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Anesthetic Volume for Ultrasound-Guided "Double Bubble" Infraclavicular Block: Comparison of Ropivacaine 0.75% 30ml Vs 35ml

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Abstract

For an UltraSound guided Infraclavicular Block, a non-inferiority randomized study was conducted comparing two volumes of ropivacaine 0.75%: 35 ml vs 30ml. Fifty 18-70 years old patients undergoing upper limb surgery, ASA I-II were enrolled. Exclusion criteria included existing neurologic disease, coagulopathy, allergy, pregnancy, previous surgery in clavicular region, BMI more than 30 kg/m^2 or patients unable to give written consent. Using US guidance, a 22 gauge/80 mm SonoPlex needle (Pajunk®) was advanced until the tip was located dorsally to the artery at a 6-o'clock position. Correct placement was ensuring by a "double bubble" sign. The block was performed by delivering ropivacaine 0.75% via an infusion pump (Alaris® PK) at 600 ml/h.

The patients were randomly allocated to receive 30 or 35 ml of anesthetic. Subsequently, the brachial plexus block was evaluated after 30 minutes according to a 3-point scale for sensitive and motor blockade in each nerve field (maximum 16 points). Block was successful if a minimal score of 14 points was achieved. Student's T test for continuous variables and Chi-Square test for qualitative variables were used. Both groups were homogeneous in terms of anthropometric data. The Block Success rate was 22/25 (88%) regardless of the group of origin (G30 or G35) (p=NS). our data showed that for an Infraclavicular Block achieved by a single injection of ropivacaine 0.75% using the "double bubble" technique a volume of 30 ml is equivalent to 35 ml.

Keywords: Anesthetics; Local; Dose response relationship; Drug; Ultrasonography; Peripheral nerves

Introduction

The UltraSound-Guided (USG) InfraClavicular Block (ICB) offers several advantages over the axillary block of brachial plexus: the single injection [1], needed in the first approach, causes less discomfort [1-4] and fewer adverse events than the multiple injections required in the latter for a comparable block success. The ICB secures a pronounced sensory and motor blockade of the musculocutaneous nerve and of an additional spectrum of nerves such as the thoracodorsal, the axillary and the medial brachial cutaneous nerves. This wide blockade extension reduces the likelihood of tourniquet pain during surgery compared to the axillary approach of the Brachial Plexus Block (BPB) [5,6]. Furthermore, an infraclavicular catheter is less amenable to dislocation and infections and does not need subcutaneous tunneling due to its anatomical position [7].

The reference point for USG-ICB is the axillary artery, even though the heterogeneous brachial plexus sonography, the presence of septa within the neurovascular sheath [8], and the absence of a clear nervous target for spreading local anesthetics complicate the study of a minimum effective anesthetic volume. However, the single-injection of anesthetics with the "double bubble" technique [9] assures a high success blockade rate [10].

Recently, Tran et al. [10] determined that the minimum effective anesthetic volume (MEAV) of lidocaine 1.5% with epinephrine 5µg/ml for ICB is 35ml. Tran et al. used a biased coin design up-and-down sequential method, where the total volume of local anesthetic administered to each patient depended on the response of the previous one. But, in our clinical experience we observed that even lower doses can be successful and, therefore, for a USG-ICB, we considered the suggested volume used by Tran et al. as a comparative standard dose for a non-inferiority study, using ropivacaine 0.75% in two volumes: the first of 35ml, equal to the one used by Tran et al. for lidocaine 1.5%, and the second, just less than the previous, of 30ml.

Methods

When using a volume of 35 ml the success rate found by Tran et al. was 91% [9]. In medical publications the USG-ICB success rate varies from 84% to 96% [1,4,11-15]. On the basis of the success rate reported in the literature, to calculate the sample size of our study, maintaining a statistical power of at least 90% and a significance level of 5%, the minimal sample size needed to nullify the hypothesis of inferiority of the smaller volume (30 ml vs 35 ml), was 25 patients [16]. Hence, we enrolled 50 patients in 2 groups. The patients were randomly allocated, using MATLAB® generator, into two groups, G35 and G30, of 25 patients each. Ropivacaine 0.75% was used in G35 and G30 at a volume of 35 ml and 30 ml respectively.

After obtaining written informed consent, fifty 18-70 years old patients undergoing upper limb surgery and with a physical status corresponding to the American Society of Anesthesiologists (ASA) I or II were enrolled. To minimize ultrasonographic difficulties, only patients with a Body Mass Index (BMI) of less than 30 kg/m2 were chosen [17]. Exclusion criteria included existing neurologic disease,

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coagulopathy, and allergy to local anesthetics agents, pregnancy, and previous surgery in clavicular region or patients unable to give written consent. Before nerve blockade, all patients received intravenous access and pulse oximetry monitoring. A standard premedication was achieved with a single intravenously administered dose of midazolam 0.03 mg/kg and of fentanyl 0.6 μg/kg.

For USG, we used a Biosound Esaote ultrasound system (Mylab 30 Gold) with a linear array ultrasound transducer (LA523) at 7.5 MHz. The probe was applied in a sterile fashion in the infraclavicular fossa immediately medial to the coracoid process with a short-axis view of the axillary artery. A skin wheal was raised with 3-5 ml of lidocaine 2%. Using an in-plane technique a 22 gauge/80 mm SonoPlex needle (Pajunk®) was advanced until the tip was located dorsally to the artery at a 6-o'clock position. Correct placement was ensured by a "double bubble" sign after 1ml test volume of saline solution, and later during Local Anesthetic (LA) injection [9]. The block was performed by delivering ropivacaine 0.75% via an infusion pump (Alaris® PK) at 600 ml/h. The pump was used to obtain a constant infusion rate.

Subsequently, the BPB was evaluated after 30 minutes. The sensory blockade of the musculocutaneous, median, radial, and ulnar nerves was graded according to a 3-point scale using a cold test: 0=no block, 1=analgesia (patient can feel touch, not cold), and 2=anesthesia (patient cannot feel touch). The sensory blockade of the musculocutaneous, median, radial, and ulnar nerves was respectively assessed on the lateral aspect of the forearm, the volar aspect of the thumb, the lateral aspect of the dorsum of the hand, and the volar aspect of the fifth finger. The motor blockade was also graded with a 3-point scale: 0=no block, 1=paresis and 2=paralysis. This motor blockade of the musculocutaneous, radial, median, and ulnar nerves was evaluated by elbow flexion (musculocutaneous), thumb abduction (radial), thumb opposition (median), and thumb adduction (ulnar). Overall, the maximal composite score was 16 points. We considered the block a success if a minimal composite score of 14 points was achieved, provided the sensory block score was equal or superior to 7 of 8 points [10].

Statistics

Anthropometric data was analyzed using Student's T test for continuous variables and Chi-Square test for qualitative variables. Chi-Square Test was also used to study the frequencies of block failure in both groups (Table 1). A value of $p<0.05$ was considered to be statistically significant.

Results

Both groups were homogeneous in terms of anthropometric data (Table 2). The Block Success (BS) and the Block Failure (BF) rate was respectively 22/25 (88%) and 3/25 (12%) (p=NS) regardless of the group of origin (G30 or G35); therefore we rejected the hypothesis of higher efficiency with a volume of 35ml instead of 30ml.

Tab 3.	BFG	BSG	P
Age (years)	33.6 ± 11.93	43.65 ± 16.74	NS
Sex (M/F)	13/12	12/13	NS
Weight (Kg)	74.4 ± 5.37	70.76 ± 11.4	NS
Height (m)	1.79 ± 0.06	1.71 ± 0.09	P<0.05
BMI (Kg/cm^2)	23.16 ± 1.97	23.92 ± 2.97	NS
ASA status	1.0 ± 0.1	1.1 ± 0.32	NS

Table 1: Comparison of anthropometric data between the Block Failure (BFG) and the Block Success (BSG) groups.

Tab 1.	G30	G35	P
Age (years)	43.3 ± 15.44	42.3 ± 17.5	NS
Sex (M/F)	13/12	12/13	NS
Weight (Kg)	69.83 ± 9.14	72.43 ± 12.16	NS
Height (m)	1.72 ± 0.09	1.73 ± 0.09	NS
BMI (Kg/cm2)	23.63 ± 2.73	23.99 ± 3.01	NS
ASA status	1.11 ± 0.33	1.08 ± 0.28	NS

Table 2: Comparison of anthropometric data and ASA physical status in G30 and G35 (30 ml vs 35 ml).

Tab 2.	G30	G35	P
Sensory Blockade	7.47 ± 1.81	7.36 ± 1.57	NS
Motor Blockade	7.13 ± 1.88	7.73 ± 0.65	NS
Total	14.59 ± 3.37	15.09 ± 2.12	NS

Table 3: Comparison of clinical assessment score of blockade efficacy in G30 and G35 (30 ml vs 35ml).

There were no differences between the mean score of blockade efficacy in both groups (G30 vs G35: 14.59 ± 3.37 vs 15.09 ± 2.12; p=NS). In particular, in G30 and G35 respectively, the Sentitive Blockade (SB) had a value of 7.47 ± 1.81 and 7.36 ± 1.57 (p=NS); and the Motor Blockade (MB) one of 7.13 ± 1.88 and 7.73 ± 0.65 (p=NS) (Table 3).

Finally, we divided the patients into a Block Failure Group (BFG) and a Block Success Group (BSG). We noticed that the mean assessment score of blockade effectiveness was of 9.75 ± 5.68 for the BFG and of 15.62 ± 0.77 for the BSG. Moreover, the SB was of 2 ± 1.41 and of 7.87 ± 0.45, while the MB was of 3.5 ± 3.5 and of 7.7 ± 0.7 for BFG and BSG respectively (Table 1). Confronting anthropometric data, only Height seems to differ statistically. In the BFG patients are taller when compared to the BSG (1.79 ± 0.06 vs 1.71 ± 0.09; p=<0.05) (Table 3).

Discussion and Conclusion

Our data showed that 30 ml for an ICB achieved by a single injection of ropivacaine 0.75% using the "double bubble" technique was not less effective than a 35 ml volume. In the "double bubble" ICB technique, the volume of LA is particularly important. This is due to the fact that the total volume is injected into one specific point at the inferior pole of the axillary artery [9], and not in or around every single nerve trunk. The infraclavicular fossa presents many anatomical variants [17]. Usually, LA depositing is located nearby the posterior trunk. To reach the medial and the lateral trunk, the LA must surround the axillary artery until reaching the inferior margin of the small pectoral muscle. This *vis a tergo* towards the other trunks is given by the volume of LA and by the upthrust of its injection. Our study showed that a 30ml volume of ropivacaine 0.75% is equally efficient as higher volumes in producing an ICB. However, in line with medical literature, our ICB failure rate was not insignificant [1,4,11-15].

Many hypotheses have tried to explain these failures. First of all, there are many anatomic variations of nerve trunk anatomy in the infraclavicular fossa [17], and since the USG technique we used does not take into consideration the localization of such structures, the spread of local anesthetic could miss the trunks which are not present in their most common "classical" position. Secondly, the axillary vein may interfere with the spread of LA towards the medial trunk even when located in a standard anatomical position. However, the position of axillary vein, with respect to the artery and nerves, and the number of such veins is markedly variable. These anatomical variants not only meddle with the medial trunk block, but also with the posterior one. Failed or partial blocks may also be caused by the presence of muscular intersepta, tendinous structures or septa within the neurovascular

sheath that can influence the pattern of local anesthetic spread [8]. Other possible variables are related to the injection duration of LA bolus, ultrasonographic imaging difficulties in visualizing infraclavicular region and anatomical structures in high BMI patients that complicate the visual control of LA injection. Last, it is important to point out the unexpected statistically significant finding: patients with failed ICB were taller than others.

Observing the infraclavicular region, we noticed that the deposition of LA occurred in a zone of which the floor is delimitated by the lateral aspect of the thorax cage at the level of the third rib. That zone, in longilineal patients, presents, for anthropometric reasons, a greater virtual volume which is needed to be filled by LA in order to achieve a successful ICB. Anthropometric factors such as height, thoracic cage shape, clavicle and ribs angulations reduce the spread of LA towards lateral and medial trunks, and thus lower the efficacy of ICB. Our study nullified the variables related to BMI and to the injection duration of LA bolus. It also highlighted the effect of another possible anatomic confounder. This confounding variable could be responsible of a block failure since the success of the procedure is more dependent on the volume of local anesthetic than on other factors. However, to confirm this hypothesis, further studies that overturn all confounding variables are needed.

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