Title

Minimum effective volume of ropivacaine 0.75% for an ultrasound-guided infraclavicular brachial plexus block

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ABSTRACT

Background: Ultrasound guidance has been shown to reduce the minimum effective volume (MEV) of local anesthetics for several peripheral nerve blocks. The lateral sagittal infraclavicular block (LSIB) is a well-established method for surgery distal to the elbow. It has not yet been investigated for its minimum effective local anesthetic volume. The standard long-duration local anesthetic in our department is ropivacaine. Our aim was to determine the MEV using ropivacaine 0.75% for LSIB.

Methods: Twenty-five adult ASA I-II patients scheduled for handsurgery received the LSIB with ropivacaine 0.75% and ultrasound guidance. A successful block was defined as anesthesia or analgesia for all five nerves distal to the elbow 30 minutes after local anesthetic injection. The MEV for a succesful block in 50% of patients was determined by using the staircase Up-and-Down method introduced by Dixon and Massey. Logistic regression and probit transformation was applied to estimate the MEV for a succesful block in 95% of patients.

Results: The MEVs in 50% and 95% of patients were 19 mL (95% CI, 14 – 27) and 31 mL (95% CI, 18 – 45), respectively. The patients received ropivacaine 0.75% volumes in the range of 12.5-30 mL, which gave incomplete blocks in 10 patients.

Conclusions: For hand or forearm surgery using the ultrasound-guided LSIB with ropivacaine 0.75%, we estimated that 31 ml would be sufficient to block all nerves distal to

the elbow in 95 % of the patients. This is a smaller volume than previously used for the same block when guided by nerve stimulation.

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Introduction

Performing regional anesthesia with a minimum effective volume of a local anesthetic (LA), may reduce the risk of systemic LA toxicity. This is of particular interest if a patient requires more than one block. Ultrasound guidance for peripheral nerve blocks allows real-time observation of the needle, nerves and LA distribution. It therefore has the potential to substantially reduce the volume of a defined LA conventionally used for blocks guided by nerve stimulation.

Regarding upper limb blocks, this expectaction has been confirmed for interscalene[1-4] and axillary[5-7] blocks, but not for supraclavicular[8,9] and not consistently for infraclavicular methods[10,11]. Ultrasound-guided brachial plexus blocks at the same anatomic level, e.g. infraclavicularly, may vary in volume requirements. Major determinants are probably the proximity of the LA injection to the cords of the brachial plexus and the pattern of LA distribution.

The lateral sagittal infraclavicular plexus block is a well-established method for surgery distal to the elbow[12-15]. However, the method's minimum effective volume of a given LA, has not yet been determined. Ropivacaine 0.75% has been our standard LA for this block and surgery of long duration . The goal of the present study was therefore to determine the minimum effective volume of this LA when performing the lateral sagittal infraclavicular block by ultrasound guidance.

Methods

The study was in accordance with the Helsinki declaration and the protocol was approved by the regional ethical committee of North Norway. Twenty-five volunteers scheduled for hand-surgery of at least one hour duration, gave written informed consent to participate in this prospective study. They suffered either from carpometacarpal arthrosis or Dupuytren´s contracture, to be operated by excision of the trapezium bone or open fasciectomy, respectively. The other inclusion criteria were American Society of Anesthesiologists physical status (ASA) I-II, age between 18 and 65 years and body mass index between 20 and 35 kg/m^2. Exclusion criteria were pregnancy, patients with contraindications to regional anesthesia, allergy to LAs, patients on major opioids because of chronic pain, atrioventricular block, drug treated diabetes and peripheral neuropathy.

Before the block all patients received oxygen supplementation by nasal cannula. Standard monitoring included electrocardiogram, non-invasive arterial pressure and pulse oxymetry. For patient comfort intravenous midazolam 0-3 mg or fentanyl 0 – 100 µg were given as needed. The ultrasound-guided lateral sagittal infraclavicular block was performed by one of two investigators who had considerable experience with the method. The patients were supine with the arm to be blocked adducted, while the hand rested comfortably on the abdomen. We used a SonoSite M-Turbo unit (SonoSite, Inc., Bothell, WA, USA) with a C11x, 8-5 MHz broadband curved array probe. A prescan was carried out to optimize the settings of the ultrasound apparatus. Sterile preparations included scrubbing the skin with Chlorhexidine 0,5%, sterile transducer covers (CIVCO, Kalona, Iowa, USA) and sterile ultrasound gel (Parker laboratories inc., Fairfield, USA). A skin wheal was raised with 1 mL lidocaine 2% before insertion of an ultrasound ecchogenic 22Gx80mm needle (PAJUNK® GmbH Medizintechnologie, Geisingen, Germany).

The needle insertion point was at the intersection between the lower edge of the clavicle and the medial surface of the coracoid process[13]. Needle advancement was in the parasagittal plane, with continuous observation of the needle tip, using the in-plane technique. Considering the artery as a clock face (Figure 1) with 12 o´clock ventral, the cords are normally found inside a periarterial sector from 3 to 11 o´clock and within 2 cm from the midaxis of the axillary artery[16]. All patient had this sector filled with their allocated volume of LA. While the initial injection usually would be at 8 o´clock, more injection sites could be utilized, trying to provide an even LA distribution of the sector. Injection points outside the sector were avoided. Moreover, we did not make a subcutaneous infiltration in the axilla to block the intercostobrachial nerve.

We tried to reduce the risk of intraneural injection by carefully observing the relationship between needle tip, injectate and nerves. Additionally we used electrical nerve stimulation (Stimuplex ® HNS12, B.Braun, Melsungen, Germany) with a current of 0.2 mA and 0.1 msec duration at 2 Hz. It was active continuously after inserton of the needle. If a motor response was obtained, the needle was withdrawn in steps of 1 mm until the response disappeared.

Ropivacaine 0.75% was administrated in a variable volume for each of the patients, according to the methodology described in Statistical Analysis. The first patient received a volume of 30 mL, which, based on our experience, was expected to be sufficient in most patients. The volume for later patients was defined by the block effect in the preceding patient. A successful block was followed by a reduction of the volume by 2.5 mL, whereas a failed block caused a 2.5 mL volume increase. To reduce the risk of systemic LA toxicity, we decided *a priori* not to exceed 40 mL injectate.

An observer blinded for details of the block and the injected volume, assessed the sensory status of the limb to be operated, while consecutively comparing with the contralateral arm. Testing times were before the block and every fifth minute for 30 minutes after finishing local anesthetic administration. Ice cubes within a plastic glove were repeatedly applied to the skin, for approximately 2 seconds, at premarked points in the areas of the radial, median, ulnar, musculocutaneous and medial antebrachial cutaneous nerves. These points were between the 1. and 2. metacarp dorsal, between the 1. and 2. metacarp volar, on the ulnar side of the 5. metacarp, the most prominent part of the brachioradial muscle belly and in the middle of the forearm on the ulnar side, respectively. A 4-divided sensory scale was used[13] : 0 = normal cold feeling, 1 = hypalgesia (patient feels coldness, but less than on the contralateral side), 2 = analgesia (patient feels touch, but not coldness), 3 = anesthesia (no feeling of coldness or touch). A block was defined as successful if all five nerves had a score of 2 or 3 within 30 minutes after completed LA injection. The block was a failure if, within the same time limit, one or more nerves had a score of 1 or 0. Patients with incomplete blocks would, on indication, receive supplementary peripheral nerve blocks or general anesthesia.

During the block procedure we recorded paresthesia, motor response to the nerve stimulator, vessel puncture by the block needle, the number of needle passes, the block performance time and the injection time. Block performance time was the time from insertion to final withdrawal of the block needle. The injection time was the interval between start and end of LA injection. An additional needle pass was defined as needle retraction of at least10 mm prior to further needle insertion. Patients were also monitored for signs of systemic LA intoxication, pneumothorax and the occurence of tourniquet pain.

For all patients hospital discharge was planned on the day of surgery. The day after surgery we telephoned the patients to learn about their block recovery. Additionally, during ambulatory controls the surgeons were required to report about sensory or motor deficits possibly related to the block procedure. The controls were for patients with Dupuytren's contracture approximately one week and for patients with carpometacarpal arthrosis five weeks after their operation.

Statistics and Power Analysis

The primary outcome measure was the minimum effective volume of ropivacaine 0.75% providing a succesful lateral sagittal infraclavicular block in 50% of the patients (MEV50). For sample size calculation we applied the formula by Dixon and Massey, $n = 2(SD/SEM)^2$, where SD is standard deviation and SEM the standard error of the mean[17]. Assuming a 5 ml SD and 1.5 ml SEM, the formula then suggests 22 patients for the study. Anticipating a maximal dropout of three patients, we decided to enroll 25 patients.

The staircase up-and-down method for large samples introduced by Dixon and Massey[17] was used to estimate the MEV_{50} and its 95 % confidence interval. For this plot we also required *a priori* a minimum of five negative-positive up-and-down deflections[4,18]. To estimate the minimum effective volume in 95 % of patients (MEV_{95}), logistic regression and probit transformation were used, applying the SAS statistical software package (SAS®, V9.2, SAS Institute Inc., Cary, NC, USA). The binary response in the logistic regression model was failed block (yes/no) with LA volume as the independent variable. Continuous data are presented as mean (SD) or median (range) as appropriate. Categorical data are presented as n (%).

Results

All patients completed the study and were included in the statistical analyses. Their characteristics are shown in Table 1. Block performance data are summarized in Table 2. LA was injected in a volume range from 12.5 mL to 30 mL. The sequence of successful and failed blocks is illustrated in Figure 2. It shows seven deflections from failed to successful block. MEV_{50} was 19 mL (95% CI, 14 – 27) and the calculated MEV_{95} 31 mL (95% CI, 18– 45).

Ten out of 25 patients had a failed block (Table 3). Insufficient effect (score 0 or 1) on the ulnar nerve was the reason among six patients. Similar status was found four times for the musculocutaneous nerve, three times for the median nerve and the radial nerve and once for the medial antebrachial cutaneous nerve. The patient who received the lowest volume of ropivacaine (12.5 ml), could 30 minutes post injection still perceive cold in the territory of the median nerve, although to a reduced degree (score 1)**.** Ten minutes later the block had developed to analgesia (score 2) for the same nerve.

When considering the area of planned surgery, only two of the ten patients with failed blocks required supplemental peripheral nerve blocks. These blocks were performed by ultrasound guidance in the axilla for the musculocutaneous and radial nerves and in the forearm for the median and ulnar nerves.

Intraoperatively intravenous fentanyl was given to nine patients and midazolam to eight patients because of patient discomfort, but never because of surgical pain. The amounts of fentanyl and midazolam to these patients had means of 58 (25) μg and 1.4 (0.7) mg,

respectively. Four patients reported tourniquet pain. This required intravenous fentanyl in only one of the patients, a single dose of 50µg with good effect. None of the 25 patients received deep sedation or general anesthesia.

Regarding side-effects and adverse events; transient paresthesia was recorded in eight patients, muscular response to the nerve stimulator in three patients and vascular puncture in two patients (one from skin vessel, one from the axillary vein). Among the three patients with a motor response to the nerve stimulator, ultrasound did not suggest an intraneural position of the needle tip. Nevertheless the needle was slightly withdrawn. All patients reported complete recovery of sensory and motor functions the day after surgery. Also during the surgical ambulatory controls, there were no signs of nerve dysfunction caused by anesthesia.

Discussion

Earlier performing the lateral sagittal infraclavicular block guided by nerve stimulation, we conventionally used a volume of ropivacaine 0.75% close to 40 mL. With ultrasound guidance the current study suggests a substantially smaller volume, 31 mL, to block all nerves distal to the elbow in 95% of the patients (MEV_{95}).

The result of our study agrees with our present practice, where we seldom inject more than about 30 ml. However, in our investigation we did not compare volume requirements for the block when guided by ultrasound or nerve stimulation. The latter technique is now very rarely used in our department. A comparison between the two techniques would have carried the risk of bias favoring ultrasound guidance.

We applied Dixon and Massey's staircase up-and down methodology, which has been validated previously and ultilized in several studies of upper limb blocks[1-9,11]. One of its advantages is the small number of patients required. As in several former studies[1,4,18,19] , we found a wide confidence interval: 95% CI, 18– 45. We think, as suggested by Renes et al.[4], that the small number of patients, particularly at the higher volume end, may contribute to this.

The MEV has been assessed for another infraclavicular block, the “double bubble” method described by Tran et al.[20]. This block implies a single LA injection immediately dorsal to the axillary artery. Using lidocaine 1.5% with epinephrine 5µg/ml they calculated a MEV_{90} of 35 ml (95% CI, 30-37.5 mL)[9]. This may possibly indicate a higher volume requirement than for

the lateral sagittal infraclavicular block. However, differences between the studies in choices of local anesthetics, definition of succesful block and statistical workout, make an appropriate comparison impossible.

Sandhu et al have been pioneers in performing an ultrasound-guided infraclavicular block with selective LA injections toward each of the three cords[21]. A MEV study of their method has not yet been performed. But in a report of bilateral blocks their group found 20 ml for each side sufficient when using 2% lidocaine with sodium bicarbonate (0.9 mEq/10 ml) and epinephrine 5µg/ml[10].

It should be noted that identifying all cords by ultrasound may be difficult[22]. Sauter et al. later defined a periarterial sector where the cords are usually located[16]. Our routine has therefore been to fill this sector with LA, applying one or more injections. This has facilitated the introduction of infraclavicular blocks to colleagues with little brachial plexus block and ultrasound practice. With increasing experience and improved resolution of ultrasound units, we are presently confident about regularly identifying the lateral and posterior cords. Increasingly, often we also recognize the medial cord. This suggests a refinement of the method with selective injections to the cords. It will probably further reduce the MEV_{95}, but this requires further investigations.

In summary, the minimum effective volume of ropivacain 0.75% in 50% of the patients was determined to be 19 mL using the ultrasound guided lateral sagittal infraclavicular plexus block method. The minimum effective volume in 95% of the patients was estimated to be 31 mL, which is a considerably smaller volume than previously used for the same method with electrolocation of the nerves.

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Conflict of interest

The autors have no conflicts of interest.

Figure 1. The periarterial sector. Schematic drawing in the parasagittal plane of the lateral sagittal infraclavicular block, showing the axillary artery (A) with clockface orientation (XII o´clock ventral), the cords and a blue-colored periarterial sector. The sector extends from III to XI o´clock and radially 2 cm from the midaxis of the artery. It usually includes the lateral (L), posterior (P) and medial (M) cords, indicated in their average periarterial positions. The point on average closest to the cords is at 8 o´clock, immediately outside the arterial wall. The study protocol implied filling up the sector with local anesthetic. The drawing is made by Axel R. Sauter, based on data and a figure from a previous study[16].

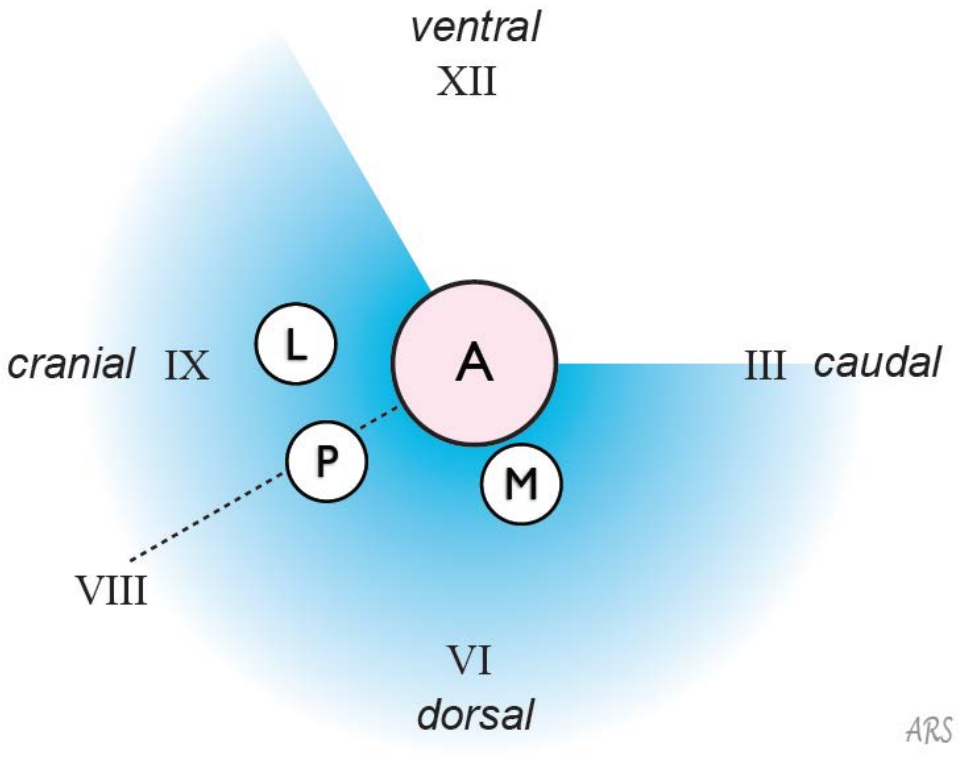

Figure 2.

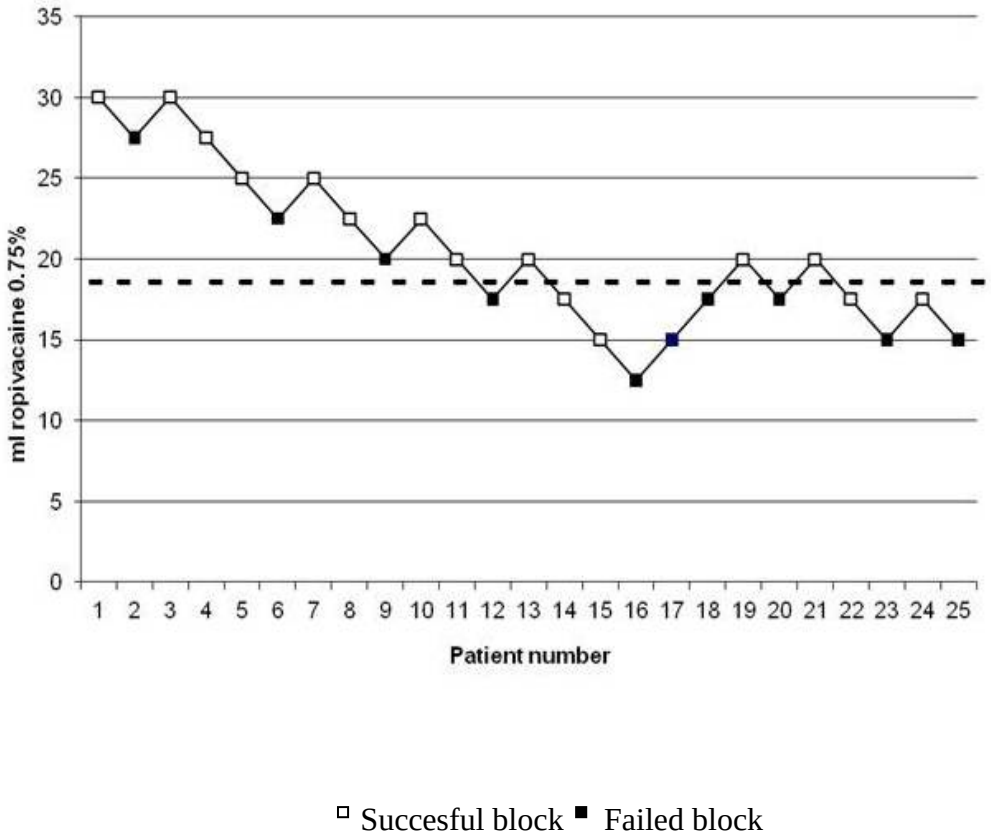

Figure 2. Sequential block results of the ultrasound-guided lateral sagittal infraclavicular block using ropivacaine 0.75%, according to the staircase up-and-down method. The horizontal dashed line - - - - - represents the minimum effective volume in 50% of the patients (MEV_{50}), 19 mL.

Table 1. Patient characteristics (N=25)

Age, mean (SD), years	57.6 (7.7)
Gender (male/female), n	14/ 11
BMI*, mean (SD), kg/m^2	26 (3.9)
ASA† physical status (I/II), n	7/ 18
Types of Surgery (Trapezius excision/ Fasciectomy Dupuytren), n	13/ 12
Duration of tourniquet	
Excision of the trapezium bone, median (range), min	73 (49-134)
Fasciectomy Dupuytren, median (range), min	99 (49-193)
Duration of surgery	
Excision of the trapezium bone, median (range), min	80 (39-132)
Fasciectomy Dupuytren, median (range), min	92 (43-207)

Continuous variables are presented as mean (SD) or median (range). Categorical variables are presented as counts.

*BMI = body mass index

† ASA = American Society of Anesthesiologists

Fasciectomy Dupuytren = open fasciectomy in patients with Dupuytren's contraction.

Table 2. Block data

Performance time, median (range), min	7.9 (4.8 - 14.2)
Injection time, median (range), min	5.9 (3.6 - 10.1)
No. needle passes, n (%)	
1	16 (64)
2	2 (8)
3	3 (12)
4	4 (16)
Paresthesia, n (%)	8 (32)
Nerve stimulation, n (%)	3 (12)
Vascular puncture, n (%)	2 (8)
Systemic toxicity to LA, n (%)	0 (0)
Pneumothorax, n (%)	0 (0)

Continuous variables are presented as means (SD) or median (range). Categorical variables are presented as count (percentage). LA= local anesthetic

Table 3. Details of the individual blocks

Patient number	Surgical procedure	Anesthesiologist	Volume, mL	Block success 30 min post injection	Supplemental LA* required for surgery
1	Trapezium excision	A	30	Yes	No
2	Trapezium excision	A	27.5	No	No
3	Trapezium excision	B	30	Yes	No
4	Trapezium excision	B	27.5	Yes	No
5	Trapezium excision	B	25	Yes	No
6	Trapezium excision	B	22.5	No	No
7	Trapezium excision	B	25	Yes	No
8	Fasciectomy	A	22.5	Yes	No
9	Fasciectomy	A	20	No	Yes†
10	Trapezium excision	B	22.5	Yes	No
11	Trapezium excision	A	20	Yes	No
12	Fasciectomy	B	17.5	No	Yes‡
13	Fasciectomy	A	20	Yes	No
14	Fasciectomy	B	17.5	Yes	No
15	Fasciectomy	A	15	Yes	No
16	Fasciectomy	A	12.5	No	No
17	Fasciectomy	B	15	No	No
18	Fasciectomy	A	17.5	No	No
19	Fasciectomy	B	20	Yes	No
20	Trapezium excision	A	17.5	No	No

21	Trapezium excision	B	20	Yes	No
22	Fasciectomy	B	17.5	Yes	No
23	Trapezium excision	A	15	No	No
24	Trapezium excision	A	17.5	Yes	No
25	Fasciectomy	B	15	No	No

* LA = Ropivacain 0.5%

†Ulnar and radial nerve

‡Ulnar, radial, median and musculocutaneous nerve

Fasciectomy = open fasciectomy in patients with Dupuytren's contraction.

The layout of this table is modified from a table by E. Duggan et al.[8]

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