

A PROSPECTIVE RANDOMIZED COMPARISON BETWEEN DOUBLE AND TRIPLE INJECTION ULTRASOUND GUIDED AXILLARY BRACHIAL PLEXUS BLOCK

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Introduction

The axillary brachial plexus block is one of the most commonly used peripheral nerve block for elbow, forearm, and hand surgery. It is an ideal choice of anesthesia technique providing satisfactory anesthesia quality comparable to infra and supraclavicular blocks with fewer complications¹⁻³. The use of ultrasound (US) guided technique allows depositing local anesthetic solution under sight control directly around the nerves reducing failure rate and risk for nerve and vascular puncture⁴. Yet the perineural technique (PN) requires multiple needle manipulation which is not only time consuming in a busy clinical practice but could also increase risk of nerve injuries⁵. Several studies⁵⁻⁷, had concluded that US guided injection of local anesthetic (LA) solution around the artery is an alternative method to achieve an axillary plexus block which provides comparable success rate with the PN technique and potentially time efficiency. However, these encouraging results are subject to controversy regarding safety and efficacy, as perivascular (PV) technique was associated with high incidence of vascular puncture^{5,6}. Furthermore, procedure time is effectively lower in the PV technique groups but is either similar⁵, or superior⁶, when compared to what has been published⁸. Subsequently, with a high risk of acute LA toxicity and no reliable time efficiency, PV technique had not raised big enthusiasm^{9,10}.

Despite all, PV technique is very attractive by its simplicity. To gain popularity, clinicians have to define the best deposition site with regard to procedure time, safety profile and success rate. Thus we designed this prospective, randomized, observer-blinded trial to compare double to triple injection PV US guided axillary brachial plexus block to assess efficacy and safety.

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Methods

After institutional Research Ethics Board approval (Kassab institute of orthopedics) and written informed consent, 60 patients undergoing elective upper limb surgery under axillary brachial plexus block were prospectively enrolled into this monocentric trial.

Inclusion criteria were: patients 18–75 years of age, American society of anesthesiology (ASA) physical status I–III, body mass index (BMI) between 25 and 35.kg/m². Exclusion criteria were inability to consent to the study, any contraindication to brachial plexus anesthesia (local anesthetic allergy, local infection and coagulopathy), preexisting neuropathy, hepatic or renal failure, pregnancy, and prior surgery in the axillary region. After arrival to the operating room, the standard monitoring including electrocardiogram, noninvasive blood pressure, and pulse oximetry was applied throughout the procedure. Intravenous premedication with midazolam (0.03 mg/kg) was administered.

Using a computer-generated sequence of random numbers and sealed envelope technique, the 60 patients included were randomly allocated to receive 2-injection or 3-injection US-guided axillary block. All blocks were performed by senior anesthesiologist, in supine position with the arm abducted to 90° and externally rotated, and their forearms were flexed to 90°.

A 22-gauge, 5-cm block needles (Echoplex®, Vygon, France), ultrasound machine (Sonosite M-Turbo, Bothell, WA), and 5 to 10 MHz linear probes (sonosite L38, Bothell, WA) were used in all patients. For both techniques, the US probe was applied in a sterile way in the axilla after the skin was cleaned, to obtain a short-axis view of the axillary artery and the musculocutaneous nerve. All blocks were performed using the in-plane technique. In the two groups, a skin wheal was raised with 3 mL lidocaine 1% (UNIMED, Tunisia) and the needle was initially advanced toward musculocutaneous nerve. Seven ml of LA (lidocaine 1.5% with epinephrine 5µg/ml) was deposited around the nerve. In the 2-injection group, the needle was then advanced until the tip was positioned just dorsal to the artery (6-o'clock position) and 28 ml of LA was deposited in this location. In the 3 injection group,

14 ml of the same local anesthetic solution were successively injected at the 6-, and 12- o'clock. Care was taken to visualize the entire length of the needle during the advancement process.

The first author was in charge of recording the performance time and the number of needle passes. The performance time was defined as the time interval between the first contact of the US probe with the skin and the end of LA injection. Thus performance time is the sum of the imaging and needling times which were not recorded separately. The initial needle insertion counted as first pass. Any subsequent needle advancement that was preceded by a retraction of at least 10mm counted for an extra pass. Thus, the number of needle passes was defined as the sum of the first and the extra needle passes. A blinded observer, who was allowed into the induction room only after the block procedure was completed, has recorded the degree of sensory block and motor block which was carried out every 5 min until 30 min after the end of the procedure. 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 but not the cold), 2 = anesthesia (patient can not feel touch and cold)⁶. Sensory blockade of the musculocutaneous, median, radial and ulnar nerves was assessed on the lateral side of the forearm, the palmar part of the thumb, the lateral part of the dorsum of the hand and the volar side of the fifth finger, respectively⁶. Motor blockade was also graded on a 3 point scale: 0 = no block; 1 = paresis; 2 = paralysis⁶. Motor blockade of the musculocutaneous, radial, median and ulnar nerves was evaluated by elbow flexion, wrist extension, thumb opposition, thumb abduction, respectively⁶. The sensorimotor composite score was defined as the sum of the score of each assessed nerve. Overall the maximal sensorimotor composite score was 16 points. Patients were considered ready for surgery when a minimal composite score of 14 points was achieved, provided the sensory block score was equal or superior to 7 out 8 points. The onset time was defined as the time required to obtain a sensorimotor composite score of 14 points. The total anesthesia-related time was equal to the sum of performance and onset time. Block success was defined as the ability of the surgeon to perform surgery without the use of any rescue block

or supplemental general anesthesia and was evaluated at the end of surgery.

The blinded observer also recorded patient’s anthropometric data. Adverse events such as toxicity of the LA and blood vessel puncture. Paresthesia and numbness were monitored while performing the block, during and up to 24 hours after surgery. Telephone follow-ups were conducted on postoperative day two and seven to check for complications. Any complication was followed once a week until complete resolution.

Statistical Analysis

Based on previous study⁶, we expected similar onset time and success rate for the two groups. However we hypothesize that needling time will be shorter in the double Injection group. Subsequently performance time and total anesthesia-related time will be shorter in the double injection group. Therefore our main outcome was the performance time. A sample size calculation was performed a priori to estimate the number of subjects required, per treatment arm. We

powered the study to detect 28% absolute difference in the performance time between the two groups, with 95% confidence and 80% power. Because of the risk of dropout, we have decided to include 30 patients per group. Statistical analysis was performed using SPSS version 20 statistical software (IBM Armonk, NY). Normal distribution of the collected data was first evaluated using the Kolmogorov–Smirnov test. Continuous variables were analyzed using the Student *t* test or the Mann–Whitney U test according to data distribution and are presented as mean (95%CI or SD) or median (range). Categorical variables were analyzed using pearson χ^2 test and data are presented as number (%). All P values presented were 2-sided, and values inferior to 0.05 were considered significant.

Results

Patient demographics and baseline clinical characteristics were similar between the 2 groups (Table 1). There was a significant reduction of the performance time (2.1 [95% IC 1.80-2.40]) vs (4.74

Table 1
Patients characteristics

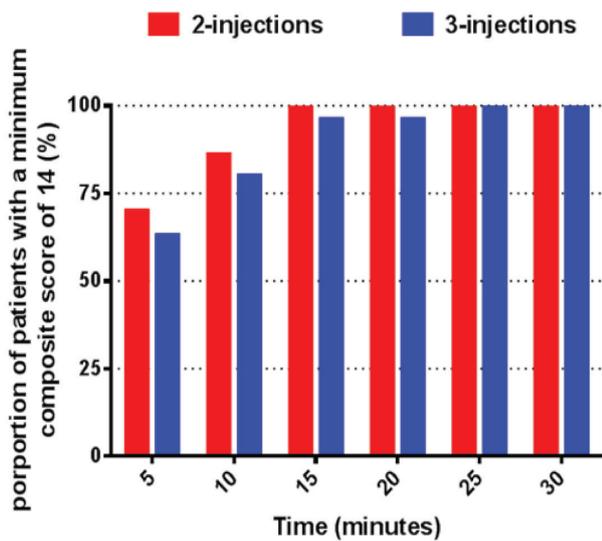
	Groups		P
	2-injections N = 30	2-injections N = 30	
Age, years	36.4 (15.9)	40.9 (15.8)	0.254
Gender male/female, n	22/8	21/9	0.651
BMI, Kg/m ²	25.3 (2.5)	25.3 (3.3)	0.721
ASA physical status - I/II/III	27/2/1	20/8/2	0.083
Type of surgery Forarm/wrist/hand	6/6/18	10/8/12	0.432

Table 2
Block performance data

	2-injections Group	3-injections Group	P
Age, years	36.4 (15.9)	40.9 (15.8)	0.254
Gender male/female, n	22/8	21/9	
BMI, Kg/m ²	25.3 (2.5)	25.3 (3.3)	
ASA physical status - I/II/III	27/2/1	20/8/2	0.083
Type of surgery Forarm/wrist/hand	6/6/18	10/8/12	

Fig. 1

Percentage of patients with a minimal composite score of 14 points



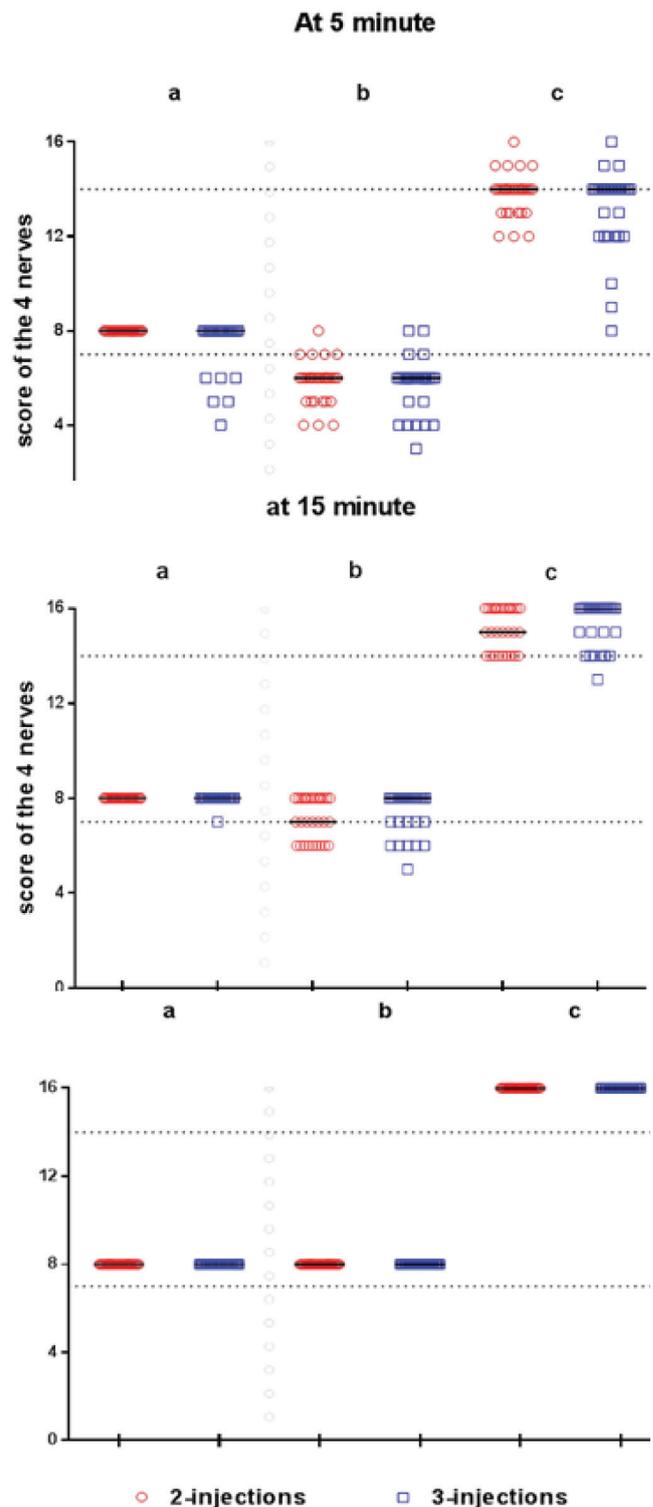
[95% IC 3.77-5.70]) minutes ($p < 0.0001$) and total anesthesia related time (9.26 [95% IC 7.80-10.73]) vs (12.7 [95% IC 10.65-14.76]) minutes ($p < 0.0001$), in 2-injection group. No significant difference in the onset time of the block was noted between the two groups ($p = 0.571$) (Table 2). The 2 techniques achieved comparable success rate (100% in both groups). Fifteen minutes after the end of the injection, 100% and 96% of patients had already achieved a composite score of 14-point in the two groups, respectively (Figures 1, 2). The proportion of patient with 14-point composite scores was not statistically different throughout the assessment period (Figure 2). Patient of the 2-injection group had less needle passes ($p < 0.0001$) to perform the axillary block. No vascular puncture was noted in both groups, whereas, paresthesia was found in 6 (20%) and 3 patients (10%) ($P = 0.472$), in the 3-injection and 2-injection groups, respectively.

Discussion

This prospective trial showed that, with PV technique, surgical anesthetic block of the brachial plexus could be achieved either with 2 injections or 3 injections. Yet, the 2-injection procedure allows a shorter performance time and consequently a shorter anesthesia-related time. Furthermore, fewer needle passes were required in the 2-injection group.

Fig. 2

Score distribution of each patient (a) sensitive score (b) motor score, (c) composite score, at 5, 15 and 30 minutes after the end of the procedure, dashed line represent minimum score to achieve for surgery, black line represent median, each symbol represent a patient



Bernucci et al.⁶ compared PV and PN US-guided axillary brachial plexus block and showed that there were no differences in success rates and total anesthesia-related times. The PV technique provides a shorter performance time. Other studies^{5,7}, have showed the same result and confirmed that there were time efficiency without any prejudicial reduction of success rate in the 2-injection group. In fact, since 1987 Partridge et al.¹¹ demonstrated that compartments surrounding nerves within the brachial plexus sheath communicate and suggest that 4 injections may not be necessary when performing axillary block. Christophe et al.¹² described topographic variations in the arrangement of the four brachial plexus nerves around the axillary artery. The median nerve was located in the 10-12 o'clock direction in 90% of the cases, the ulnar nerve was located in the 1-3 o'clock direction in 96% of the cases. The radial nerve was located in the 3-5 o'clock direction in 78% of the cases and in the 6-7 o'clock direction in 20% of the cases. The musculocutaneous nerve was close to the artery in 18% of the patients. Although, PV technique was described in the early 1960's with De Jong's report¹³. With the introduction of ultrasound guidance, site depositing accuracy permitted improvement of the overall success rate of axillary blocks. Thus, in our trial, we have supposed that axillary block can be successfully performed by injecting 28 ml of local anesthetic at the 6-o'clock position of the axillary artery. In the 3-injection group, splitting this volume in two equal parts neither increased success rate nor shorten onset time, but it extended over all procedure time. Same results were found in Tran DQ study⁵, underling that single PV injection is sufficient to successfully perform an axillary plexus block.

In our study, single injection around the artery was associated with a significant reduction in performance time. Imasogie et al.⁷ as well as Bernucci et al.⁶ showed that PV injection reduces procedure time from 11 to 8 minutes ($p = 0.003$) and from 15 to 8 minutes ($p < 0.0001$) between 2 and 4 injections group, respectively. Tran DQ et al.⁵ compared procedure time for PV block with one or multiple injections, and did not show any difference between groups, 11 min in the 2, 3-injection groups versus 12.2 min in 4-injection group. Chan et al.⁸ demonstrated that PN axillary plexus block could be performed in 9.3 minutes, thus performance time in

these studies^{5,6}, except for those of Imasogie trial⁷, who used neurostimulation in association to US guidance, were slightly higher than those of Chan trial⁸, therefore the reduced time in performance within the 2-injection groups is not clinically relevant. In contrast, we have performed the block in only 2 minutes in double injection group and 4 minutes for the 3-injection one. Multifactorial reasons could sustain this substantial difference. The first one is surely the experience level of the operators, as in all these studies blocks were mainly performed by trainees. Even if clinical study should mirror real practice conditions to ensure reliable results, establishing time efficiency, safety and efficacy for any new technique must be assessed by expert. Once confirmed as reliable technique, teaching them to trainees is more efficient and secure. Secondly, to ensure spread of local anesthetic solution to the intended targets, authors of these studies⁵⁻⁷, aimed to perform a "donut sign" or "silhouette sign". In our practice we do not intend to obtain such an image since all compartments inside the axillary sheath communicate, and any injected volume will finally spread around the artery to achieve the desired image of blurring the arterial wall supported by the pressure applied by the latsimus dorsi muscle. Subsequently, in our trial, the required time to readjust the needle position was saved.

In our study, block onset time was 7.16 min and 7.97 min in the 2-injection and the 3-injection group, respectively. Tran DQ et al.⁵ reported a significant longer onset time which was 18.6 and 19.5 min in the 2-injection and the 3-injection group, respectively. Furthermore, even with PN technique, onset time was of 13.8 min in the Bernucci trial⁶. In these studies^{5,6}, although block approach aimed to a circumferential spread of LA around the artery as recommended to intend a quick onset of the block¹⁴, the onset time remained too long. This can be explained by the fact that blocks were performed by trainees. The rapid onset of the blocks in our study may be attributed to the local anesthetic solution used, as well as the total injected volume and an adequately positioned needle tip in order to get a pattern of distribution which entirely and rapidly envelops the artery. Topographic anatomy of the nerves around the artery and distances separating radial, ulnar and musculocutaneous nerves of the axillary artery can also be considered to have

an influence on the onset and the success rate¹⁵. We presume that nerves closer to the injection site are those which are blocked first. In contrast with other studies^{5,6}, no vascular puncture was noted in our study, showing that type of complication is not as common as it was described. Site et al¹⁶.

have shown that the incidence of unintended vascular puncture in a large series of US guided nerve blocks of all sorts is 0.6 per 1000. Even if our study was not powered to detect such complication, PV technique could be considered as safe, using a 22 gauge neurostimulation needle. On the other hand, being blinded to nerves and taking into account only vessels had increased the risk of paresthesia and numbness. These postoperative neurological symptoms (PONS) could be considered as minor as they lasted less than 24 hours and was not associated with neurologic deficit.

Our study carried out some limitations. Originally our trial was designed to assess the block onset in a 5 minutes interval. As onset of sensory block achieved the maximal possible score of 8 points before the first assessment point, we were unable to detect the onset time of each nerve independently, which is likely to be inferior to 5 minutes. Over all, we designed this study as a superiority trial to detect 28% absolute difference in

the performance time between the two groups and was not powered to detect potentially procedure failure or to assess complications, and as such the data provided in our study are only informative. Retrospectively, we could have designed our study as a non-inferiority trial and conducted a joint hypothesis testing including superiority in performance time and non inferiority for success and complication rate. Our performance time included imaging time and needling time which was not separately recorded as we supposed that imaging time will not differ between groups, so the difference in performance time will be held by the difference in needling time. Even if this time does not include skin and probe preparation, maybe it is more interesting to determine time for each step.

Conclusion

Double and triple injection ultrasound-guided PV axillary brachial plexus block result in comparable success rate. Because it reduces total anesthesia-related time and it requires fewer needle passes, the double-injection technique is a simple alternative for US-guided axillary brachial plexus block easy to learn and perform especially for regional anesthesia trainees.

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