ORIGINAL ARTICLE

# A Randomized Controlled Trial of Ultrasound Versus Nerve Stimulator Guidance for Axillary Brachial Plexus Block

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**Background:** Ultrasound-guided techniques improve outcomes in regional anesthesia when compared with traditional techniques; however, this assertion has not been studied with novices. The primary objective of this study was to compare sensory and motor block after axillary brachial plexus block when performed by novice trainees allocated to an ultrasound- or nerve–stimulator-guided group. A secondary objective was to compare the rates of skill acquisition between the 2 groups.

**Methods:** This study was a prospective, randomized, observer-blinded, 2-arm controlled trial. Anesthesia trainees participating in this trial were novices to axillary brachial plexus block and sonography. All trainee participants underwent a standardized training program. The primary outcome was combined sensory and motor block in the relevant territories 30 minutes after completion of block. A global rating scale was used to assess trainee block performance.

**Results:** The study was ceased after 12 trainees completed 153 blocks. There was no difference between groups in combined motor/sensory score ($P = 0.28$) or as a function of block number ($P = 0.38$). There was no difference in onset between groups ($P = 0.38$). In both groups, there was an increase in the global rating scale score ($P < 0.0001$) and reduced preblock survey and block performance times ($P = 0.001$) with experience.

**Conclusions:** We were unable to demonstrate a difference in the efficacy of axillary brachial plexus block performed by novices when ultrasound guidance was compared with a nerve stimulator technique. There was evidence of similarly improved clinical performance of novices in both groups.

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Ultrasound imaging has been a significant advance in regional anesthesia, providing a mechanism to dynamically image needle, target, and local anesthetic injectate. Systematic reviews and meta-analyses of randomized controlled trials (RCTs) demonstrate that ultrasound-guided techniques improve outcomes (faster block performance, fewer needle passes, reduced incidence of vascular puncture, faster sensory block onset, and success rate) when compared with traditional techniques.[1–6] Limitations of existing RCTs comparing ultrasound guidance with traditional techniques included having operators with a wide range of expertise, including both consultant and trainees performing the intervention. The authors of a 2015 review noted that, currently, there are no high-quality randomized studies that evaluate the learning of ultrasound-guided peripheral nerve blockade by novices.[6]

In this randomized, observer-blinded, controlled trial, we compared blocks performed by trainees taught to perform ultrasound-guided axillary brachial plexus blockade to those trained to perform a nerve stimulator technique. To evaluate learning, all trainees were novices to both brachial plexus block and sonography. The primary objective was to compare sensory and motor blockade of relevant territories below the elbow 30 minutes from completion of block between the ultrasound-guided group and the nerve stimulator technique group. A secondary objective was to compare the rates of skill acquisition between the 2 groups.

## METHODS

This study was a prospective, randomized, observer-blinded, 2-arm controlled trial with an allocation ratio of 1:1. The study was conducted at St Vincent's Hospital, a University of Melbourne–affiliated hospital located in metropolitan Melbourne, Australia. St Vincent's Hospital, Human Research and Ethics Committee approved this study (HREC—A 125/05). The trial was registered with the Australian and New Zealand Clinical Trial registry (ACTRN registration number 12605000750684). Anesthesia trainees participating in this trial were novices to axillary brachial plexus block and sonography and had given written consent to be taught and supervised axillary brachial plexus block using ultrasound guidance or a nerve stimulator technique. Trainees were randomized to the ultrasound group (UG) or the nerve stimulator group (NSG) using a computer-generated schedule in permuted blocks of 4. The randomization sequence was stored in opaque envelopes by a competent individual not involved in the study. Patient inclusion criteria were American Society of Anesthesiologists (ASA) physical status I to III who were scheduled to have elective forearm, wrist, or hand surgery appropriate for axillary brachial plexus blockade. Written informed consent was obtained from all patients. Exclusion criteria were patient refusal to receive regional anesthesia, nonsuitability for regional anesthesia, allergy to study drugs, opioid dependence, cognitive impairment, body weight less than 55 kg, and neurological disease of the upper extremity. Patients received axillary brachial plexus block according to the trainee group allocation.

### Initial Training

All trainee participants underwent a standardized training program that comprised a didactic program and demonstration of block according to their group allocation. The didactic content included anatomy and pharmacology relevant to the brachial plexus, theory and application of nerve stimulation including evoked motor responses, preparation/positioning, and safety. Trainees randomized to the NSG received detailed training specific to nerve stimulator technology including the required motor responses. The NSG participants observed the motor responses

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using percutaneous electrical stimulation with a Stimuplex HNS 12 (B. Braun, Melsungen, Germany) stimulator. This was demonstrated using a pen device that allows percutaneous nerve localization without skin puncture. This technique is associated with improved outcomes after axillary brachial plexus blockade.[7] Trainees in the NSG practiced percutaneous stimulation of the terminal branches of the brachial plexus in 5 volunteers. Trainees randomized to the UG received training specific to ultrasound technology including the physics and technology of ultrasound, machine familiarity, sonographic recognition of nerves, vessels and musculoskeletal structures, transducer manipulation, optimization of images, and practice of maintaining needle in alignment of ultrasound on phantoms. Trainees in the UG had the sonoanatomy relevant to axillary brachial plexus blockade demonstrated to them. Trainees in this group then practiced acquiring and optimizing the required images in 5 volunteers. The approximate time spent on didactic and hands-on learning was 2 and 1 hour, respectively. A LOGIQ e (GE Healthcare, Richmond, Australia) ultrasound machine with a 12-L, 38-mm linear array transducer, 13 to 6 MHz was used for pretraining and all procedures performed by UG participants. A study investigator (M.J. B.) supervised practice of both practical skills (acquiring ultrasound images and eliciting the motor responses).

## Axillary Brachial Plexus Block Technique

In both groups, sedation and analgesia were provided with midazolam 0.05 mg/kg and fentanyl 0.25 to 0.5 μg/kg IV, respectively. Axillary brachial plexus blockade was then performed at the level of the insertion of pectoralis major muscle into the humerus. The patients were positioned supine with arm abducted to 90 degrees and elbow flexed. After skin preparation with antiseptic solution and local anesthesia infiltration, a 22-gauge, 50-mm short-bevelled insulated needle (Stimuplex; Braun) was connected to a nerve stimulator with an initial setting of 0.1-millisecond pulse width, 2-Hz frequency, and current output of 1.0 mA. A preblock survey to identify neural structures was performed with percutaneous stimulation or sonography in the NSG and UG, respectively. The trainee received feedback from the supervisor to ensure that the image or motor response was correctly interpreted. Ropivacaine 0.75% 30 mL (225 mg) was used with the following increments (radial nerve 13 mL, median nerve 12 mL, and musculocutaneous nerve 5 mL). At the time of study protocol design, there was evidence that a multi-injection technique was the best practice for the NSG.[8] Specifically, a triple injection technique superior to axillary artery to locate median and musculocutaneous nerves and inferior to locate radial nerve was used,[9] and the ulnar nerve was not located separately as recommended.[10] In the NSG,[9] the objective was to inject local anesthetic when an appropriate motor response was present less than 0.6 mA at 0.1-millisecond pulse width. For the UG, a real-time in-plane ultrasound technique was used with the goal being perineural spread of local anesthetic. Nerve stimulation was used in the UG for educational purposes, with the observed motor response confirming to the trainee that the structure being imaged was a nerve. Nerves stimulator thresholds were recorded in NSG only. There was a 15-minute time limit for procedures with the procedural time commencing when block needle entered the skin and completed at the final injection of local anesthetic.

## Assessments and Outcomes

A trained assessor (unaware of randomization sequence) who was absent during the procedure, and therefore blinded to group assignment, evaluated the sensory and motor block at 5-minute intervals to 30 minutes. Assessments commenced when the final local anesthetic injection was made and the needle removed from the skin. Signs of group allocation (eg, ultrasound gel on patient) were removed before the assessor arrived. Regardless of group allocation, an ultrasound machine was placed in an appropriate position so as to mask the casual observer not involved in the study. Sensory block was assessed in the 5 sensory distributions below the elbow: musculocutaneous (lateral forearm), radial (dorsum of first web space), median (thenar eminence), ulnar (medial border of hand), and median cutaneous nerve of forearm (medial side of forearm). Sensory block was graded using a 3-point score as follows: 1, normal sensation (no block); 2, reduced pinprick sensation (partial block); and 3, absent pinprick sensation (complete block). Motor function was assessed using the following movements: elbow flexion (musculocutaneous nerve), wrist extension (radial nerve), thumb index finger opposition (median nerve), and finger abduction (ulnar nerve). Motor block was graded using a 3-point score as follows: 1, normal power; 2, partial block, able to move but not against resistance; and 3, absence of movement. Contralateral assessments were used to assist with sensory and motor assessment.

A technical skills global rating scale (GRS) was used to assess trainee block performance. The GRSs have appropriate attributes for procedural assessment including content and construct validity. This scale has been validated over time for procedural skill assessment in surgery and regional anesthesia.[11] The GRS assessed the following domains of performance: ergonomics, respect for safety, time and motion, use of assistants, and knowledge of procedure. For the GRS that assessed NSG participants, 2 domains were added, use of nerve stimulator and recognition of motor responses. For the GRS that assessed UG participants, 4 domains were added: machine settings and optimization, sterile technique, survey scan, and knowledge of anatomy and needle-transducer orientation. A 5-point text-anchored Likert scale was used to grade performance in each domain. The sum of the scores in each domain was used to assess procedural performance. Because the total scores in both study groups were different, a percentage of a total achievable score was calculated to compare results between groups.

Patient data collected comprised age, sex, height, weight, ASA physical status, and diabetes. Surgical data comprised surgical site (forearm, wrist, and hand), tourniquet, and surgical duration. Block-related data comprised duration of preblock survey (with percutaneous stimulation or sonography), block performance duration, motor responses in NSG, requirement for general anesthesia, and presence of tourniquet pain. The following data were recorded in the postanesthesia care unit (PACU): patient readiness for discharge and suitability for PACU bypass (using a modified Aldrete score) and maximum pain scores. Duration of postoperative analgesia was recorded from the time the block was complete until patients' first request for analgesia. Patients were contacted after surgery to detect potential neurological sequelae.

## Statistical Analysis

The primary outcome was combined sensory and motor blockade using 3-point scores over the 5 sensory and 4 motor distributions described previously at 30 minutes. Therefore, the maximum and minimum scores possible were 27 and 9, respectively. Sample size determination was based on an expected increase in score from a baseline of 21 (Department Audit) to 24 using ultrasound compared with a nerve stimulator technique. To achieve a power of 80% with probability of type 1 error of 0.05, it was planned that a total of 450 patients were to be recruited, with a total of 30 trainees each performing 15 axillary blocks. Data are

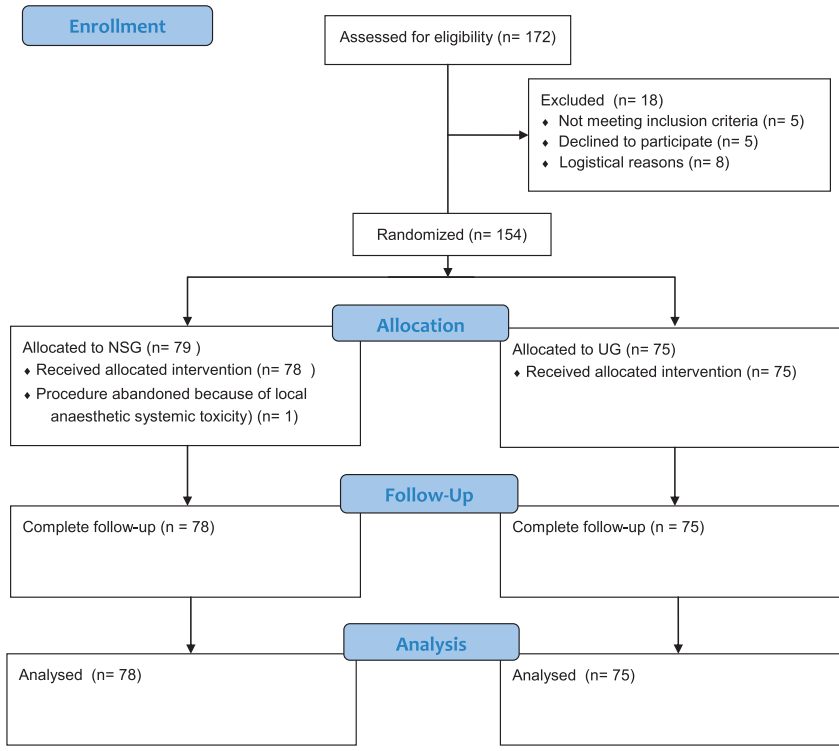


**FIGURE 1.** Consolidated standards of reporting trials diagram summarizing the flow of patients through the study.

summarized using means and SDs for continuous data. Ordinal or skewed continuous data are described using median (10th–90th percentiles) and categorical data as number and percentage. Block characteristics and outcomes were compared between the 2 groups (for all blocks combined) using *t* tests, Mann–Whitney tests, or Fisher exact tests, depending on the characteristics of the data. General estimating equations with robust standard errors were used to determine the impact of group allocation and block number (1 to 15) on our primary outcome, technical skills GRS, and times to complete the block. Analysis was performed using Stata Version 13 (StataCorp, College Station, Texas). For all analyses, $P < 0.05$ was used to define statistical significance.

## RESULTS

The trial did not attain its planned size and was ceased prematurely. This was related to the growing perception that ultrasound technology was advantageous and lack of trainee acceptance of being randomized to the NSG. The period of recruitment was April 17, 2007, to January 7, 2011. Figure 1 summarizes the flow of patients and their progress through the study. A total of 154 patients were randomized, one had their intervention abandoned because of local anaesthetic systemic toxicity (mild in severity: central nervous system features including agitation). The results from 153 recruited patients are included in this analysis. Nine trainees completed 15 blocks (4 in NSG; 5 in the UG), 1 trainee completed 7 blocks (NSG), 1 trainee completed 6 blocks (NSG), and 1 trainee completed 5 blocks (NSG). Patient and surgical characteristics are summarized in Table 1 with no confounding characteristics identified. Block characteristics and outcomes are reported in Table 2. There were no differences between the groups including the primary outcome, combined sensory/motor score at 30 minutes [NSG, 22 (19–27); UG, 24 (19–27); $P = 0.05$, 95% confidence interval (CI) for difference between groups was −0.8–2.8] for all blocks combined. Figure 2 illustrates the combined motor/sensory score at 30 minutes as a function of block number. There was no difference between groups ($P = 0.28$) or as a function of block number ($P = 0.38$). Figure 3 illustrates the combined motor/sensory score at 5-minute intervals as a measure of onset with no difference in onset between groups ($P = 0.38$). Consistent with local anesthetic effect, over the first 30 minutes, in both groups there was an increase in the combined score ($P < 0.0001$). Figure 4 illustrates the GRS score as a function of block number with no difference between groups ($P = 0.83$); however, an increase in the GRS score was noted with experience ($P < 0.0001$). Figures 5 and 6 graph the preblock survey and block performance durations as a function of trainee block number. There were no significant differences in these parameters between groups ($P = 0.99$ for preblock survey;

**TABLE 1.** Characteristics of Patients and Surgery

| Characteristic | NSG, n = 78 | UG, n = 75 |
|---|---|---|
| Age, y | 43.5 (17.2) | 45.0 (16.4) |
| Sex (male) | 66 | 74 |
| Height, cm | 172.8 (10.3) | 173.1 (10.3) |
| Weight, kg | 79.8 (18.2) | 78.3 (13.9) |
| BMI, kg/m$^2$ | 26.7 (5.4) | 25.9 (4.4) |
| ASA III | 11.7 | 15.1 |
| Diabetes | 2.6 | 5.5 |
| Surgical site (forearm/wrist/hand) | 1.3/29.9/68.8 | 4.1/16.4/79.5 |
| Tourniquet duration, min | 50 (23–95) | 43 (10–82) |
| Surgical duration, min | 50 (23–107) | 45 (18–84) |

Data are presented as mean (SD), median (10th–90th centile), or percentage.

BMI indicates Body mass index.

**TABLE 2.** Block Characteristics and Outcomes

| Characteristic | NSG, n = 78 | UG, n = 75 | *P* |
|---|---|---|---|
| Preblock scanning duration, min | 6 (4–8) | 5 (3–9) | 0.5 |
| Block performance duration, min | 11 (7–15) | 12 (8–16) | 0.05 |
| Pain during block | 19 (24) | 6 (8) | 0.007 |
| Sensory/motor score at 30 min | 22 (19–27) | 24 (19–27) | 0.05 |
| Conversion to general anesthetic | 7 (9.0) | 6 (8.0) | 0.54 |
| Tourniquet pain | 6 (7.7) | 3 (4.1) | 0.27 |
| PACU duration, min | 9 (0–60) | 30 (0–62) | 0.10 |
| PACU pain score | 2 (1–6) | 2 (0–3) | 0.12 |
| Duration of postoperative analgesia, hours | 12 (6–20) | 12 (6–16) | 0.47 |
| Willingness to have repeat procedure | 70 (90) | 62 (84) | 0.20 |

PACU pain was worst pain measured using numerical rating scale (0, no pain; 10 worst pain ever experienced).
Data are presented as mean (SD), median (10th–90th centile), or n (percentage).

$P = 0.083$ for block performance). However, preblock survey and block performance durations reduced with experience in both groups ($P = 0.001$). Fewer patients in the UG reported pain (yes/no) during the block compared to those in the NSG [6 (8) compared to 19 (24), n (percentage)]. A similar proportion of patients met the criteria for bypassing PACU [n (%): 23 (32) and 24 (35) in groups NSG and UG, respectively].

## DISCUSSION

In this RCT with novices performing all blocks, we were unable to demonstrate a difference between the NSG and UG in the efficacy of axillary brachial plexus blockade evaluated using a combined motor and sensory blockade at 30 minutes. There was also no difference in block onset between study groups. However, in both groups, there was evidence of improved trainee performance with experience. There was an increase in the GRS score and reduced preblock survey and block performance times. Fewer patients in the UG experienced pain during the block and this was potentially related to the use of nerve stimulation in the NSG for localizing nerves, rather than confirming the acquired ultrasound image.

This study is unique because all participants were novices and underwent a standardized pretraining program specific to group allocation. The authors of a recent Cochrane Database Systematic review to May 2015 (including 32 RCTs and 2844 participants) who compared ultrasound-guided regional anesthesia of the upper and lower extremity, alone or combined with other methods of nerve localization, commented that the source trials often provided insufficient detail on the experience and expertise of practitioners and whether experience was equivalent between intervention and control groups.[6] This current study indicates that a significant improvement in clinical performance by novices can occur within a finite period of experience (15 procedures). The Cochrane reviewers also comment that there were variations in quality, for example, insufficient effort to explain allocation concealment or ensure masking of outcome assessors in the source trials. This is in contrast to our current study where we made comprehensive efforts to conceal group allocation and to ensure that outcome assessors were masked to group assignment.

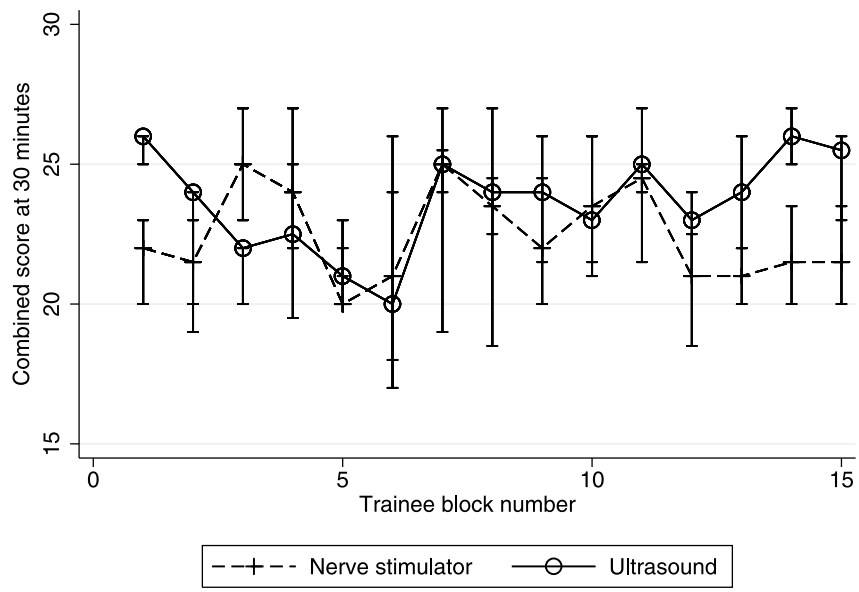


**FIGURE 2.** Combined motor/sensory score at 30 minutes as a function of trainee block number. There was no difference between groups ($P = 0.28$) or as a function of trainee block number ($P = 0.38$).

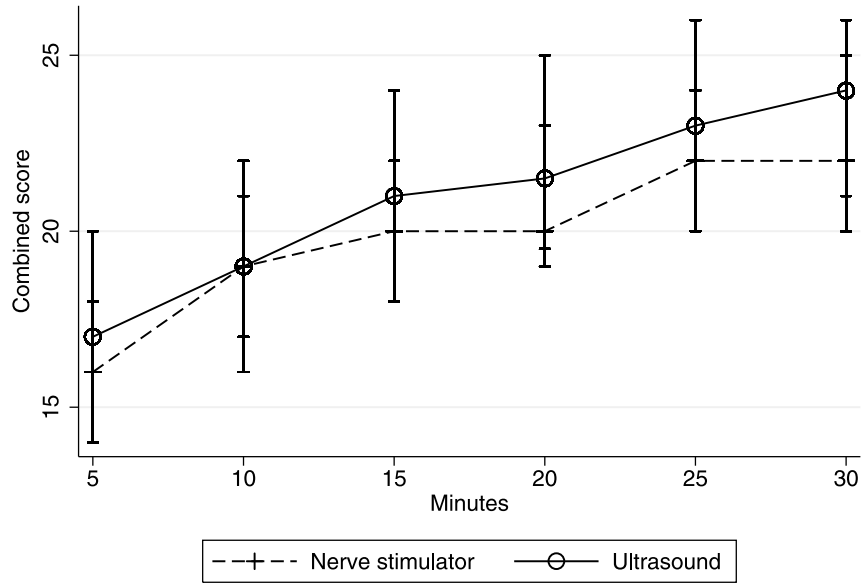


**FIGURE 3.** Combined motor/sensory score at 5-minute intervals as a measure of onset. Results expressed as median (interquartile range). There was no difference in onset between groups ($P = 0.38$); however, during the 30-minute assessment period, in both groups, there was an increase in the composite score ($P < 0.001$).

There are several limitations with this study. Due to the type of intervention, we were unable to blind trainees and supervisors; therefore, this is an unavoidable source of performance bias. It is possible that our supervisors were more experienced in one technique compared to another. If this were a source of bias, because of the timing of this study, relatively early in the evolution of ultrasound-guided peripheral nerve blockade, it would have been in favor of nerve stimulation. We cannot determine if feedback given to the trainee after the preblock survey was more helpful in one group compared to the other or equally helpful. On the other hand, feedback should be a part of teaching novices and hence our study represents real-world training. We were unable

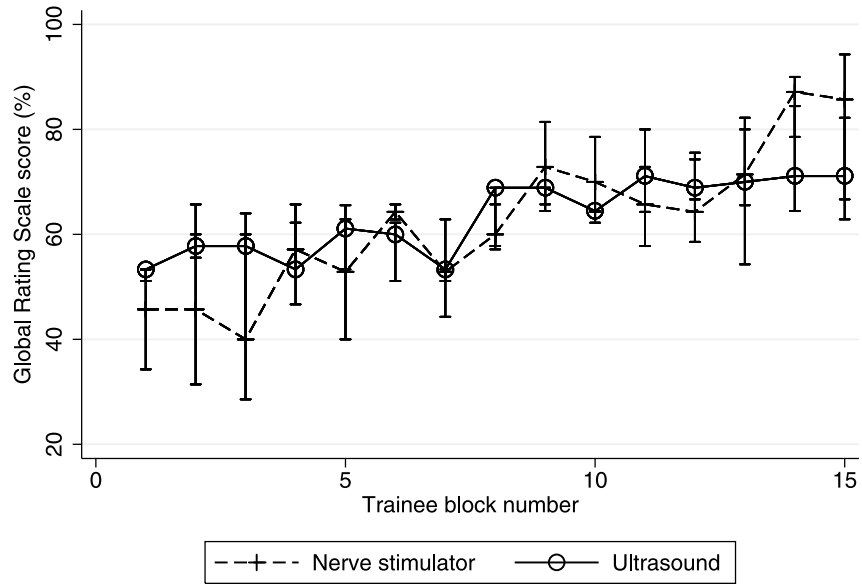


**FIGURE 4.** Global rating scale score as a function of trainee block number with no difference between groups ($P = 0.83$); however, an increase in the score was noted with experience ($P < 0.0001$). Domains of performance assessed the following: ergonomics, respect for safety, time and motion, use of assistants, and knowledge of procedure. For NSG participants, 2 domains were added: use of nerve stimulator and recognition of motor responses. For UG participants, 4 domains were added: machine settings and optimization, sterile technique, survey scan, and knowledge of anatomy and needle-transducer orientation. A 5-point text anchored Likert scale was used to grade performance in each domain (1, very poor; 3, competent; 5, clearly superior). The sum of the scores in each domain was used to assess performance. The percentage of the total achievable score was calculated to compare results between groups.

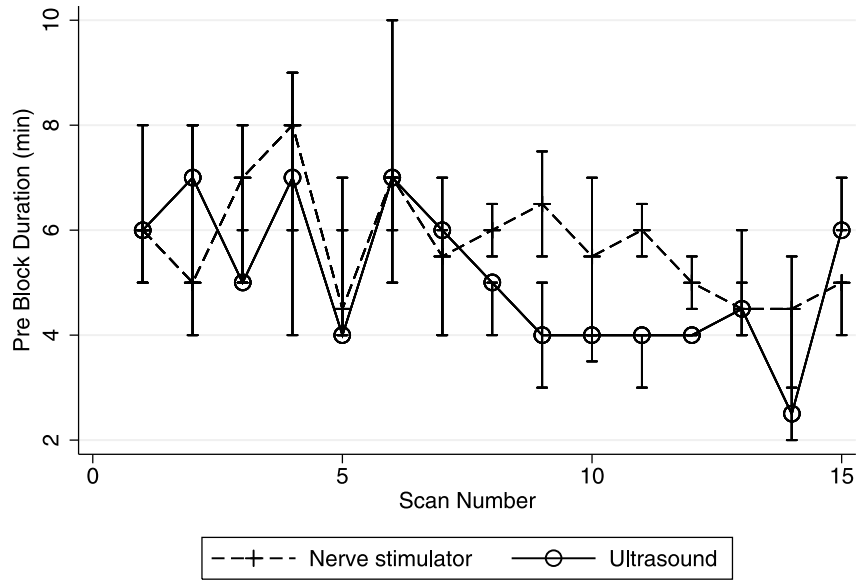


**FIGURE 5.** Preblock survey duration (minutes) with nerve stimulation or ultrasound, as a function of trainee block number. Results expressed as median (interquartile range). There was no difference between study groups ($P = 0.99$); however, duration was reduced in both groups as a function of trainee block number ($P = 0.001$).

to reach our target enrollment and therefore it would be expected that our study is underpowered to conclude that there is no difference in efficacy between groups. However, the 95% CI for the difference between groups in our primary outcome was −0.8 to 2.8, indicating that any difference between groups is unlikely to be greater than the effect size of 3, which we used to estimate our sample size. This relatively narrow CI is likely due to the fact that the variability of our study data was less than the data variability used in our sample size estimate and therefore we overestimated the sample size required. The required sample size is proportional to the variance of the data and we initially estimated sample size using an SD of 2.75, whereas the actual SD of the primary outcome (combined motor/sensory block scores) was 1.56. Overall, this indicates that this study is adequately powered to detect a difference between groups (an effect size of 3 for the combined motor/sensory block at 30 minutes).

In conclusion, in this study, we were unable to demonstrate a difference in the efficacy of axillary brachial plexus block performed by novices when ultrasound guidance was compared to a nerve stimulator technique. There was clear evidence of similarly

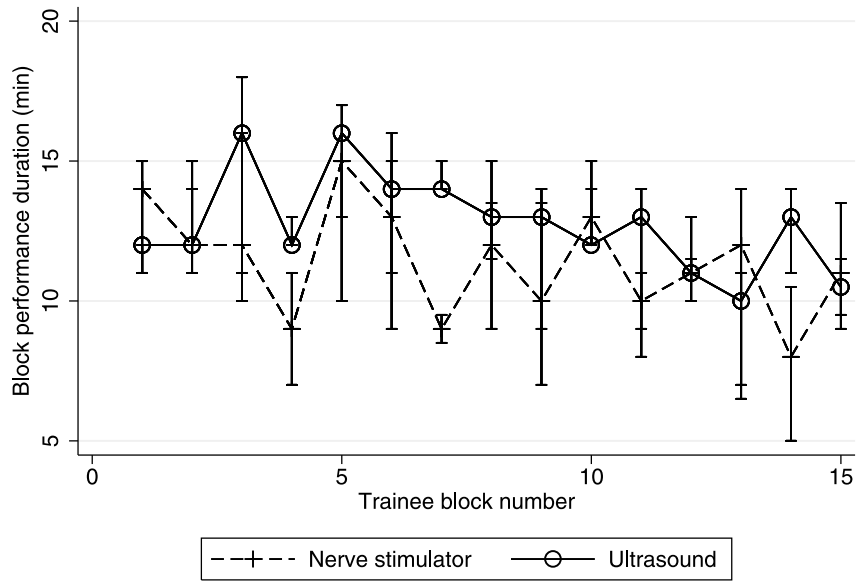


**FIGURE 6.** Block performance duration (minutes) as a function of trainee block number. Results expressed as median (interquartile range). There was no difference between study groups ($P = 0.083$); however, duration was reduced in both groups as a function of block number ($P = 0.001$).

improved clinical performance of novices in both groups within the period of study.

## ACKNOWLEDGMENTS

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