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ORIGINAL ARTICLE

Use of a curved needle to facilitate lateral sagittal infraclavicular block performance: a randomized clinical trial

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Abstract

Purpose Failed needle-tip positioning in an ultrasound-guided infraclavicular block can be due to improper needle insertion point and steep needle insertion angle. Needle pre-curving enables the user to pass the needle with different curved trajectories on approaching the brachial plexus. Aim of the study was to compare curved and non-curved needles as regards the time needed to perform the lateral sagittal infra-clavicular block.

Methods Sixty-nine patients undergoing surgery distal to the elbow were randomly allocated to two groups: group A ($n=35$), which received ultrasound-guided infraclavicular block using the curved needle; and group B ($n=34$), which received the infraclavicular block using the non-curved needle. The primary outcome measure was the time needed to perform the infra-clavicular block. Anesthetist's experience with the curved vs. non-curved needle was noted.

Results Mean (SD) recognition time (120 ± 48 vs. 179 ± 72 s, $P=0.0002$) and injection time (54 ± 23 vs. 88 ± 36 s, $P=0.0001$) were shorter in group A compared to group B. Median (IQR) procedure pain score was less in group A 2 (1–2) than in group B 2 (2–3); $P=0.001$. Median (IQR) satisfaction score was higher with regards to the curved needle 4 (4–5) than non-curved needle 3 (3–4) in performing infraclavicular blockade; $P=0.001$.

Conclusion The use of a curved needle reduces the time required to perform the lateral sagittal infraclavicular block. The curved needle provides less procedure pain and higher satisfaction levels among anesthetists than the non-curved needle.

Trial registration The trial was registered (04/26/2016) with the ClinicalTrials.gov ID: NCT02799576. Approval Number: #2543. Board Name: Research Ethics Committee. Board Affiliation: Suez Canal University, Faculty of Medicine, Suez Canal University hospital, Ismailia, Egypt, 41522.

Keywords Block needle · Infra-clavicular block · Lateral sagittal approach

Introduction

Infraclavicular brachial plexus block provides reliable surgical anesthesia and offers expanded dermatomal coverage in patients undergoing elbow, forearm, and hand surgeries [1]. The position of the neurovascular bundle relative to the coracoid process is critical for performing the lateral sagittal infraclavicular block. The transducer is typically placed on the medial aspect of the coracoid process in the parasagittal plane so that the plexus can be scanned transversely [2, 3]. It is crucial to correctly identify the position of the brachial plexus cords [4]. However, the accurate placement of the block needle might be challenging.

The positioning of the clavicle and its related curvatures may offer less flexibility to decide on the optimal needle path to the target brachial plexus. The failed needle-tip positioning in an infraclavicular block under ultrasound guidance is due to less flexibility on needle insertion point and needle path because of the insufficient space between the transducer and the clavicle, leading to the need for steep needle insertion angle. The block needle might shift due to the anatomical obstacle from friction along the needle shaft beside the clavicle. The cranial displacement of the clavicle with arm abduction [5] might be viewed as disappointing by the patient if severe pain is experienced by positioning the fractured limb. The prominent humerus may hinder the

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accurate maneuverability of block needle in the patient with a deep deltopectoral groove [6].

The needle designs may play an integral role in determining the needle insertion angles and the planned needle trajectory routes. The straight needle only moves in one direction; namely forward–backward movement. The straight block needle must be withdrawn subcutaneously in order to change the needle path to reach the target structures.

Needle pre-curving has the potential to improve the infraclavicular block procedure by allowing increased accuracy through more control of the needle tip path and acquisition of targets not accessible by straight-line trajectories. The needle curvature can create enough windows between the clavicle and the block needle to work. The curved needle form can be used to improve the target accessibility by avoiding clavicle away from the needle path. The operator can easily change the needle path either from superficial to deep or from side to side by manipulating the proximal needle end. The adjustment of the curved needle path can be accomplished by stepwise needle rotation (clockwise or anticlockwise) around its long axis.

The primary endpoint of the study was to compare the curved and non-curved needles as regards the time needed to perform the lateral sagittal infra-clavicular block. Other studied endpoints included the procedural pain and anesthetist's satisfaction with the use of a curved needle vs. non-curved needle on performing the nerve blockade.

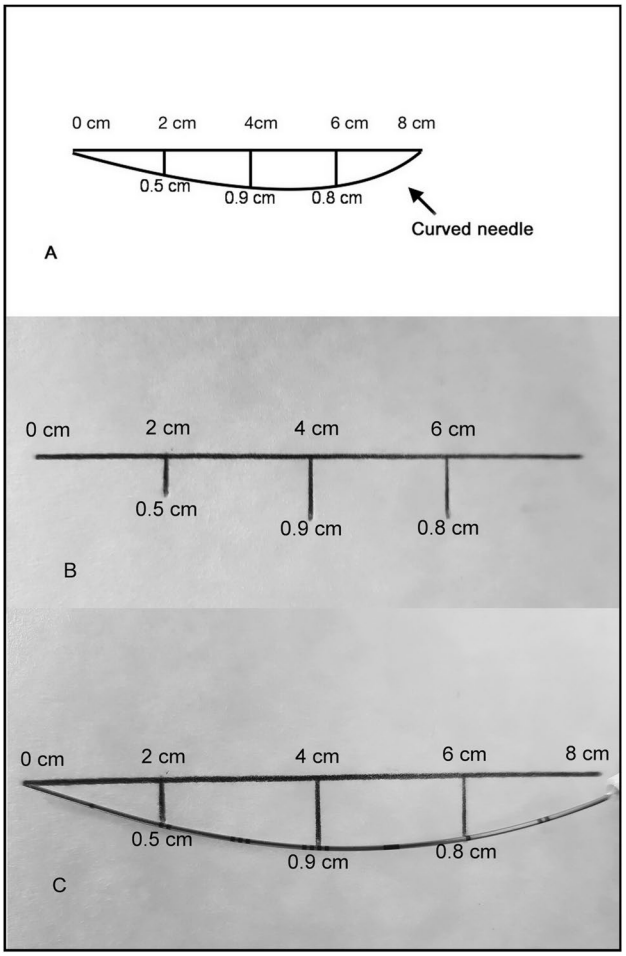

Fig. 1 **a–c** Pre-curving the block needle using a template to process the needle in a standardized way and get the same needle contour (**a**, **b**); the needle curvature starts beyond the distal end needle point and increases gradually and smoothly toward the periphery. The compound curved needle is in one plane. The inner side surface of the curvature always faces the bevel opening (**c**)

Methods

The study was approved by the Institutional Review Board, Suez Canal University hospital (reference no: 2543) and written informed consent was obtained from each patient participating in the trial. The trial was registered prior to patient enrollment at ClinicalTrials.gov (NCT02799576, Principal investigator: Tarek F. Tammam, Date of registration: 04/26/2016). Sixty-nine patients between the ages of 18 and 60 years with American Society of Anesthesiologists (ASA) physical status I–III, scheduled for elective surgery distal to the elbow were enrolled in the prospective randomized observer blinded clinical trial. The study was conducted from July 2016 to October 2017. Patients who had coagulopathies, local infections or neuropathies were excluded from the study. Patients with history of allergy to local anesthetics, receiving chronic analgesic therapy or by reason of refusal were also excluded.

Patients were randomly assigned into one of two groups in a one-to-one ratio; group A in whom ultrasound-guided infraclavicular block was performed using a curved needle (Fig. 1a–c), and group B in whom the ultrasound-guided infraclavicular block was performed using a non-curved needle. Randomization was performed outside the study center using a computer-generated random number table. Group allocation was concealed in a sealed opaque envelope that was not opened till the last practical moment.

The lateral sagittal infraclavicular blockade [7] was performed in the block room under complete aseptic conditions. All the infraclavicular blocks were performed under ultrasound guidance. The block procedures were performed behind an opaque screen so that patients could not see which needle was being used. The linear array transducer (6–15 MHz) (M-Turbo, HFL50x; Fujifilm Sonosite, Bothell, WA) was placed below the clavicle and just medial to the coracoid process. A parasagittal scanning of the infraclavicular region was performed with adjustment of the depth, frequency and gain; to determine the best short-axis view of the axillary artery and its surrounding brachial plexus cords.

A local infiltration with 2 ml of lidocaine (10 mg/ml) was made at the cephalad aspect of the ultrasound probe. An 80 mm, 22-gauge, insulated, short-bevel (curved or non-curved) needle (SonoPlex Stim cannula NanoLine® 001185-71, Pajunk®, Germany) was attached to the nerve stimulator delivering a current of 1.2 mA at a frequency of 2 Hz. The block needle was inserted just inferior to the clavicle and directed toward the posterior aspect of the axillary artery (i.e., the 6 o'clock position). The needle was advanced in-plane until it was in close proximity to the target; confirmed by obtaining a motor response of the posterior cord (finger or wrist extension) [8] with a current intensity of 0.5 mA or less. The ultimate goal is to achieve a U-shaped distribution of local anaesthetic solution with anterior displacement of the axillary artery [9, 10]. It was based on imaging feedback and confirmed by multiple test injections of 1 ml 5% dextrose solution. Thirty millilitres of local anaesthetic mixture (1% lidocaine and 0.25% bupivacaine, 1:1 ratio) was incrementally injected after negative aspiration under real-time ultrasound imaging.

The curved needle was prepared before the commencement of block procedure by an anesthetist (Tammam TF) not involved in the block administration or further follow-up after the procedure. The needle was curved using a template to process the needle in a standardized way (Fig. 1a–c). The needle end placed within the body tissue is considered the distal end, while the other end remaining outside the body is the needle proximal end.

The anatomic relationship of the brachial plexus and the axillary artery to the clavicle leads to characteristics of the compound curved needle (length, shape, and degree of curvature). The brachial plexus and the axillary artery are typically identified at a depth of 3–5 cm underneath the patient's skin in average size patients [11]. If the brachial plexus is 4 cm in depth, and the approach equals 45°, the site of needle entry must be around 5.66 cm from the target (Pythagoras' theorem). The use of the curved needle with 8 cm would be sufficient to reach the brachial plexus. We used a triple curve of 20° at 2 cm from the needle tip (first curved configuration), 25° at 4 cm from the needle tip and another 15° at 6 cm. Although these curves are continuous mathematical objects, they must nevertheless be represented in discrete forms. The needle curvature is smoothly formed to maintain the internal and external diameter of the needle. The needle should be flushed and checked for patency before the procedure. The compound curved needle has a maximum central curvature point at 4 cm corresponds to the depth of brachial plexus. Therefore, the anesthetist can easily keep the needle in the posterior aspect of the axillary artery and achieve a U-shaped distribution of the anesthetic solution. The proximal needle curvature was designed to avoid friction with the clavicle and assists in making needle movements easier. Additionally, the compound curved needle is in one plane. The inner side surface of the curvature always faces the bevel opening.

All block procedures were performed preoperatively by 1 of 6 anesthetists, who have the same substantial expertise (at least 5 years) in the ultrasound-guided infra-clavicular block. The anesthetists had at least 20 successful infraclavicular blocks, using the curved needle, before participating in the study. They were not involved in the patient's evaluation.

Primary outcome included the time required to perform the lateral sagittal infra-clavicular blockade. The performance time was defined as the sum of recognition time and anesthetic injection time. The recognition time was defined as the time interval from the first needle contact with the skin to the achievement of proper motor response. The anesthetic injection time was defined as the time from proper motor response to completion of anaesthetic injection. Secondary outcomes included the number of needle attempts required to elicit the proper motor response. The initial needle insertion counted as one needle attempt. New attempt was defined as needle reinsertions through a separate skin puncture. The number of needle redirections required to complete the blockade was also noted. Needle redirection was defined as drawing back a needle at least 10 mm and subsequent forward needle movement if no proper nerve response could be elicited. The distance from the skin to the posterior wall of the axillary artery in the anterior–posterior direction was used to measure the depth of brachial plexus. However, the distance from the puncture site on the skin to the posterior wall of the axillary artery was used to measure the depth of needle insertion.

All patients were asked to rate their pain during the performance of the block, using the verbal rating scale (VRS: 0, no pain; 10, the worst pain). We also recorded if the patients would accept the same anesthetic again in the future (if required). The patient survey was administered at the time of discharge from the block room by an observer who was blinded for group allocation.

The sensory blockade was evaluated every 2 min in the distribution of radial (lateral aspect of the dorsum of hand), median (the volar aspect of the index), ulnar (the volar aspect of the fifth finger), and musculocutaneous (lateral aspect of the forearm) nerves. The patient's response to the stimulus (blunt 23-gauge needle) was observed and compared with the contra-lateral side. The sensation was scored as follows: 0, normal sensation; 1, diminished sensation; and 2, no sensation. The motor blockade was also tested every 2 min for the radial (wrist extension), median (thumb-fifth finger opposition), ulnar (fifth finger abduction), and musculocutaneous (elbow flexion) nerves. The rating was undertaken using the following scale: 0, normal strength; 1, weakness; 2, no movement.

A successful infraclavicular blockade was defined as complete loss of pinprick sensation (radial, median, ulnar,

and musculocutaneous nerves) within 30 min of anesthetic administration. A partial successful block was defined as inadequate sensory blockade after 30 min of anesthetic administration and if supplementation (anesthetic infiltration or IV analgesic; fentanyl) was needed to complete the surgical procedure. A failed block was defined as inadequate sensory blockade after 30 min of anesthetic administration and if general anesthesia was required to complete the proposed surgery.

Patient demographics, type and duration of surgery, tourniquet time, and the patient's ASA physical status were recorded. The procedure-related adverse effects and complications (blood aspiration, hematoma, infection, and neuropathies) were recorded for the first 48 h postoperatively by an investigator blinded to the aim of the study. The patients were questioned by phone for any delayed complication after discharge. If complications occurred, they were followed up at the outpatient clinic and noted for the study. The research personnel conducting the post-block assessments, data collection, and data analysis were blinded to the treatment allocation.

A written questionnaire was used to evaluate the anesthetists' experience of using the curved and the non-curved needle for the infraclavicular block placement. A pilot study for the clarity of the questionnaire was carried out on a small group prior to selection of the target population. Each anesthetist was interviewed at the end of block procedure by an assessor blinded to the group allocation. The anesthetist was asked to rate how easy was it to obtain favorable needling window, handle and guide the block needle to the desired target, readjust the needle path; if needed, to reach the target, achieve adequate needle visualization during blockade, reposition of the needle tip to maximize the anesthetic spread around the brachial plexus, and recapture the needle trajectory once the operator loses visualization of the block needle. The answers were based on a five-point Likert scale [12] (never/ seldom/ sometimes/ often/ almost always) with 1 being "never", 3 being "sometimes" and 5 being "almost always". Anesthetists also reported Likert scales for: How likely is it that anesthetist would recommend the same used needle to practice a colleague in the future (not at all/ slightly/ moderately/ very/ extremely: where 1 is not at all, 3 is moderately, and 5 is extremely), and how was his overall experience with using the block needle (very poor/below average/average/above average/excellent: where 1 is very poor, 3 is average, and 5 is excellent).

The sample size was calculated using Stata® version 13 programs. The primary outcome of this study was time to perform the lateral sagittal infraclavicular block. Based on an alpha error of 0.05, a beta error of 0.2 and an earlier pilot study in 24 patients (It showed that the performance time was 3.9 ± 2.0 min with the conventional non-curve needle, while it was estimated to be 2.5 ± 1.91 min with the curved needle); the required sample size was 32 patients per group. Thirty-five patients were enrolled per group to allow for dropouts and protocol violations.

Statistical analysis

Data were analyzed using Statistical Package for the Social Sciences (SPSS) program, version 20.0 (SPSS Inc, Chicago, IL). The data were presented as mean ± standard deviation (SD) for normally distributed continuous variables, median and interquartile range (IQR) for non-normally distributed continuous quantitative or ordinal variables, and counts and percentages for nominal variables. Normality of data was tested using Kolmogorov–Smirnov test. Student's *t* test or Mann Whitney test was used for group comparisons as appropriate. Categorical variables were statistically analyzed by Chi square analysis or Fisher's exact test. A *p* value of less than 0.05 was used to define statistical significance.

Results

Sixty-nine patients were recruited in the study. One patient was excluded from analysis in the group B because of missing data (flow study diagram) (Fig. 2). There were no significant differences between the groups with respect to patient characteristics, depth of brachial plexus, duration of surgery and tourniquet time; $P > 0.05$ (Table 1).

The mean recognition time (120 ± 48 vs. 179 ± 72 s, $P = 0.0002$) and the injection time (54 ± 23 vs. 88 ± 36 s, $P = 0.0001$) were significantly shorter in the group A compared to the group B (Table 2). The median (IQR) number of needle attempts required to elicit the targeted motor response was significantly less in the group A than in the group B [1 (1–1) vs. 1 (1–2), $P = 0.029$] (Table 2).

The group A required fewer needle redirections 2 (1–2) than the group B 3 (2–3); $P = 0.0001$ (Table 2). The patients in the group A reported less pain 2 (1–2) during the performance of blockade compared with those in the group B 2 (2–3); $P = 0.001$ (Table 2). There were no significant complications and no recorded cases of nerve palsy related to the curved and non-curved needle.

Assessments of the difficulty level on the block procedure by operators are shown in Table 3. The anesthetists were more satisfied with the curved needle than the non-curved needle in the infraclavicular block placement (Table 3). There were no significant differences in the onset time of sensory and motor blockade between the two groups; $P = 0.367$ and $P = 0.548$, respectively (Table 4).

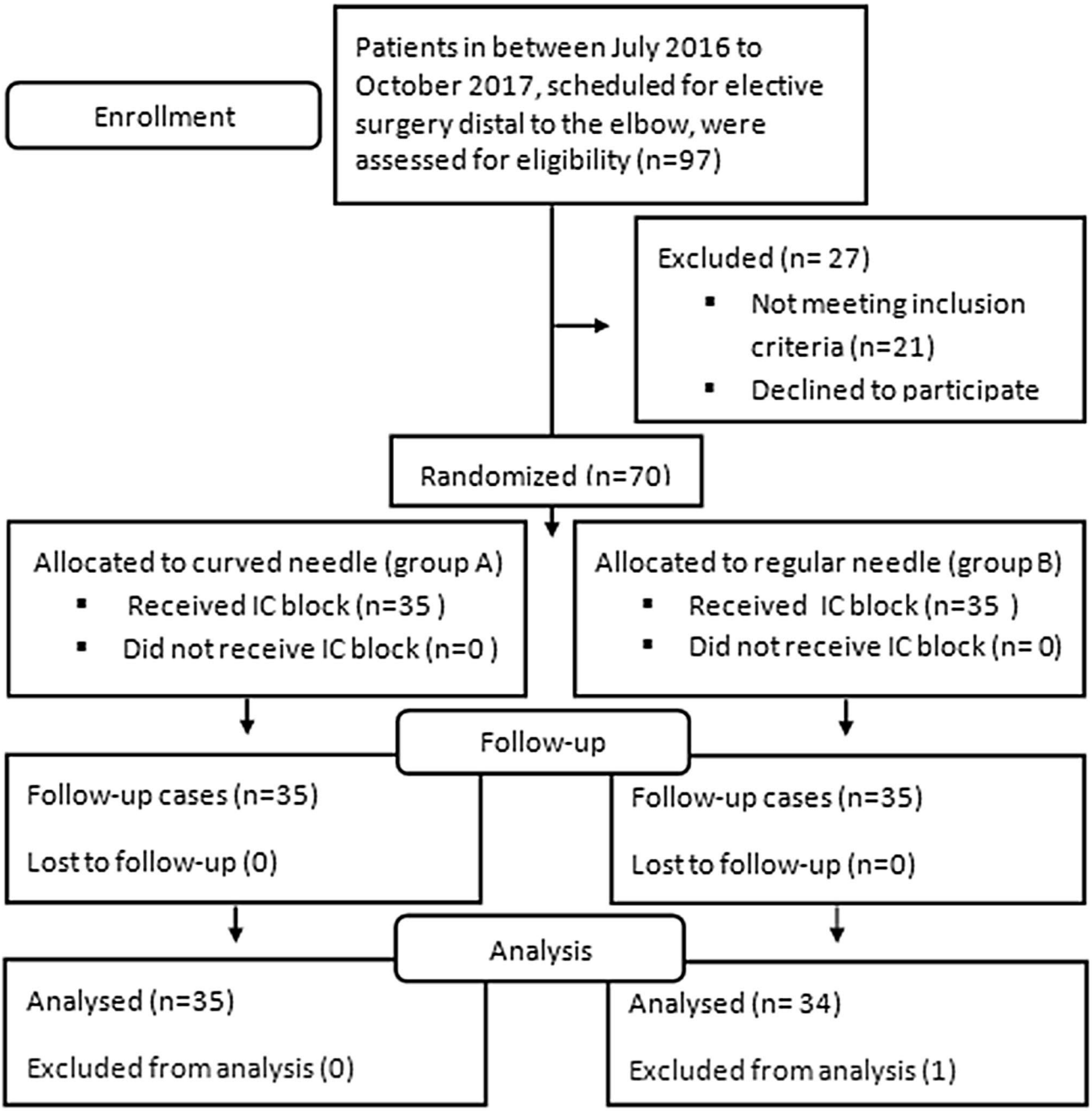

Fig. 2 CONSORT flow diagram

Discussion

The curved block needle makes the lateral sagittal infraclavicular block easier to perform compared to the non-curved needle. The curved needle allowed less recognition time and less anesthetic injection time in comparison with the non-curved needle. The use of the curved needle reduced the numbers of needle passes and needle redirections required to perform the block. The curved needle form provided less procedure pain and higher satisfaction levels among anesthetists than the non-curved needle.

The lateral sagittal infraclavicular approach necessitates proficiency in tracking the block needle advancement relative to the brachial plexus [13]. The infraclavicular block is performed at the level of plexus cords within the infraclavicular fossa [10, 14]. The three brachial plexus cords are closely arranged around the axillary artery and vein [2]. The failed needle-tip positioning under ultrasound can

Table 1 Patient demographics and clinical characteristics

Parameters	Group A ($n=35$)	Group B ($n=34$)
Age (years)	42 ± 11	40 ± 13
Male/female	20/15	21/13
BMI (kg/m^2)	24.9 ± 3.7	25.4 ± 4.5
ASA grade I/II/III	24/10/1	24/9/1
Brachial plexus depth (cm)	3.75 ± 0.25	3.84 ± 0.35
Needle insertion depth (cm)	5.73 ± 0.45	5.91 ± 0.51
Tourniquet time (min)	75 ± 19	72 ± 16
Surgery: hand/wrist/forearm	10/8/17	11/8/15
Surgery time (min)	80 ± 23	81 ± 21

Values are expressed as mean ± standard deviation or absolute numbers as indicated. No statistically significant differences among groups for all baseline characteristics. Group A, block needle is curved and group B, block needle is non-curved

BMI, body mass index; ASA, American Society of Anesthesiologists

be due to the improper needle insertion point, the steep needle insertion angle, and the needle deflection as it travels through soft tissues.

Using the curved block needle offers a wide range of benefits compared to the straight needle.

The user can pass the curved needle at different angles to the skin. The curved needle has the potential to avoid anatomical obstacles like the clavicle on approaching the brachial plexus. Due to its curved design, the block needle traverses a path somewhat different from the straight needle. It comes to the vicinity of the target plane by a circuitous route rather than a linear one [15]. Clear needle visibility is an essential point for the success of peripheral nerve blockade. The conventional straight needles are less visible at steep insertion angles [16, 17]. The valuable role of the curved needle in performing the infraclavicular brachial plexus block is that the distal portion of the needle advances almost perpendicularly to the ultrasound beam, resulting in better needle visibility (Fig. 3a, b). By providing proper insertion

Table 2 Block performance characteristics

Parameters	Group A ($n=35$)	Group B ($n=34$)	*P* value
Performance time (s)	174 ± 76	267 ± 112	0.0001†
Recognition time (s)	120 ± 48	179 ± 72	0.0002†
Injection time (s)	54 ± 23	88 ± 36	0.0001†
Number of attempts	1 (1–1 [1–2])	1 (1–2 [1–3])	0.029*
Number of needle redirections	2 (1–2 [1–3])	3 (2–3 [1–4])	0.0001*
Current intensity (mA)	0.44 ± 0.06	0.45 ± 0.07	0.528†
Procedure pain (VRS)	2 (1–2 [1–3])	2 (2–3 [2–5])	0.001*
Patients can accept the same nerve block again in the future	33 (94.3%)	27 (79.4%)	0.08**

Values are presented as mean ± SD or median (IQR [range]) as indicated

*Mann–Whitney test

**Fisher's exact test

†Student *t* test. Group A, block needle is curved and group B, block needle is non-curved

Table 3 Impact of curved vs. non-curved needle on the technical characteristics of nerve block

Measurement items	Group A (35)	Group B (34)	*P* value
How easy was it to			
Obtain favorable needling window	4 (3–4 [2–5])	3 (2–4 [1–4])	0.02*
Handle and guide block needle to the target	4(4–5 [3–5])	3 (3–4 [2–4])	0.001*
Readjust the needle path; if needed, to reach the target	4 (4–5 [3–5])	3 (3–4 [2–4])	0.001*
Achieve adequate needle visualization	4 (3–4 [2–4])	3 (2–4 [1–4])	0.013*
Reposition the needle tip to maximize anesthetic spread around brachial plexus	4 (3–5 [3–5])	3 (3–4 [2–4])	0.001*
Recapture needle trajectory once the operator loses its visualization	4 (4–5 [3–5])	3 (3–4 [1–4])	0.0001*
How was the overall experience with using the block needle	4 (4–5 [3–5])	3 (3–4) (2–4])	0.001*
How likely is it that anesthetist would recommend the same used needle to practice a colleague	4 (4–5 [4, 5])	3 (3–4) (2–4])	0.001*

Values are presented as median (IQR [range])

*Mann–Whitney test. Group A; block needle is curved and group B; block needle is non-curved

Table 4 Outcome variables of the nerve blockade

Variables	Group A ($n=35$)	Group B ($n=34$)	P value
Onset of sensory blockade (min)	16.5 ± 5.8	17.8 ± 6.1	0.367*
Onset of motor blockade (min)	19.4 ± 6	20.3 ± 6.4	0.548*
Successful block (n), %	32 (91.4%)	31 (91.2%)	1.0**
Partial successful block (n), %	3 (8.6%)	3 (8.8%)	1.0**

Values are presented as mean ± SD or absolute numbers as indicated

*Student t test

**Fisher's exact test. group A; block needle is curved and group B; block needle is non-curved

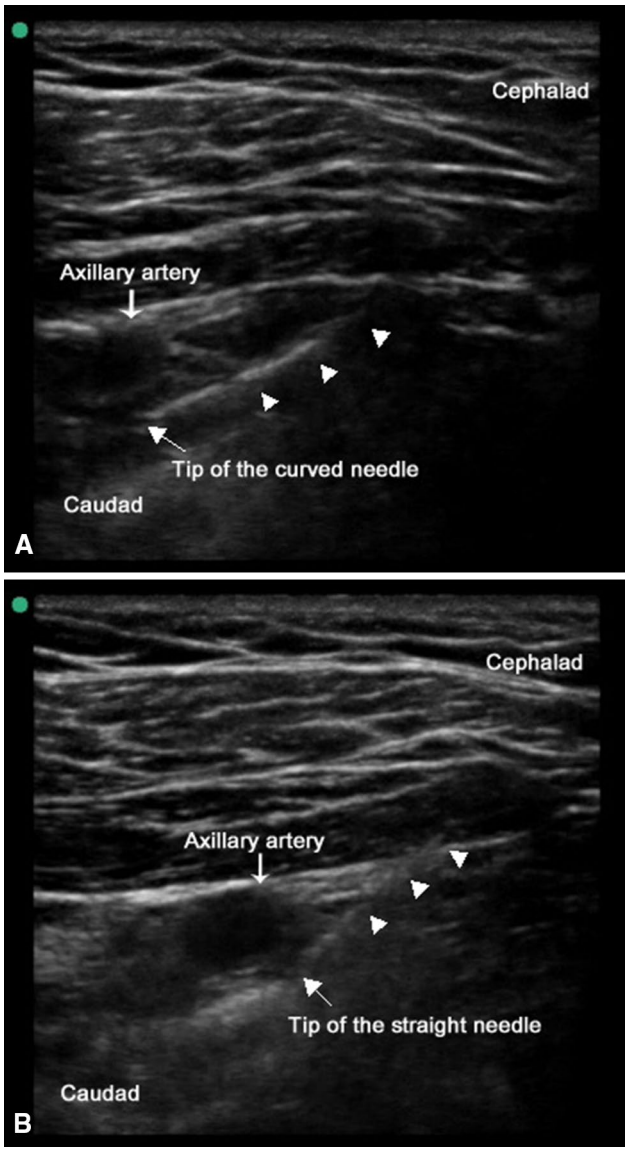

Fig. 3 **a**, **b** The block needle was advanced in-plane and directed toward the posterior aspect of the axillary artery. Due to its curved design, the distal portion of the curved needle is advanced almost perpendicularly to the ultrasound beam (**a**) compared to the straight needle (**b**), resulting in better needle visibility in performing the infraclavicular brachial plexus block

angle and optimal needle path trajectory, the curved needle offered less time to complete the infraclavicular block when compared with the non-curved needle.

The moving distance of the curved needle tip is not shorter than the non-curved needle tip towards the brachial plexus. However, changing the curved needle's path in mid-course can be accomplished without having to withdraw the block needle back to the skin. The needle curvature can be utilized to correct for needle misalignment by needle rotation. By rotating its base, the curved needle tip orientation can be changed, allowing the block needle to reach the brachial plexus easily. The broad ranges of curved needle movements can lead to avoiding unnecessary manipulation of the block needle into the brachial plexus. The needle-related procedure pain can be consequently reduced by minimizing needle manipulation error and soft-tissue trauma. The curved needle showed less patient discomfort, reflecting the lesser time spent in refining the position of the block needle close enough to the brachial plexus.

The design features of each block needle could have an impact on the capacity to control the needle advancement towards a target. Due to the lack of validated scales for performance characteristics of the block needles in the literature, the Likert scaling method [12] was employed to measure the impact of needle pre-curving on the technical parameters of the infraclavicular blockade. In the current study, the anesthetists were, in general, more satisfied with the use of curved needle than non-curved needle in performing the lateral sagittal infraclavicular block. The anesthetists can obtain a favorable needling window to approach the brachial plexus easily. The needle curvature enables the user to pass the needle at different insertion angles through the underlying soft tissues. The curvature enables the user to pass the needle with different curved trajectories on approaching the brachial plexus. The angle of needle insertion and the needle path can be optimized according to the depth of brachial plexus.

In the current study, there are no significant complications and no recorded cases of nerve palsy related to the use of the curved and non-curved needle. The ultrasound guidance may provide the benefits of real-time imaging of the targeted structures and safety in terms of injury to the

adjacent anatomical structures [18]. The in-plane ultrasound imaging has the advantage of showing the block needle as it progresses towards the target. If the curved block needle lies outside of the ultrasound plane, experienced anesthetists can recapture the distal needle portion and its trajectory by slight needle rotation and probe adjustment. Clinical training is highly required to develop and strengthen the skills necessary to use the curved needle in the peripheral nerve blockade. Proper training allowed the anesthetists to cross the steep initial curve of learning before venturing to the real-time clinical scenario. It has helped to mitigate this limitation when conducting the study.

The limitation of the study is that the anesthetists, who did all blocks, as well as the observer evaluating the block techniques, could not be blinded to the group allocation. Therefore, they were not involved in further follow-up after the block procedure.

In conclusion, the use of the curved block needle is associated with a shorter performance time and fewer needle redirections to complete the infraclavicular blockade when compared with the non-curved needle. The curved needle provides less procedure-related pain and higher satisfaction levels among anesthetists than the non-curved needle.

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Author contributions TFT: Role: This author described and recommended the curved needle for technically easier infraclavicular block performance. The author was involved in the design of the study; analysis, interpretation of data and preparation of the manuscript. GAK: Role: This author was involved in the design of the study; analysis of data and preparation of the manuscript.

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Compliance with ethical standards

Conflict of interest The authors declare no conflicts of interest.

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