Randomized Controlled Trial

A Randomized Comparison Between Two Injections from Two Planes versus Two Injections with a Uniplanar Approach for Ultrasound-Guided Supraclavicular Block

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Background: Background: The brachial plexus courses along the lateral to posterior aspect of the subclavian artery located within the supraclavicular region as a trunk or division. Therefore we hypothesized that 2 injections, one along the lateral and one along the posterior aspect of the brachial plexus, could be performed by changing the angle of the ultrasound probe, thereby achieving a 3-dimensional (3-D) even distribution of local anesthetics. Previously, we confirmed the efficacy of this type of approach with that of a single cluster approach. These findings represent a subsequent study.

Objectives: This study was conducted to confirm the superiority of block quality achieved by 2 injections from 2 planes (control group; group C) over 2 injections in one plane (experimental group; group E).

Study Design: A randomized, controlled trial.

Setting: Department of Anesthesiology and Pain Medicine, Gachon University Gil Medical Center.

Methods: In group C (n = 35), the brachial plexus sheath was penetrated in 2 planes by anteriorly altering the angle of the ultrasound probe without changing its position. In group E (n = 35), the upper and lower portions of the brachial plexus sheath were penetrated in one plane. A total of 15 mL of lidocaine 1.5% containing epinephrine (1:200,000) was injected at each point in both groups. The ultrasound-guided supraclavicular brachial plexus block was evaluated every 5 minutes for 30 minutes. The main outcome variables were rates of blockage of all 4 nerves and ulnar nerve sparing.

Results: The rate of blockage of all 4 nerves (median, ulnar, radial, and musculocutaneous nerves) was not significantly different between the 2 groups (94% in group C vs. 86% in group E, respectively; $P = 0.232$). The number of spared ulnar nerves was similar (1 vs. 5, respectively; $P = 0.088$). Group procedure times, onset times, and Visual Analog Scale scores for the blocks were similar.

Limitations: For the 2 plane, 2 injection approach, only 2-D imaging was performed rather than 3-D imaging.

Conclusions: Two injections performed in one plane offered similar benefits to 2 injections performed in 2 planes. The 2 techniques provided comparable block qualities and could be viewed as equally effective alternatives.

Key words: Brachial plexus block, multiple injection, supraclavicular block, ultrasound

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The supraclavicular approach is known to provide a dense block for any surgery distal to the mid-humerus region, just like "spinal anesthesia" does for the lower extremities, because the brachial plexus has a compact arrangement at the supraclavicular level (1). Therefore this approach remains an attractive means of regional anesthesia despite the risks of pneumothorax or subclavian artery puncture (2). However, no matter how compact the brachial plexus divisions are gathered, nerve sparing cannot be prevented if local anesthetics (LAs) do not spread evenly within the entire brachial plexus sheath.

The brachial plexus courses along the lateral to posterior aspect of the subclavian artery located within the supraclavicular region as a trunk or division (3). Therefore we hypothesized that 2 injections, one along the lateral and one along the posterior aspect of the brachial plexus, could be performed by changing the angle of the ultrasound probe, thereby achieving a 3-D even distribution of LAs. Previously, we confirmed the efficacy of this type of approach with that of a single cluster approach (4).

In this study, we evaluated whether the superiority of block quality from 2 injections using 2 differing planes (control group; group C) is maintained over 2 injections performed in one plane (experimental group; group E) for an ultrasound-guided supraclavicular brachial plexus block (US-SCBPB).

Methods

Study Population

After obtaining approval from our institutional ethics committee (GAIRB2015-45), written informed consent was obtained from each patient. In addition, the study was registered at the World Health Organization International Clinical Trials Portal (NCT02533557). Each of the 70 patients was scheduled for forearm or hand surgery. Patients were aged 18 to 80 years, and of American Society of Anesthesiologist physical status (ASA) I or II. Exclusion criteria included preexisting neuropathy in the operated limb, ASA III or greater, a coagulation disorder, known allergy to LAs, local infection at the puncture site, chronic obstructive pulmonary disease or respiratory failure, pregnancy, breastfeeding, prior surgery in the supraclavicular region, a body mass index of 35 kg/m2 or more, failure to cooperate, and refusal to participate.

The study was conducted using a randomized, controlled, parallel group design. Written informed consent was obtained days before surgery. Patients were randomly assigned to 1 of 2 groups: either a control group (C), or an experimental group (E) using a random integer generator (http://www.random.org/). The group allocation ratio was 1:1. The authors were not involved in the randomization or enrollment procedures, and patients were not informed of group allocations. All surgeries were conducted in the operating room of Gil Medical Center, Gachon University College of Medicine, Incheon, South Korea.

Procedures

Supplemental oxygen (supplied via a nasal cannula at 4 L/min) and standard monitoring (noninvasive blood pressure, electrocardiogram, and pulse oximetry) were applied throughout block procedures; anxiolysis was not established. For procedures, a patient was positioned supine with a small roll beneath the ipsilateral shoulder and their head was turned to the contralateral side. The supraclavicular region was prepared with povidone iodine solution. A 10-MHz linear probe (Zonare Medical Systems, Mountain View, CA) with a sterile plastic cover and gel were used for guidance. The probe was positioned parallel with and immediately above the clavicle to visualize the subclavian artery and brachial plexus above the first rib or pleura. A nerve stimulator (Stimuplex HNS 12; B. Braun, Melsungen, Germany) was used in both groups.

In group C, subcutaneous 2% lidocaine (1 mL) was injected in a fan-like manner because 2 skin punctures were required. A 22-gauge, 120-mm stimulating needle (Stimuplex insulated needle; D Plus, B. Braun) was advanced using an ultrasound in-plane approach from lateral to medial. After the needle had penetrated the nerve sheath cephalad, 15 mL of LA (1.5% lidocaine mixed with 1:200,000 epinephrine) was injected when the distal motor response was observed at 0.5 mA. Following anterior angulation of the ultrasound probe to visualize the more posterior structures, a second skin puncture was performed. The nerve sheath was penetrated caudally, and 15 mL of LA was injected in the same manner as described earlier (at 0.5 mA) (Fig. 1 a–c).

In group E, after subcutaneously injecting 2% lidocaine (1 mL), a 22-gauge, 120-mm stimulating needle was advanced using an ultrasound in-plane approach from lateral to medial. Following needle penetration of the lower and upper portion of the brachial plexus sheath, 15 mL of LA was injected at each point where the distal motor response in the hand was observed at 0.5 mA (Fig. 1 d–f).

All injections were performed after intermittent negative aspiration under direct ultrasound visualization of LA spread while ensuring expansion of LA with-

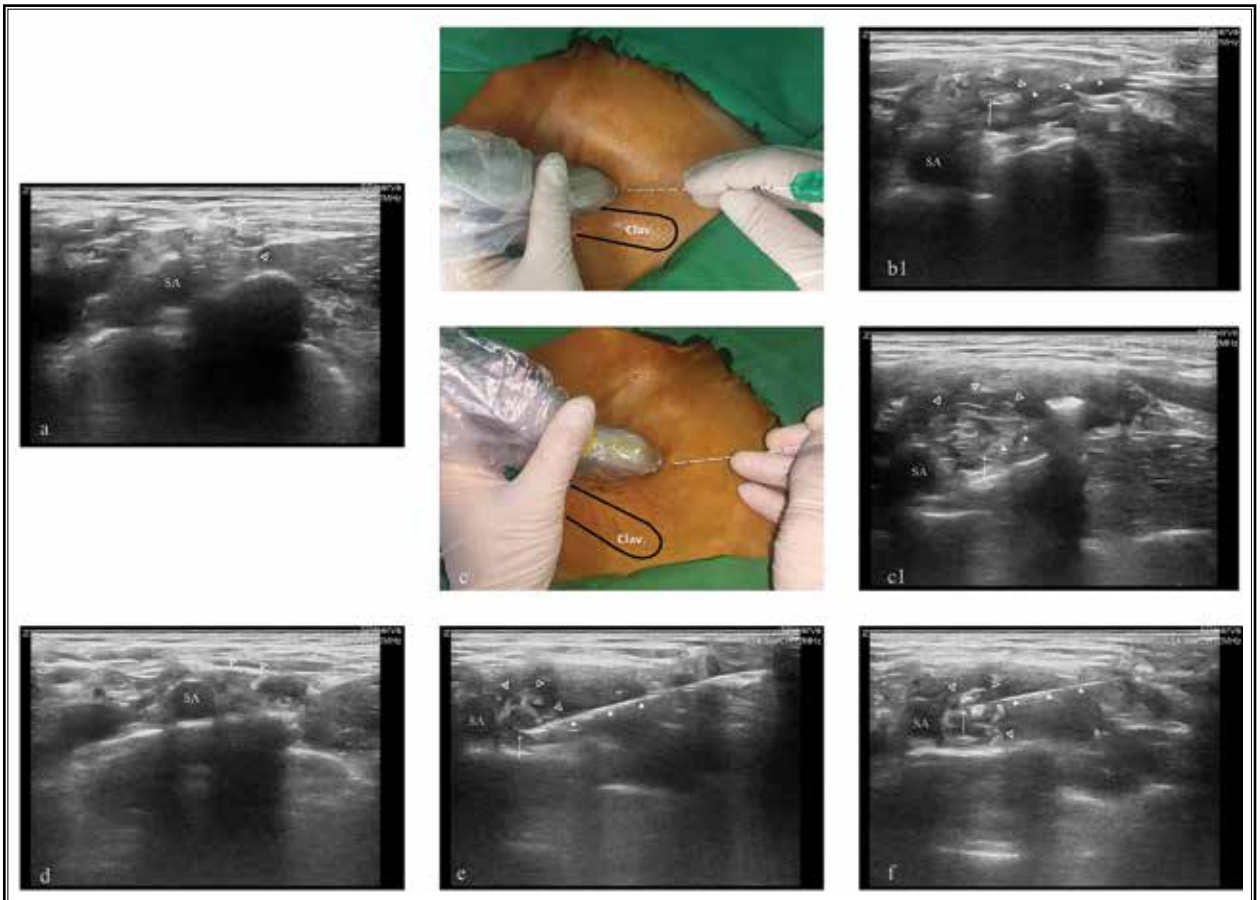

Fig. 1. *Control group versus experimental group in supraclavicular block. Group C patients underwent 2 injections using 2 different ultrasound planes. Group E patients underwent 2 injections using only one ultrasound plane. Group C is shownn in a-c. After penetration, LA was injected cephalad at the first puncture site (b, b1). LA was injected caudally at the second puncture stie (c, c1). Group E is shown in d-f. Preinjection and needle penetratin to the upper and lower parts of the brachial plexus sheath are shown. The white arrow indicates the needle tip, the white arrowhead indicates the needle shaft, and the open arrowhead indicates the brachial plexus cluster. Clav. = clavicle. SA = subclavian artery. (Images b and c were adapted from reference 4, which was written by the same corresponding author of this study. The figure was prepared by Dr. Ju Ho Kim, Gachon University Gil Hospital.)*

in the brachial plexus sheath. If paresthesia was elicited during the procedure, the needle was withdrawn 2 to 3 mm. The anesthesiologist ensured no further paresthesia was elicited before injecting the LA. All blocks were performed by an anesthesiologist with experience of more than 60 cases and were supervised by the coauthors who had experience performing both techniques.

Evaluations

Brachial plexus blockade was evaluated immediately after LA injection and every 5 minutes for 30 minutes by an independent observer unaware of group allocations. The sensory block was evaluated using an alcohol swab on 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 forearm) nerves (4). Patients quantified the level of sensory block using an 11-point scale (0 = no sensation to cold, 10 = normal sensation). Complete sensory block was defined as a score of 0 for each nerve dermatome. Motor block was evaluated using a 3-point scale where 0 = no block, 1 = paresis, as indicated by reduced force as compared with the contralateral arm, and 2 = paralysis, indicated

an incapacity to overcome gravity of the whole arm (4). Accordingly, a complete motor block was defined as a score of 2. After completing this evaluation, the patient was transported to the operating room for surgery.

Performance time was defined as time from probe positioning to the completion of LA injection (4). Onset time was defined as the time required to obtain full sensory and motor blocks of the median, ulnar, radial, and the musculocutaneous nerves for up to 30 minutes following the second LA injection (4). Cases with incomplete nerve block were not included in the calculation of onset time. Anesthesia grade was assessed after the end of surgery using a 4-point scale, where excellent = completion of surgery with brachial plexus block alone; good = when the patient felt discomfort necessitating intravenous (IV) medication (< 100 µg fentanyl and midazolam 5 mg), insufficient = when IV medication of ≥ 100 µg fentanyl and midazolam 5 mg, propofol infusion (25–80 µg/kg/min), or additional local injection at the operative site was required, but surgery was finished successfully; and failure = the need for general anesthesia to complete surgery (4). We did not perform an additional nerve block at any operative site. When a patient requested sedation during surgery, midazolam 2 to 5 mg was administered at the decision of an anesthesiologist regardless of anesthetic grade. The anesthesiologist was unaware of group allocations.

Patients were asked to rate procedure-related pain using a 11-cm Visual Analog Scale (VAS) (0 cm = no pain, 10 cm = worst imaginable pain) (5) and satisfaction with the procedure (0–100%) in the postanesthesia care unit (PACU). Complications detected in the PACU were evaluated by an independent observer unaware of group allocations.

The primary outcomes were rate of blockage of all 4 nerves, rate of ulnar nerve sparing, and the anesthetic grade. The secondary outcomes were procedure times, onset times, and VAS scores on block.

In a preliminary study, ulnar nerve sparing occurred in 0 of 10 patients in group C, but in group E, the ulnar nerve was spared in 2 of 10 patients. Thirty-five patients were required per group for an α value of 0.05 and a power of 90%.

Results are presented as means ± standard deviations or as numbers (percentages). The statistical analysis was performed using SPSS Version 13.0 for Windows (SPSS Inc., Chicago, IL). The χ^2 test was used to analyze categorical data, and the Student unpaired t-test to compare continuous data. *P* values of < 0.05 were considered statistically significant.

Results

Patient recruitment took place from August 2015 to December 2015. Seventy patients were included in the present study. The patient enrollment algorithm is illustrated in Fig. 2.

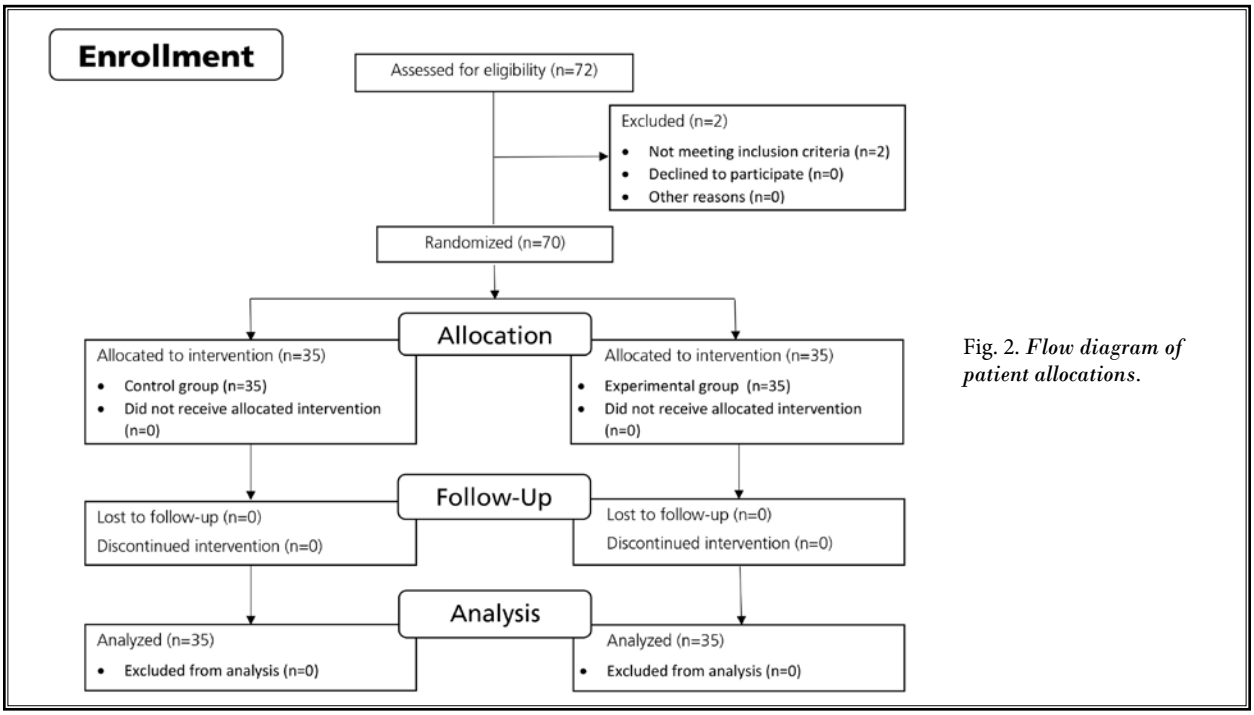

Fig. 2. *Flow diagram of patient allocations.*

Group demographic data are shown in Table 1. No significant difference was observed between these 2 groups even with the exception of ASA classification.

US-SCBPB data are summarized in Table 2. Rates of blockage of all 4 nerves and ulnar nerve sparing rates were not significantly different between the 2 groups. One case in group E failed in anesthetic grade due to a VAS score of 3 to 4 in all 4 nerves at 30 minutes. Group performance times, onset times, and VAS scores on block were similar.

Proportions of patients with complete sensory and complete motor blocks at each evaluation time (up to 30 minutes post-block) were similar between the 2 groups (Fig. 3).

No vascular or pleural puncture occurred during the procedures, and no patient complained of tourniquet-related pain. Complications were reported in the PACU. Reported complications in group C were paresthesia (2 cases), bruising at the injection site (1 case), and shivering (2 cases). Reported complications in group E were paresthesia (1 case), chest tightness (2 cases), shivering (1 case), and ptosis (3 cases). No paresthesias remained at the 1-week follow-up visits as determined by the chart reviews.

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

	Group C (n = 35)	Group E (n = 35)	*P* value
Age (yrs)	49 ± 19	46 ± 14	0.444
Gender (M/F)	23/12	16/19	0.092
Height (cm)	165.7 ± 10.3	165.7 ± 8.7	1.000
Weight (km)	65.0 ± 14.0	67.1 ± 12.4	0.507
ASA Class (I/II)	23/12	32/3	0.009*

Results are means ± standard deviations or numbers of patients. Group C: patients who underwent 2 injections from 2 ultrasound planes; Group E: patients who underwent 2 injections in one ultrasound plane.
* Statistical significance was accepted for *P* values of < 0.05.

Table 2. *US-SCBPB data.*

	Group C (n = 35)	Group E (n = 35)	*P* value
Type of surgery (fracture vs nonfracture)	20/15	19/16	0.810
Performance time (min)	5.9 ± 1.5	5.3 ± 1.6	0.091
Surgery time (min)	55.5 ± 29.3	56.2 ± 28.0	0.921
Tourniquet time (min)	54.3 ± 25.7	55.3 ± 27.7	0.869
Onset time (min)	13.3 ± 7.5	13.2 ± 7.1	0.928
Rate of all 4 nerves blocked (n)	33 (94%)	30 (86%)	0.232
Median nerve sparing number	1	1	1.000
Ulnar nerve sparing number	1	5	0.088
Radial nerve sparing number	0	1	0.314
Musculocutaneous nerve sparing number	0	2	0.151
Anesthesia grade (excellent/good/insufficient/fail)	33/2/0/0	32/2/0/1	0.602
Sedative/analgesic drugs			
Midazolam (n)	18	27	0.025*
Fentanyl μg (n)	2	3	0.643
VAS block	1 ± 2.0	1 ± 1.4	0.691
Satisfaction (%)	96.5 ± 4.9	96.7 ± 6.1	0.906

Results are expressed as means ± standard deviations or numbers of patients. Group C: patients who underwent 2 injections from 2 ultrasound planes; Group E: patients who underwent 2 injections in one ultrasound plane. *Statistical significance was accepted for *P* values < 0.05.

Discussion

Our results show that 2 injections in one plane produce a similar performance time and onset time, and an appropriate sensory and motor block on all 4 nerves when comparing with the results obtained using 2 injections performed at 2 different planes.

Techasuk et al (6) introduced a targeted intracluster injection technique whereby a main cluster injection with additional satellite cluster injection were performed and achieved a 100% success rate. However, targeted intracluster injection needs multiple injections, a high level of knowledge of ultrasound image interpretation, and a high needling skill level. The approaches used in our study can be performed easily while keeping imaging interpretation minimalized to a level appropriate even for novices.

In the Techasuk et al (6) study, the targeted intracluster approach has been compared with 2 injections (corner pocket + cluster approach) in one plane, but we do not use the corner pocket approach despite its high success rate because it is associated with greater risks of pneumothorax or subclavian artery puncture owing to the anatomic accessibility of the block needle to pleura or subclavian artery (4,7,8).

Several studies have compared the block qualities of 2 injections versus a single injection in one ultrasound plane (9,10). Most of these studies have concluded that 2 injections offer no benefit over a single injection for US-SCBPB. However, our previous study demonstrated that 2 injections from 2 planes achieved a better block quality than a single injection in one plane (4).

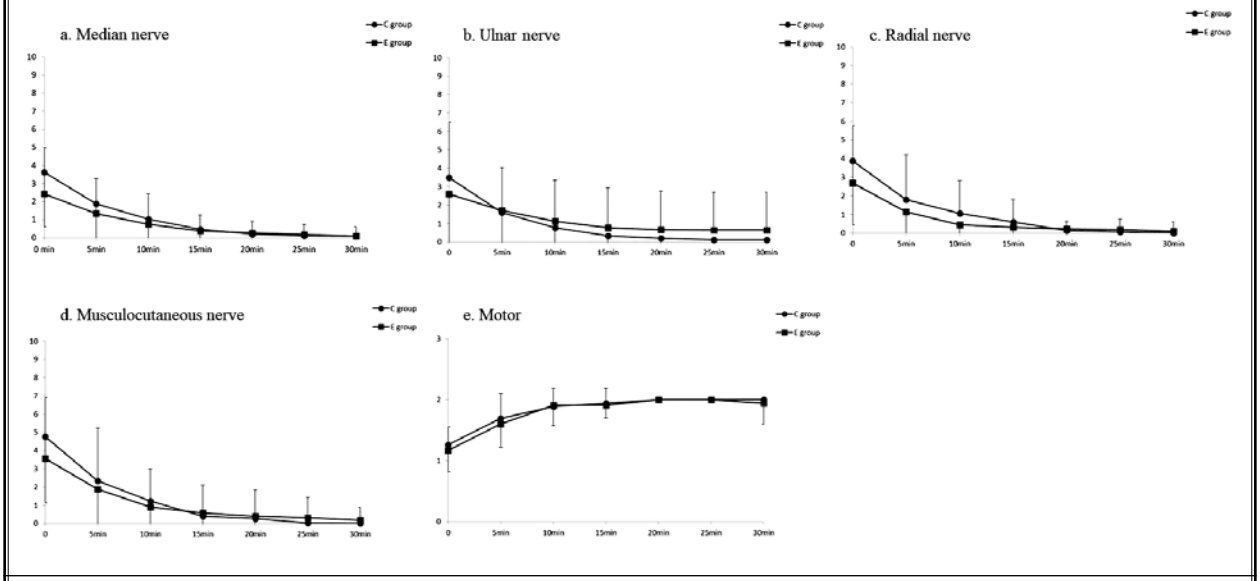

Fig. 3. *Time courses of sensory and motor testing of median, ulnar, radial, and musculocutaneous nerves. Group C: patients who underwent 2 injections from 2 ultrasound planes. Group E: patients who underwent 2 injections in one ultrasound plane. The vertical axis represents an 11-point scale (0 = no sensation to cold, 10 = normal sensation) (a-d), or a 3-point scale (0 = no block, 1 = paresis, 2 = paralysis) (3). Graphs were prepared by Dr. Ju Ho Kim, Gachon University Gil Hospital.*

In addition, it has been shown that a single injection technique tends to increase the risk of asymmetric LA spread (11,12).

The trunks, divisions, and cords of the brachial plexus form a "Phrygian cap" slightly over and behind the subclavian artery; the posterior cord is laid posteriorly and laterally, the lateral cord superficially, and the medial cord deep to the cap (3). In regard to group C in this study, we wanted to inject LA 3-dimensionally based on considerations of the anatomic structure, but strictly speaking, the actual injections were made using still 2-D ultrasound imaging.

Reported rates of ulnar nerve sparing are generally greater than median, radial, and musculocutaneous nerve sparing even when US-SCBPB is performed using the corner pocket approach (13,14). In the present study, even 2 injections from 2 planes did not totally prevent ulnar nerve sparing.

The risk of nerve injury when the needle is gradually advanced within the sheath is a major concern of the cluster approach (15). In the supraclavicular area, connective tissues comprise more than 50% of the tissue within the brachial plexus sheath where the LA is deposited (2), as such, we used a nerve stimulator and ultrasound guidance simultaneously to advance the needle into the sheath. We checked the distal motor response at 0.5 mA prior to administering LA (16). We did not change the needle position in the course of injection. Nerve injury is a critical concern, and we agree with the view of Gadsden and Orebaugh (15) that the number one focus is patient safety rather than the achievement of complete nerve block.

We consider increased block consistency more important than shorter procedural or onset times because failure to block even one nerve can result in failed anesthesia (4). Meco et al (17) performed their brachial plexus blocks with distal nerve blocks on each nerve (median, ulnar, and radial nerves) simultaneously to increase their success rate.

All blocks in this study were performed by one anesthesiologist who was aware of the group allocations. However, primary and secondary end point evaluations were performed by independent blinded observers. Therefore we believe that unintentional bias had little impact on the overall results of this study (18). Although this limitation may have eliminated interoperator variability, it may have reduced the generalizability of our findings (16).

Moving the probe during a nerve block can be disorienting if the surgeon is less familiar with ultra-

sound anatomy. The patient's body habitus can also limit anatomic definition. In our study, a slight change in probe angulation without changing the position of the probe, allowed for additional site imaging without having to reorient to the areas anatomic structures.

Conclusions

Although 2 skin punctures were required in group C, the patients did not report discomfort about that owing to the broad fan-like effect of the first subcutaneous LA injection (4). The 2 approaches in our study have additional pros and cons. Each practitioner will have to determine which approach best suites their skill level, their patient's body habitus, and which approach may provide better results based on the surgery to be performed. In conclusion, performing 2 injections in one plane offered similar benefits to performing 2 injections at 2 different planes. The 2 techniques provided comparable block qualities and should be viewed as equally effective alternatives.

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