among them, the excellent grade was measured as the success rate.

The presence of hemidiaphragmatic paralysis (HDP) by comparison of pre- and post-operative chest radiographs and the presence of other complications (e.g., hematoma formation, pneumothorax, spinal or epidural anesthesia, Horner's syndrome, hoarseness, respiratory distress, neurological complications, and nausea and vomiting) were assessed in the post-anesthetic care unit by an independent observer who was blinded to the group allocations. HDP was diagnosed when the diaphragm elevation was ≥ 4 cm above its preoperative position (7). The primary outcome variable was the success rate, and secondary outcome variables were the rate of all 4 nerves blockade and onset time.

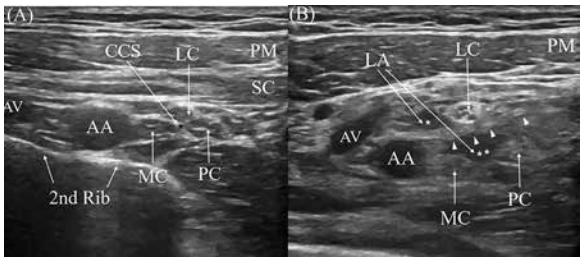

Fig. 2. *Single- (SI) vs septum-based double injection (DI) costoclavicular approaches. A) In pre-block state, all 3 cords of the brachial plexus can be visualized laterally to the axillary artery. In the SI group, the block needle is advanced to the center of the 3 cords (*). After the correct needle tip position is confirmed, 25 mL of the local anesthetic (LA) is slowly injected. B) In the DI group, the block needle is advanced to the lateral cord; then, one-half of the LA volume is injected (*). After that, the needle is advanced deeply breaking through the septum to the gap between the medial and posterior cords, then the remaining half of the LA volume is injected (**).*
The white arrowheads indicate the septum. PM, pectoralis major muscle; SC, subclavius muscle; CCS, costoclavicular space; AA, axillary artery; AV, axillary vein; LC, lateral cord; MC, medial cord; PC, posterior cord; LA, local anesthetics.

Statistical Analyses

In a preliminary study, the success rate (surgery completed with only BPB required) was observed in 7 out of 10 SI-treated patients and 9 out of 10 DI-treated patients. Thirty-four patients were required per group for an α value of 0.05 and a power of 90%. Therefore, 68 patients were recruited. The results are presented as mean ± standard deviation unless otherwise indicated. The statistical analysis was performed using SPSS software version 22.0 (IBM Corporation, Chicago, IL). The chi-square or Fisher's exact test was used to analyze the categorical data, and the Student's unpaired t-test was used to compare the continuous data. A *P* value < 0.05 was considered statistically significant.

Results

The demographic data of the patients are presented in Table 1. No significant differences were observed between the 2 groups.

In the US view, the septum was identified before the procedure in 60.3% of the patients. A pop-off feeling of the septum was noted in 54.4% of the patients during the procedure. The motor responses observed during the procedure were biceps brachii contraction (47.1%), forearm pronation response (32.4%) from lateral cord stimulation, finger flexion (25%) from medial cord stimulation, and finger/wrist extension (11.8%) from posterior cord stimulation. The differences between the groups are presented in Table 2.

Skin puncture was performed once in both groups. Details of the US-guided infra-BPB are shown in Table 3.

Among the patients with sensory and motor blockade, the sensory block in all 4 nerves was more significantly decreased in the DI group than in the SI group at most evaluation times up to 30 minutes after the block (Fig. 3).

Table 1. *Patient characteristics in the 2 groups.*

	SI Group (n = 34)	DI Group (n = 34)	*P* value
Age (years)	49 ± 18	42 ± 16	0.068
Gender (M/F, n)	23/11	23/11	0.602
Height (cm)	166.4 ± 9.4	170.6 ± 9.0	0.062
Weight (kg)	67.9 ± 10.5	70.4 ± 12.9	0.371
ASA PS class (I/II/III, n)	8/22/4	8/25/1	0.369

Values are presented as a mean ± standard deviation or as the number of patients. SI Group, patients who received a single injection; DI Group, patients who received double injections. ASA PS, American Society of Anesthesiologists Physical Status.

No vascular or pleural punctures occurred during the procedures. HDP was seen in 7 cases in the SI group and 6 cases in the DI group. No patients with HDP had dyspnea. Other complications were ptosis (3 cases), hoarseness (2 cases), and nausea (1 case) in the SI group

Table 2. *Septum and motor responses from stimulation of the 3 cords.*

	SI Group (n = 34)	DI Group (n = 34)	*P* value
US view of the septum before the procedure (n,%)	20 (58.8%)	21 (61.8%)	0.50
Pop-off feeling of the septum during the procedure (n,%)	12 (35.3%)	25 (73.5%)	0.002*
Motor response of biceps brachii contraction (n,%)	18 (52.9%)	14 (41.2%)	0.233
Motor response of forearm pronation (n,%)	7 (20.6%)	15 (44.1%)	0.034*
Motor response of finger flexion (n,%)	5 (14.7%)	12 (35.3%)	0.046*
Motor response of finger or wrist extension (n,%)	1 (2.9%)	7 (20.6%)	0.027*

Values are presented as the number of patients. SI Group, patients who received a single injection; DI Group, patients who received double injections. The motor responses from lateral cord stimulation were biceps brachii contraction or pronation of the forearm the motor response. The motor response from medial cord stimulation was finger flexion, and that from posterior cord stimulation was finger or wrist extension. * A *P* value of < 0.05 was considered statistically significant.

Table 3. *Details of the ultrasound-guided infraclavicular brachial plexus block.*

	SI Group (n = 34)	DI Group (n = 34)	*P* value
Type of surgery (n) (fracture vs nonfracture)	10/24	10/24	0.605
Image time (sec)	17.6 ± 7.9	19.2 ± 7.7	0.406
Needling time (min)	2.0 ± 0.6	2.2 ± 0.6	0.154
Performance time (min)	2.3 ± 0.6	2.5 ± 0.7	0.085
Tourniquet time (min)	38.3 ± 17.2	47.9 ± 24.3	0.066
Surgery time (min)	36.4 ± 17.2	45.9 ± 24.3	0.066
Anesthetic grade (n) (excellent/insufficient/ failure)	22/9/3	31/1/2	0.017 *
Success rate (n,%)	22 (64.7%)	31 (91.2%)	0.009 *
Rate of blockade of all 4 nerves (n,%)	15 (44.1%)	31 (91.2%)	0*
Onset time (min)	26.3 ± 5.6	21.2 ± 6.2	0.01 *

Results are presented as mean ± standard deviation or the number of patients. SI Group = patients who received a single injection, DI Group = patients who received double injections. The success rate was assessed at the end of the surgery, measuring the excellent anesthetic grade. *A *P* value of < .05 was considered statistically significant.

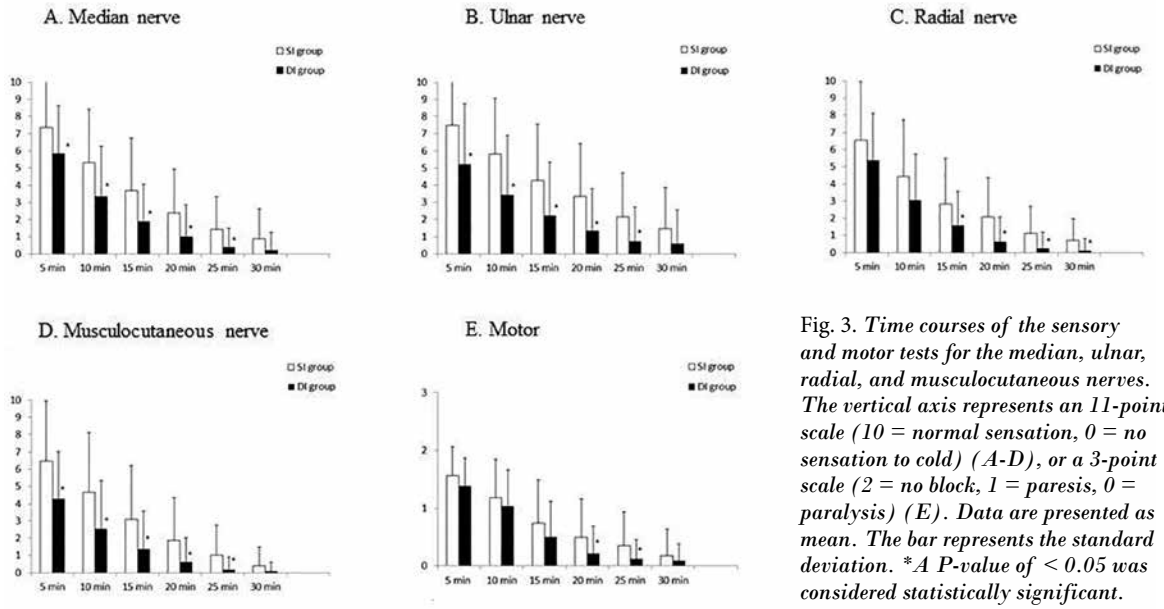

Fig. 3. *Time courses of the sensory and motor tests for the median, ulnar, radial, and musculocutaneous nerves. The vertical axis represents an 11-point scale (10 = normal sensation, 0 = no sensation to cold) (A-D), or a 3-point scale (2 = no block, 1 = paresis, 0 = paralysis) (E). Data are presented as mean. The bar represents the standard deviation. *A P-value of < 0.05 was considered statistically significant.*

and ptosis (2 cases), hoarseness (1 case), and nausea (1 case) in the DI group. Complete recovery of sensory and motor function was confirmed in all patients. No neurologic complications were reported at the 1-week follow-up.

Discussion

The primary finding in this study is that the success rate and rate of blockade of all 4 nerves in infraclavicular BPB was greater, and onset time was shorter in the septum-based DI group than in the SI group.

In our previous study, we targeted each of the 3 cords separately in order to facilitate an even spread of the LA (3). Although the rate of blockade of all 4 nerves was improved with the triple injection compared to the SI group, the triple injection was technically more difficult compared to a single injection (3). Therefore, we referenced studies on the septum, which provided a possible explanation for block failure in single infraclavicular BPB, even in the presence of ultrasound guidance (4).

In the SI group, we used a conventional method (needling to the center of the 3 cords), regardless of the presence of the septum, as a control (3). In the septum-based DI group, the block was administered based on the location of the septum. In some patients in whom the septum was not visible, a superficial lateral cord was injected first, and then deep medial and posterior cords were injected, assuming that the 2 compartments were divided by the septum. We used the same volume of 25 mL as in single vs triple approach study (3).

Monzó et al described that identifying the septum by US before the procedure was challenging (observed in 46.2% of patients), but following the injection, the presence of a septum was confirmed in 94.2% of patients by checking the septum pushed back after the LA injection in the US; they described that septum at this stage was similar to a hyperechoic thick fascia with elastic characteristics (8). However, in our study, when a patient was slightly obese or muscular, the cord cluster became bulging and deep down after LA injection; therefore, when the septum was pushed down by the bulging cluster, it was difficult to find, especially when the septal plane was nearly perpendicular to the overlying skin (4).

When several ways of confirming the septum were studied (Table 2), it did not look easy to confirm the septum before injection on the US view, which was similar with other studies (8). The pop-off feeling of the septum during the procedure was also same (the feeling in the DI group showed a much higher frequency than that of the SI group; 35.3% in the SI group vs 73.5% in the DI group, *P* value = 0.002). Motor response from each cord stimulation showed that the feeling in the DI group was more apparent than that in the SI group, but it was less likely to appear overall (< 50%). Therefore, it does not seem easy to officially check the septum in all patients despite the knowledge that administering the LA based on the septum is more effective.

In our clinical experience as we applied to the DI group in this study, it is enough for practitioners to inject the LA into the lateral cord and into the gap between the medial and posterior cord when the septum itself cannot be found.

We considered that the location of the septum was always between the lateral cord superficially and the medial/posterior cords below it. Areeruk et al also described that only 2% of their cases had other combinations (the lateral and posterior cords in anterior compartment and the medial cord in the posterior compartment) (9). Previous studies have shown the presence of a barrier as a septum between the 2 compartments; however, the presence of a septum between the posterior and medial cords has not been clearly identified (1,4,8). Monzó et al (8) described the structure of the 3 cords: the lateral cord separately and the medial and posterior cords bundled together with their microscopic structural details. The motor response evoked from the first injection in our study was always stimulated from the lateral cord.

Layera et al (2) already studied the SI vs DI CC approaches; however, they did not find a difference in the success rate, although the volume of LA (35 mL) used in their study was higher than that in our study. They performed a second injection in the space between the medial cord and the subclavian artery. We selected the space between the medial cord and the posterior cord for the second injection in this study, and we were able to notice that the space between the 2 cords widened after LA injection. While the number of needle insertions is important for success rate, we think the injection site against the septum is also important.

Limitations

There are some limitations in this study. First, only one anesthesiologist performed all blocks and thus was not blinded to the group allocations. However, the sensory and motor evaluations were performed by an independent blinded observer (3). Therefore, we think that unintentional bias towards positive results had little impact on overall results (3). Second, we did not evaluate the presence of the septum after LA injection in the US image, which has been more definitely defined than the septum before LA injection in other studies (8,9).

Conclusion

To summarize, we suggest that septum-based DI is better than an SI for an even spread of the LA around the 3 cords. When considering the presence of a septum, double injections into 2 compartments that are divided by a septum are sufficient for blockade, without a need to target each of the 3 cords separately.

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