Randomized Comparison of Extrafascial Versus Subfascial Injection of Local Anesthetic During Ultrasound-Guided Supraclavicular Brachial Plexus Block

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Background and Objectives: The optimal site for local anesthetic injection during an ultrasound-guided supraclavicular brachial plexus block (BPB) is not known. We tested the hypothesis that local anesthetic injected deep to the "brachial plexus sheath" during supraclavicular BPB would produce faster onset of surgical anesthesia than an injection superficial to the sheath.

Methods: After research ethics approval and informed consent, 32 patients undergoing upper-extremity surgery under an ultrasound-guided supraclavicular BPB were randomly assigned to receive 25 mL of a 1:1 mixture of 2% lidocaine with 1:200,000 epinephrine and 0.5% bupivacaine, deep to (subfascial, Gp SF) or superficial to (extrafascial, Gp EF) the brachial plexus sheath. Sensory-motor blockade of the ipsilateral musculocutaneous, median, radial, and ulnar nerves and time to "readiness for surgery" (defined as a sensory and motor block scale of 1 in all the 4 nerves tested) were assessed by a blinded observer, using a 3-point qualitative scale (2 to 0), every 5 minutes for 40 minutes and at 2, 4, 6, 8, 10, 12, and 24 hours after surgery.

Results: The time to "readiness for surgery" was significantly shorter (Gp SF: 7 ± 3 minutes vs Gp EF: 20 ± 10 minutes; $P < 0.001$), and the duration of postoperative analgesia was longer (Gp SF: 9.3 ± 1.4 hours vs Gp EF: 6.1 ± 1.4 hours; $P < 0.001$) in the subfascial group than in the extrafascial group. There were no complications directly related to the technique or the local anesthetic injection.

Conclusions: Injection of local anesthetic deep to the brachial plexus sheath at the supraclavicular fossa, under ultrasound-guidance, results in faster onset of surgical anesthesia and prolonged duration of postoperative analgesia than an injection superficial to the sheath.

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Ultrasound guidance allows the anesthesiologist to accurately deposit local anesthetic (LA) close to a nerve during peripheral nerve blockade.[1] Nevertheless, the optimal site for LA injection during peripheral nerve blockade is unclear and controversial.[2,3] Supraclavicular brachial plexus block (BPB) is frequently used for surgical anesthesia during upper-extremity surgery. However, although the trunks and divisions of the brachial plexus are clustered together at the supraclavicular fossa, relatively large volumes (30–40 mL) of LAs are required to produce reliable surgical anesthesia.[4,5] Recent improvements in ultrasound technology and, in particular, high-definition ultrasound imaging have made it possible to define connective tissue sheaths [6] and fascial compartments surrounding the sciatic nerve.[7] There are also data demonstrating that a subfascial injection deep to the "paraneural sheath" during a sciatic nerve block at the popliteal fossa improves block dynamics.[8–10] The nerves of the brachial plexus at the supraclavicular fossa are also surrounded by a "brachial plexus sheath."[11] An ultrasound-guided injection deep to this fascial sheath, as a "targeted intracluster injection,"[12] at the supraclavicular fossa results in very rapid onset of brachial plexus blockade[12,13] that is faster than that after an infraclavicular BPB.[13] However, there are no data evaluating block dynamics after LA injection deep to (subfascial) or superficial to (extrafascial) the brachial plexus sheath during an ultrasound-guided supraclavicular BPB. We hypothesized that a subfascial injection would produce faster onset of sensory blockade, and thereby earlier "readiness for surgery," than an extrafascial injection during an ultrasound-guided supraclavicular BPB.

METHODS

This prospective, randomized study was approved by the institutional human ethics committee of the Mahatma Gandhi Medical College and Research Institute, Puducherry, India (MD/MS/2013/06), and registered with the Clinical Trial Registry of India (registration no. CTRI/2013/12/004180). Of the 40 patients screened for recruitment, 32 adult patients, younger than 60 years, American Society of Anesthesiologists physical status 1 to 3, who gave written informed consent and were undergoing elective or emergency upper-extremity surgery at or below the elbow under an ultrasound-guided supraclavicular BPB, met the inclusion criteria (Fig. 1). Patients were excluded if they refused to participate or gave history of allergy to LA drugs or if there was evidence of coagulopathy, neurological deficit, or infection at the supraclavicular fossa.

Randomization

Patients were randomized to 1 of the 2 study groups: extrafascial (Gp EF) or subfascial (Gp SF) by drawing sequentially numbered, coded, sealed opaque envelopes that contained a card with the computer-generated allocation number. The envelopes were prepared by a third party (resident in anesthesia) who took no further part in the study.

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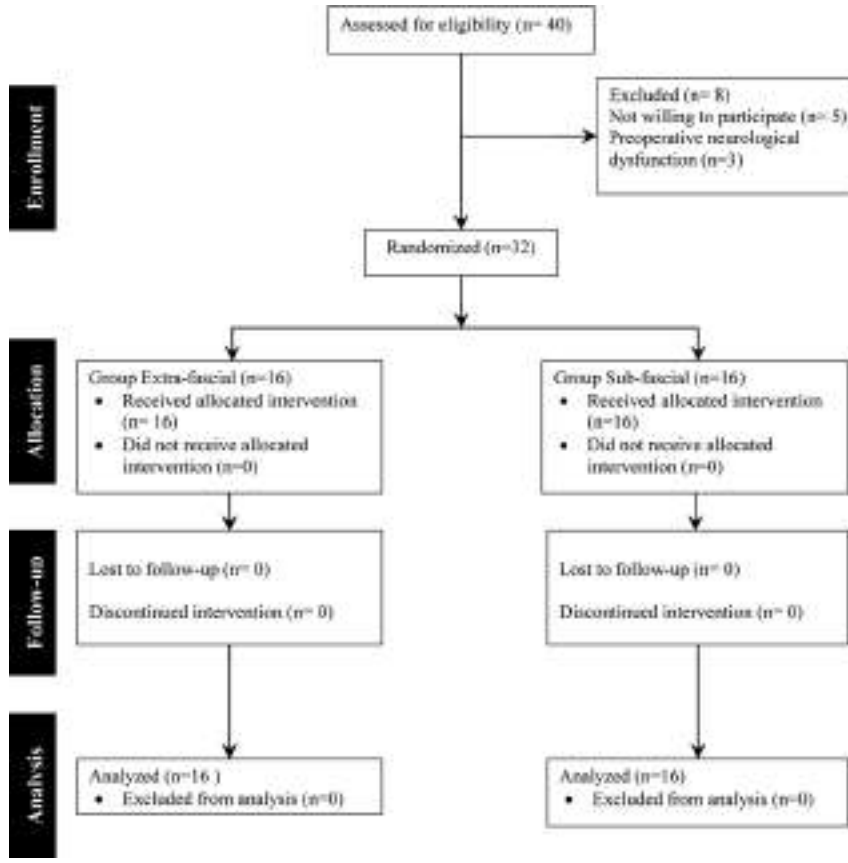

FIGURE 1. Consort E-flowchart.

Extrafascial Group (Gp EF)

The LA was injected external to the hyperechoic brachial plexus sheath (Figs. 2–4). Sonographic criteria used to define correct extrafascial needle placement included (*a*) indentation of the brachial plexus sheath and nerves by the tip of the block needle (Fig. 2); (*b*) observing localized spread of the LA external to the brachial plexus sheath and without any obvious separation, swelling, or distension of the brachial plexus elements (Fig. 4); and (*c*) displacement of the nerves, away from the needle tip, after the LA injection (Figs. 3 and 4).

Subfascial Group (Gp SF)

The LA was injected deep to the hyperechoic brachial plexus sheath (Figs. 5 and 6). Sonographic criteria used to define correct subfascial needle placement included (*a*) visualization of the needle tip deep to the hyperechoic brachial plexus sheath and external to the elements of the brachial plexus (Fig. 5) and (*b*) spread of the test bolus injection deep to the brachial plexus sheath and within the connective tissue matrix but also without any obvious swelling of the individual trunks or division of the brachial plexus (Fig. 6).

Blinding

The principal investigator (T.S.) performed all ultrasound-guided supraclavicular BPBs and collected procedural data and took no further part in data collection. Patients recruited for the study were unaware of group allocation. The anesthesiologist (outcome assessor) who performed the sensory-motor assessment after the BPB was not present in the anesthetic procedure room during block placement and was also blinded to group allocation.

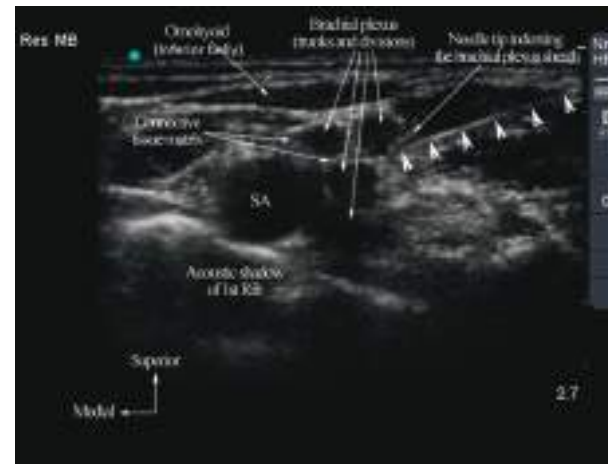

FIGURE 2. Transverse sonogram showing the sonoanatomy of the brachial plexus at the supraclavicular fossa. The trunks and divisions of the brachial plexus are seen as multiple hypoechoic round to oval structures lying superolateral to the subclavian artery (SA). Also note the hyperechoic layer of connective tissue external to the brachial plexus elements, the "brachial plexus sheath," which is being indented by the tip of the block needle (white arrow heads). The connective tissue matrix in between the nerves appears hyperechoic.

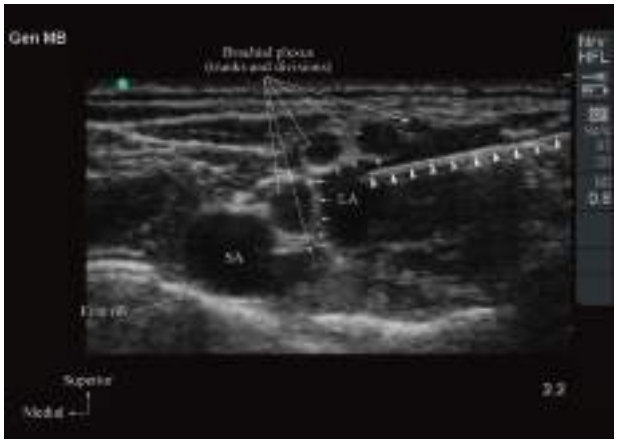

FIGURE 3. Transverse sonogram of the supraclavicular fossa showing extrafascial injection of LA posterolateral to the trunks and divisions of the brachial plexus. Note the position of the needle (white arrow heads) tip and how the nerves have been pushed away (medially) by the LA.

Preoperative Visit

All patients were seen the day before surgery, and written informed consent was obtained. Patients were also instructed on the use of a 3-point qualitative scale for assessment of loss of sensation to cold (using ether soaked cotton swabs) after the BPB: grade 2, presence of cold and touch sensation; grade 1, loss of cold but not touch sensation; and grade 0, loss of both cold and touch sensation. No premedication was prescribed prior to arrival in the operating room suite.

Ultrasound-Guided Supraclavicular BPB

All supraclavicular BPBs were performed in the anaesthetic procedure room, approximately 1 hour before the planned surgery. Intravenous access and routine monitoring (electrocardiogram; arterial oxygen saturation, Sa_{O_2}; and noninvasive arterial blood pressure) were established prior to the BPB. Patients were then positioned in the supine position, with the arms by the side and the head turned slightly to the contralateral side, for the BPB.

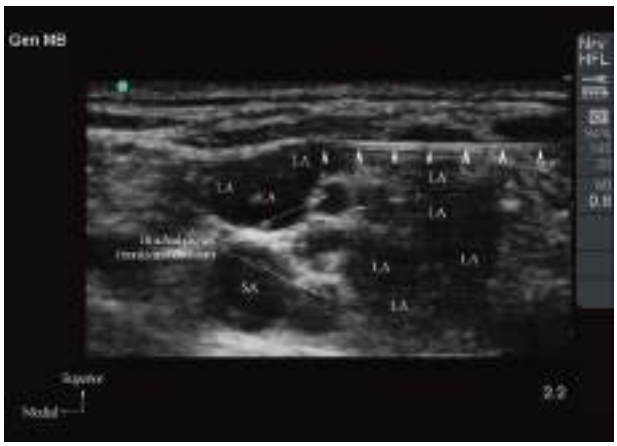

FIGURE 4. Transverse sonogram of the supraclavicular fossa showing extrafascial injection of LA with the needle (white arrow heads) positioned superior and medial to the brachial plexus. Note the spread of the LA relative to the trunks and division of the brachial plexus.

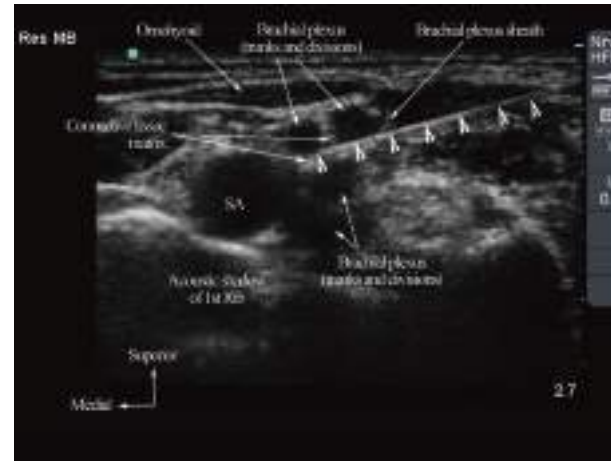

FIGURE 5. Transverse sonogram of the supraclavicular fossa showing subfascial placement of the needle tip. Note the needle (white arrow heads) has traversed the brachial plexus sheath, and its tip is lying in the connective tissue matrix inside the supraclavicular nerve cluster. SA indicates subclavian artery.

All the supraclavicular BPBs were performed under ultrasound guidance and under strict aseptic precautions. A SonoSite MicroMaxx (SonoSite, Bothell, Washington) ultrasound system with multibeam (compound imaging) capability and with a high-frequency linear array transducer (HFL38, 13–6 MHz), was used for the ultrasound guidance. The transducer was placed just cephalad and parallel to the clavicle, and the ultrasound beam was insonated toward the posterior aspect of the clavicle. Initially, the subclavian artery was identified as a hypoechoic and pulsatile structure, on top of the first rib (Fig. 2). In the optimized sonogram, the trunks and division of the brachial plexus were visualized as multiple hypoechoic round to oval structures lying superolateral to the subclavian artery (Fig. 2). The brachial plexus elements were also embedded in a hyperechoic connective tissue matrix and collectively surrounded by a hyperechoic fascial layer (Fig. 2), the brachial plexus sheath.[11]

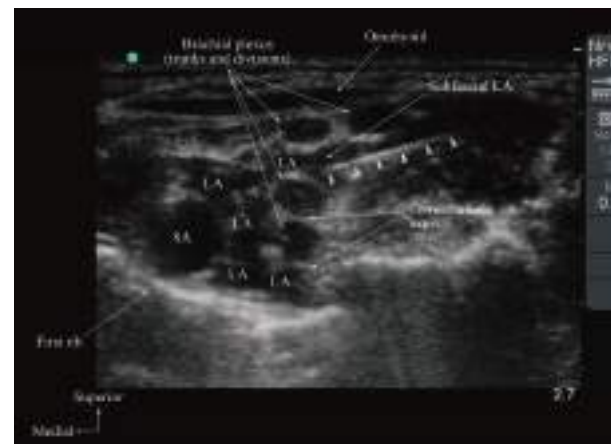

FIGURE 6. Transverse sonogram of the supraclavicular fossa showing subfascial injection of LA with the needle (white arrow heads) tip positioned between the nerves inside the supraclavicular nerve cluster. Note there is distension of the subfascial plane by the LA, but there is no obvious swelling of the individual trunks or division of the brachial plexus. SA indicates subclavian artery.

A 5-cm, 21-gauge, short-beveled (17 degrees) nerve block needle (Locoplex; Vygon, Ecouen, France) was used to perform the BPB. The brachial plexus was approached with the nerve block needle inserted either in-plane or out-of-plane depending on the ergonomics achieved and the operator's convenience. In the extrafascial group, the needle was advanced until slight indentation of the brachial plexus sheath and nerves was visualized (Fig. 2). In the subfascial group, the nerve block needle was advanced through the brachial plexus sheath until its tip was seen to lie within the connective tissue inside the nerve cluster (Fig. 5). A test bolus of 1 to 2 mL of saline was injected, initially to confirm correct needle tip position (extrafascial or subfascial), before the LA was injected.

Injection pressure during the extrafascial or subfascial injection of the LA was also monitored using a syringe pump (Injectomat MC Agilia; Fresenius Kabi AG, Bad Homburg, Germany) as described by Siegmueller and Ramessur.[14] A 1:1 mixture of 2% lidocaine with 1:200,000 epinephrine and 0.5% bupivacaine, at 0.5 mL/kg (maximum volume limited to 25 mL), was used for the BPB. During the LA injection, if the injection pressure exceeded 500 mm Hg (9.6 psi) or patient-reported pain, discomfort, or paresthesia, the injection was discontinued, and the position of the needle tip was adjusted before the injection was recommenced. Also, small aliquots (5–6 mL) of the LA solution were injected at multiple sites to ensure uniform distribution of the LA in both study groups (thus multiple site injection). In the extrafascial group, a conscious effort was made to avoid puncturing the hyperechoic outermost fascial layer (Figs. 2 and 3), and the LA was deposited external to the brachial plexus sheath (Figs. 3 and 4).

Outcome Measures After the BPB

For timing, removal of the nerve block needle at the end of the LA injection was defined as the completion of the BPB (time 0). Sensory blocks in the cutaneous distribution of the ipsilateral median (MN), radial (RN), ulnar (UN), and musculocutaneous (MCN) nerves were assessed and graded according to the 3-point qualitative scale (2 to 0) described above. Motor block of each of the 4 nerves in the anesthetized upper extremity was also assessed and graded using a 3-point qualitative scale: 2 = normal motor function (motor power grade 4/5, 5/5), 1 = weakness against resistance (motor power grade 3/5, 2/5), and 0 = paralysis (motor power grade 0/5, 1/5). Elbow flexion, wrist flexion, finger abduction, and wrist extension were used to test motor blockade of the MCN, MN, UN, and RN, respectively. The sensory-motor assessment was performed every 5 minutes for 40 minutes or until both sensory and motor scale of 0 was achieved in all the 4 nerves tested, whichever was earlier. Thereafter, sensory-motor assessments were made at 2, 4, 6, 8, 10, 12, 24 hours after surgery., Whenever the sensory-motor blockade assessment registered scale of 1 (at least loss of cold sensation and motor weakness of grade 2 or 3) in all the 4 nerves tested and the patient reported no pain during the motor assessment, the patients were transferred to the operating room for surgical preparation, and this time was recorded as the time to "readiness for surgery." This method was adapted to improve workflow and avoid delays in the operating room schedule.

Intraoperative Management

Patients were sedated for comfort during surgery, using small doses of intravenous midazolam (1–3 mg), such that they were calm, comfortable, and asleep, but still arousable. The BPB was considered a failure if the patient complained of pain during surgery or required more than 2 μg/kg of fentanyl for rescue analgesia. In the event of a failed block, the choice of subsequent anesthetic management was left entirely to the discretion of the attending anesthesiologist.

Postoperative Management

On completion of surgery, patients were transferred to the postanesthesia care unit where they were observed for an hour after which they were transferred to the surgical ward. Postoperative pain was assessed using a 10-point numeric rating scale (0 = no pain and 10 = worst imaginable pain) at 2, 4, 6, 8, 10, 12, and 24 hours after surgery. Paracetamol (1 g) and diclofenac sodium (50 mg) were administered intravenously, as a slow infusion (each over 15 minutes), for rescue analgesia whenever the numeric rating scale pain score was greater than 5. The time of administration of the first dose of rescue analgesia was also recorded. Regression of motor blockade was also assessed at the same time intervals by determining the patient's ability to squeeze the outcome assessor's fingers using the 3-point qualitative scale described above. Total duration of motor blockade was defined as the time interval between the time when complete motor block was achieved after the BPB (time 0) to when finger flexion in the hand recovered to scale 2. Sensory-motor assessment was also repeated at 24 hours after the BPB to ensure that there was no residual block, neurological deficit, or both. Patients were also directly questioned for the presence of any symptoms suggestive of persistent paresthesia or dysesthesia in the upper extremity ipsilateral to the BPB. Any report of persistent sensory-motor deficit at the follow-up visit with the surgeon, 1 week after surgery, was also reported back to the research team.

Statistical Analysis

Sample Size Estimation

PS Power and Sample Size Calculation Software (version 3.0, January 2009, developed by William D Dupont and W. dale Plummer, Jr. and licensed under Creative Commons Attribution - Non commercial - Noderivs 3.0 United States license) was used to calculate the sample size using the time to "readiness for surgery" as the primary outcome variable. In a pilot study, we found that the time to "readiness for surgery" was 10 minutes faster when a subfascial injection was performed for a supraclavicular BPB. Therefore, it was estimated that a sample size of 32 patients (16 patients per study group) would provide 90% power to demonstrate a difference of 10 (SD, 8.5) minutes in the time to "readiness for surgery" between the 2 study groups with an α error of 0.05.

Data Analysis

SPSS for Windows 16.0 (SPSS Inc, Chicago, Illinois) was used for statistical analysis. Normality of the data was tested using the Kolomogorov-Smirnov test. Data that are normally distributed were analyzed using unpaired Student t test, and non–normally distributed data were analyzed using Mann-Whitney U test. $P < 0.05$ was considered statistically significant.

RESULTS

The 2 study groups were comparable with respect to demographic data, type of surgery performed, and clinical characteristics (Table 1). The ultrasound-guided supraclavicular BPB was successfully performed in all patients, as per their randomization, and there were no complications directly related to the technique or the LA injection. Three patients in the extrafascial group achieved a maximum sensory and motor blockade scale of 1 at the end of the 40-minute observation period after the BPB, Hence,

TABLE 1. Demographic Data and Clinical Characteristics of the Study Groups

	Extrafascial Group (n = 16)	Subfascial Group (n = 16)	*P*
1. Age, y	33 ± 12	37 ± 18	0.43
2. Weight, kg	63 ± 10	57 ± 17	0.25
3. Height, cm	169 ± 9	166 ± 13	0.478
4. BMI, kg/m^2	22 ± 3	20 ± 5	0.262
5. Sex (male: female), n	9:7	3:13	0.23
6. Type of surgery (a/b/c), n	2/10/4	2/10/4	1.0
7. Duration of surgery, h	1.9 ± 1.0	1.6 ± 0.6	0.37

Data are presented as mean ± SD except for sex and type of surgery, which are presented as frequency (n). type of surgery: a, soft tissue surgery, b, surgery involving both the radius and ulna, c, surgery involving fracture around the wrist.

BMI indicates body mass index; F, female; M, male.

they were excluded from the data analysis of complete sensory and motor blockade, but their data were included for analysis of time to readiness for surgery (Table 2).

The time to readiness for surgery was faster (Gp EF: 20 ± 10 minutes vs Gp SF: 7 ± 3 minutes; $P < 0.001$), and the total duration of postoperative analgesia was significantly longer (Gp EF: 6.1 ± 1.4 hours vs Gp SF: 9.3 ± 1.4 hours; $P < 0.001$) in the subfascial group when compared with that in the extrafascial group. Also, the total duration of motor blockade (Gp SF: 9.7 [95% confidence interval, 9.0–10.4 hours] vs Gp EF: 6.3 [95% confidence interval, 5.6–7.1 hours]; $P < 0.001$) was significantly longer in the subfascial group. Complete sensory or motor blockade of each of the MCN, MN, RN, and UN and when all the 4 nerves were considered together, developed significantly faster ($P < 0.01$) in the subfascial group (Table 2). Even though this study was not powered to analyze the difference between sensory and motor blockade, we noted complete sensory blockade of all the 4 nerves preceded the complete motor blockade (mean difference, 3 minutes [95% confidence interval, 1–6 minutes]; $P < =0.006$) in the extrafascial group, but not in the subfascial group (mean difference, −0.3 minutes [95% confidence interval, −2 to 3 minutes]; $P = 0.54$). The time it took to perform the BPB (Gp EF: 6 ± 2minutes vs Gp SF: 6 ± 2 minutes; $P = 0.5$) and the highest mean injection pressure recorded (Gp EF: 176 ± 92 mm Hg vs Gp SF: 155 ± 67 mm Hg; $P = 0.9$) were similar in the 2 study groups. Also, irrespective of the group allocation, all the supraclavicular BPBs were successful. None of the patients reported persistent neurological symptoms or signs at 24 hours after the BPB or at the 1-week follow-up after surgery.

DISCUSSION

In this prospective, randomized trial, we compared the time to "readiness for surgery" after injection of LA deep to (subfascial) or superficial (extrafascial) to the brachial plexus sheath at the supraclavicular fossa. Under the conditions of this study, we found that the time to onset of complete sensory and motor blockade of all the 4 nerves of the ipsilateral upper extremity and thereby "readiness for surgery" were significantly shorter when the LA was injected beneath (inside) the brachial plexus sheath. Differential onset of sensory versus motor blockade was noted in the extrafascial group but not in the subfascial group. The subfascial injection also resulted in prolongation of the duration of motor blockade and postoperative analgesia. We could not identify any previous reports of faster onset of sensory-motor blockade and prolongation in the duration of postoperative analgesia with subfascial injection of LA, when compared with an extrafascial injection, after a supraclavicular BPB.

Using high-frequency ultrasound imaging, we were able to visualize a hyperechogenic fascial layer surrounding the brachial plexus at the supraclavicular fossa deep to the clavicle, which could be indented with the block needle (Fig. 2). It is controversial whether the brachial plexus is surrounded by a brachial plexus sheath at the supraclavicular fossa.[15] Franco and colleagues[11] recently demonstrated, in cadavers, that the neurovascular structures at the supraclavicular fossa are surrounded by a fibrous brachial plexus sheath. It is an extension of the prevertebral fascia[16] and continuous distally with the axillary sheath.[11] We believe the hyperechogenic fascial layer that we visualized at the supraclavicular fossa is the ultrasound correlate of the brachial plexus sheath.

TABLE 2. Time It Took to Develop Complete Sensory and Motor Blockade of the MCN, MN, RN, and UN and All the 4 Nerves Considered Together After Supraclavicular BPB

Outcome Measure	Extrafascial Group (n = 13)	Subfascial Group (n = 16)	*P*
1. Time to complete sensory blockade in the area innervated by the MCN, min	10 (6–14)	5.0	0.003
2. Time to complete sensory blockade in the area innervated by the MN, min	13 (9–17)	8 (5–10)	0.009
3. Time to complete sensory blockade in the area innervated by the RN, min	13.8 (11–17)	7 (5–9)	0.000
4. Time to complete sensory blockade in the area innervated by the UN, min	18 (14–22)	9 (7–12)	0.000
5. Time to complete sensory blockade of all the 4 nerves, min	19 (14–23)	11 (8–14)	0.003
6. Time to complete motor blockade (motor score = 0) of the MCN, min	11 (7–15)	5.0	0.002
7. Time to complete motor blockade of the MN, min	17 (12–21)	8 (5–10)	0.000
8. Time to complete motor blockade of the RN, min	17 (13–22)	7 (5–9)	0.000
9. Time to complete motor blockade of the UN, min	21 (17–25)	10 (7–13)	0.000
10. Time to complete motor blockade of all the 4 nerves, min	22 (18–27)	11 (7–14)	0.000

Data are presented as mean (95% confidence interval).

The ideal technique for ultrasound-guided supraclavicular BPB is not known, and several different approaches have been described.[17–19] Franco[16] opines that the block needle should traverse the brachial plexus sheath and the LA injected in the connective tissue matrix between the neural elements. This was also the basis of our subfascial injection and is similar to the targeted intracluster-injection technique recently described by Techasuk and colleagues.[12] The safety of needle tip placement and injection inside the nerve cluster at the supraclavicular fossa may be questioned. Whereas Bigeleisen and colleagues [20] claim that this constitutes an intraneural injection,[20] our observations agree with those of Franco[16] because the integrity of the epineurium of none of the nerves within the supraclavicular neural cluster is intentionally breached during the injection. The technique may be better described as a subfascial "intracluster-injection," and cumulative evidence supports the safety of this technique.[12,13] However, because there is limited experience with the technique, there is need for future research to establish its safety in a larger patient sample.

Although both study groups developed surgical anesthesia, the onset of complete sensory-motor blockade and the time to "readiness for surgery," as defined above, were significantly faster in the subfascial group. We believe a reduction of 13 minutes in the time to "readiness for surgery" is clinically significant. Similar results have been reported after subfascial sciatic nerve block at the popliteal fossa.[8,9] We also noted a significant differential blockade in the extrafascial group but not in the subfascial group. When LA is injected outside a peripheral nerve, it has to diffuse from the outside (mantle) toward the center (core) of the nerve along a concentration gradient, including diffusion through various extraneural connective tissue barriers,[21] to produce sensory-motor blockade. This constitutes the latency time and includes time taken for both extraneural and intraneural diffusion of the LA. Winnie and colleagues[22] demonstrated that three-fourths of the latency after a subclavian perivascular BPB was due to extraneural diffusion and only one-third due to intraneural diffusion. Our findings of faster onset of complete sensory-motor blockade and time to "readiness for surgery" in the subfascial group can be explained by less diffusion barrier for the LA and thus a shorter extraneural diffusion time.

The duration of postoperative analgesia and motor blockade was significantly prolonged in the subfascial group. However, increased duration of motor blockade may not be desirable. The duration of action of sensory-motor blockade after a peripheral nerve block depends on multiple factors including the rate of removal of the LA from the target site by systemic absorption and eventually elimination.[23] Slower washout of the larger mass of LA from inside the brachial plexus sheath in the subfascial group may be the possible cause for prolongation in the duration of postoperative analgesia and motor blockade when compared with the extrafascial group. There are no data available to decide the minimum effective anaesthetic volume producing reliable surgical anesthesia during subfascial injections. But in the authors' experience, 20 to 25 mL of LA volume produced reliable surgical anesthesia and analgesia for a duration of 5 to 10 hours. The present study results indicate that there is scope for significant LA volume reduction during subfascial injections.

One limitation of our study is its lack of assessment for neurologic dysfunction beyond the 24-hour study period. Also, our study sample was small, and it is conceivable that subclinical neurological symptoms and signs may have gone unrecognized.

In conclusion, we have demonstrated that injection of local anaesthetic deep to the brachial plexus sheath under ultrasound guidance at the supraclavicular fossa results in faster onset of surgical anaesthesia and prolonged duration of postoperative analgesia than an injection superficial to the sheath. Further studies are required to confirm the safety of the ultrasound-guided subfascial intracluster-injection technique described in this report.

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