Comparative Study of The Effects of Three Different Volumes and Concentrations of Levobupivacaine on The Block Characteristics in Upper Limb Surgeries Using Ultrasound-Guided Supraclavicular Block

Aruna Manaswini Murugesan[1*], Anand Subramaniam[2]

[1]Senior Resident, Department of Anaesthesiology, Jawarhalal Institute of Postgraduate Medical Education and Research, Jipmer campus Rd, Dhanvantari Nagar, Puducherry, India, [2] Professor, Department of Anaesthesiology, Cheittinad Hospital and Research Institute, Chettinad Health City, Kelambakkam, Tamil Nadu, India

Backgrounds and objectives: This an attempt to compare the effects of 15ml of levobupivacaine 0.75%, 20 ml of levobupivacaine 0.375% and 30ml of levobupivacaine 0.25% with fixed dosage (75mg) on block characteristics in upper limb surgeries using ultrasound guided supraclavicular block.

Materials and methods: Titled "Comparative study of the effects of three different volumes and concentrations of Levobupivacaine on the block characteristics in upper limb surgeries using ultrasound guided supraclavicular block" performed in Department of Anaesthesiology, Chettinad Hospital and Research Institute from March 2020 to April 2021.
Group A – 15mL of Levobupivacaine 0.5% , Group B – 20mL of Levobupivacaine 0.375%
Group C – 30mL of Levobupivacaine 0.25%

Results: Onset of Sensory block:
This study observed that mean onset of sensory block was earlier in 15mL was 22±5.25 minutes in comparison 20mL was 29±6.42 minutes and 30mL 37.5±6.17 minutes which is significant. Onset of Motor block: It was observed that mean onset of motor block was earlier in 15mL was 33±6.57 minutes when compared to 20mL was 36±6.87 minutes and 30mL 44±7.67 minutes which is significant. Duration of Analgesia: This study observed the mean Duration of analgesia was longer in 15mL 19.25±2.52 hours when compared to 20mL and 30mL Group having 15.5±1.88 hours and 12±1.94 hours respectively, which is significant.
Diaphragmatic involvement: This study observed that the mean diaphragmatic involvement was longer in 15mL 25.6±13.291% when compared to 20 mL and 30mL having 33.76±9.76% and 52.435±12.6% respectively, which is significant.

Conclusion:15mL Levobupivacaine of 75mg has an early onset of Sensory and Motor blockade and Prolonged Duration of Analgesia and lesser diaphragmatic involvement compared to 20mL and 30mL.

Key words: levobupivacaine, upper limb surgeries, ultrasound guided supraclavicular block

*Correspondence: Aruna Manaswini Murugesan

Email: arunamanaswini1@gmail.com

https://orcid.org/0000-0002-1738-0228

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Introduction

Peripheral nerve block has evolved as the most commonly preferred technique for upper limb surgeries over the past few decades. The important prerequisite for the regional anaesthesia is its success rate and safety.[1] These dual benefits have been provided since the introduction of ultrasound in the modern practice of regional anaesthesia. Ultrasound helps in shortening block performance time, reduces the

number of needle insertions and shortens the block onset time.[2]

Though it provides a greater advantage over general anaesthesia, it is not devoid of its own complications. One such complication being the hemi diaphragmatic paresis due to the involvement of the phrenic nerve. Supraclavicular block has 50 – 67% incidence of hemidiaphragms paresis.[3] It is higher when performed at the level of Interscalene (100%),[4] and decreases as it moves caudally away from the plexus. This involvement of the diaphragm could possibly be due to the rostral spread of the local anaesthetics to C3, C4 and C5 roots of the cervical plexus when given in larger volume or its spread directly to the phrenic nerve.[5] Though hemi diaphragmatic paresis is not the highest among the supraclavicular block it can still be a threat which reduces its usage in patients with limited pulmonary reserve.

We hypothesised that usage of lesser volume and higher concentration of local anaesthetic which can provide earlier onset of sensory and motor blockade with longer duration of action, and also lessen the incidence of hemi diaphragmatic paresis compared to volumes commonly recommended.

This study is an attempt to compare the effects of 15ml of levobupivacaine 0.75%, 20 ml of levobupivacaine 0.375% and 30ml of levobupivacaine 0.25% with fixed dosage (75mg) on onset of sensory blockade, onset of motor blockade, duration of analgesia and involvement of the diaphragm followed by ultrasound guided supraclavicular block for upper limb surgeries.

Methodology

After obtaining approval from our Institutional Human Ethical Committee (reference - IHEC No.: 633 / IHEC / 12 - 19), Clinical Trial Registration (CTRI/2021/07/035024) and informed and written consent 75 patients undergoing Upper limb surgeries were included as per the criteria [Table 1] in this prospective, randomized double blinded study.

Patients were randomized using a computer-generated randomization sequence and using sealed, opaque envelopes to three groups. They received Levobupivacaine (75mg)
Group A (n=25) – 15 mL – 0.75%, Group B – (n = 25) – 20 mL – 0.325% and Group C – (n = 25) – 30 mL – 0.25% under ultrasound guided supraclavicular block.

Table 1*: Inclusion and Exclusion Criteria*

INCLUSION CRITERIA	1. American Society of Anaesthesiologists (ASA) Grade – I, Grade –II and Grade III of status physical. 2. Age between 18 - 60 years
EXCLUSION CRITERIA	1. Severe Bronchopulmonary disease 2. Neurologic or neuromuscular disease 3. Disorders relating to coagulation 4. Infection occurring at the site of injection 5. Any prevailing allergy to the drug used 6. Body mass index more than 30kg/m^2

The patient will be made to lie supine. Using low frequency ultrasound transducer (Esaote MyLab 25 Gold) The diaphragm was visualized in B-mode, and it was viewed as a single thick echogenic line using M-mode. The movement of the diaphragm from the resting position to the deep inspiratory position was measured using the freeze frame just prior to the supraclavicular block being administered. It was considered as the baseline diaphragmatic excursion.Patient was positioned with the head turned to the opposite side, the skin was disinfected, and the field was draped with a sterile cloth. A high frequency liner ultrasound transducer was placed in the supraclavicular fossa to visualize the subclavian artery, the first rib, pleura and brachial plexus. Local anaesthetic (LA) was administered into the corner pocket and into the plexus equally. The exact time of administering the drug was recorded.

The time gap between the complete administration of the anaesthetic infiltration and complete disappearance of cold temperature perception in the dermatomes supplied by the plexus was termed as the onset of the sensory blockade.

The time gap between the complete administration of the drug infiltration and the complete disappearance of the motor activity was termed as time of onset of the motor blockade. It was assessed by the motor activity of the forearm muscles.

If the patient complained of pain in any area after the block it was considered as patchy analgesia. If supplemented with LA or if administered with General Anaesthesia or IV sedation, it was considered as block failure. Both patchy analgesia and block failure were excluded from this study.

The time gap from the complete infiltration of anaesthetic agent to the administration of analgesic for the first time after request by the patient in the postoperative period was defined as the duration of the action.[11]

After 10 minutes of the administration of the block, the diaphragmatic movement was measured. It was considered as the Post block diaphragmatic excursion.

Diaphragmatic Movement Reduction (DMR) is the difference in percentage of change in the amplitude of the diaphragmatic movement both before and after administration of the block. Complete paresis is when the DMR is higher than 75% or paradoxical movement. Partial paresis is when the DMR ranges from 25 – 75%. No paresis is when the DMR is lower than 25%. Diaphragm movement was calculated in centimetres. [6,10]

Statistical analysis

Data was entered using Microsoft Excel and statistical analysis was done using SPSS version 20. Sample size was estimated using the software G*Power 3.0.10. The median and range of onset of sensory blockade was converted into mean and standard deviation (SD) for all the groups using the online tool Vasser stats.
Median (range) of 0.75 group 5 (5-20) converted to mean (SD) 8.75 (4.36)
Median (range) of 0.5 group 10 (5-20) converted to mean (SD) 11.25 (4.34)
Median (range) of 0.25 group 20 (5-30) converted to mean (SD) 18.75 (6.2)
Using the mean and SD of three groups, effect size F was calculated to be 0.864. using these effect size F, alpha error of 0.05 and power 80%, the minimum sample size was estimated to be 75 (25 in each group). Sample size was calculated assuming the mean for the onset of sensory blockade such as, 5 (5-20) minutes - 0.75 %, 10 (5-20) minutes – 0.5%,20 (5-30) minutes, 0.25 % groups respectively as per study by Wenwen Zhai et al [7]. The other details needed for the calculation of the sample size were α error of 5% and 80% study power. To check the normality of all the continuous variables the test used was Shapiro Wilk test. Variables with p value more than 0.05 was considered to be normally distributed. A p value less than 0.05 was considered statistically significant.

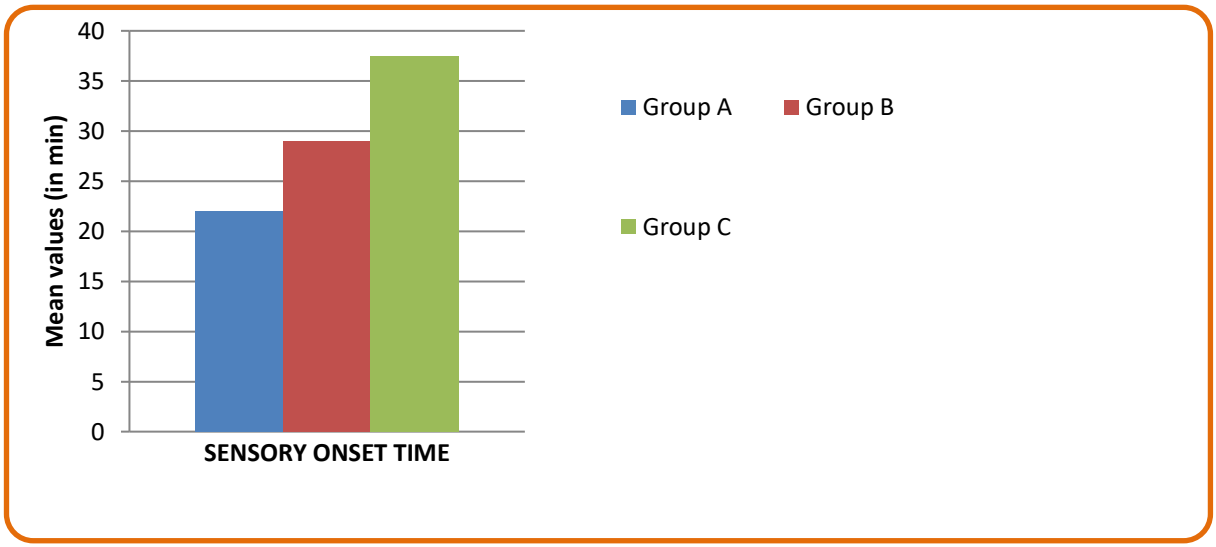
Results

This prospective, randomized, double blind trial compared the clinical effects of 3 combinations of volumes and concentrations of Levobupivacaine (15mL of 0.75%, 20mL of 0.325% and 30mL of 0.25%) whose dosage is equal at 75mg in the ultrasound guided supraclavicular block.

Table 2: *Onset of Sensory blockade, Onset of Motor Blockade, Duration of Analgesia and Diaphragmatic Movement Reduction (DMR) values*

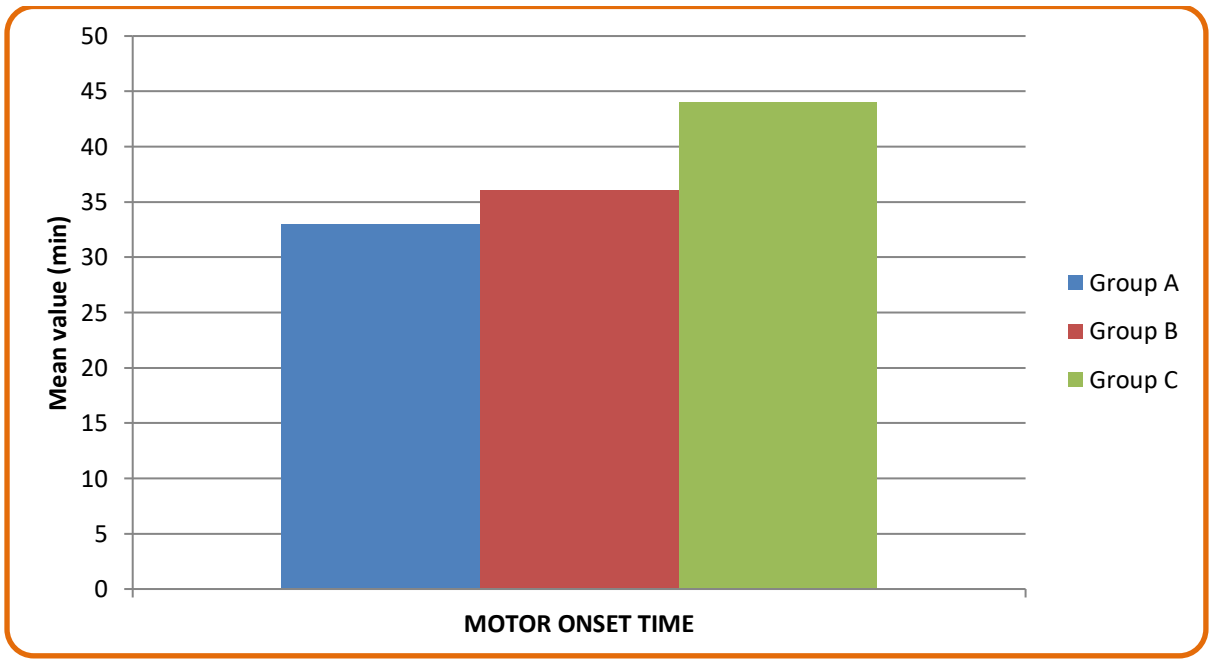
STUDY VARIABLE		*GROUP A*	*GROUP B*	*GROUP C*	*p VALUE*
SENSORY (in mins)	*Mean Onset*	22±5.25	29±6.42	37.5±6.17	0.0001
	Interquantile range	19 – 27.5	27 – 31	33 – 44	
MOTOR (in mins)	*Mean Onset*	33±6.57	36±6.87	44±7.67	0.0001
	Interquantile range	28 – 37.5	32 – 39	40 – 51	
DURATION OF ANALGESIA (in hours)	*Mean*	19.25±2.52	15.5±1.88	12±1.94	0.0001
	Interquantile range	17.5 – 27.5	14 – 17	10.5 – 13.5	
DIAPHRAGMATIC MOVEMENT EXCURSION	*Mean DMR (%)*	25.61±13.29	33.76±9.76	52.435±12.6	0.0001
	Interquantile range (%)	22.035 – 38.275	29.25 – 43.28	47.65 - 66.93	

Figure 1: *Onset of Sensory Blockade in 3 groups*



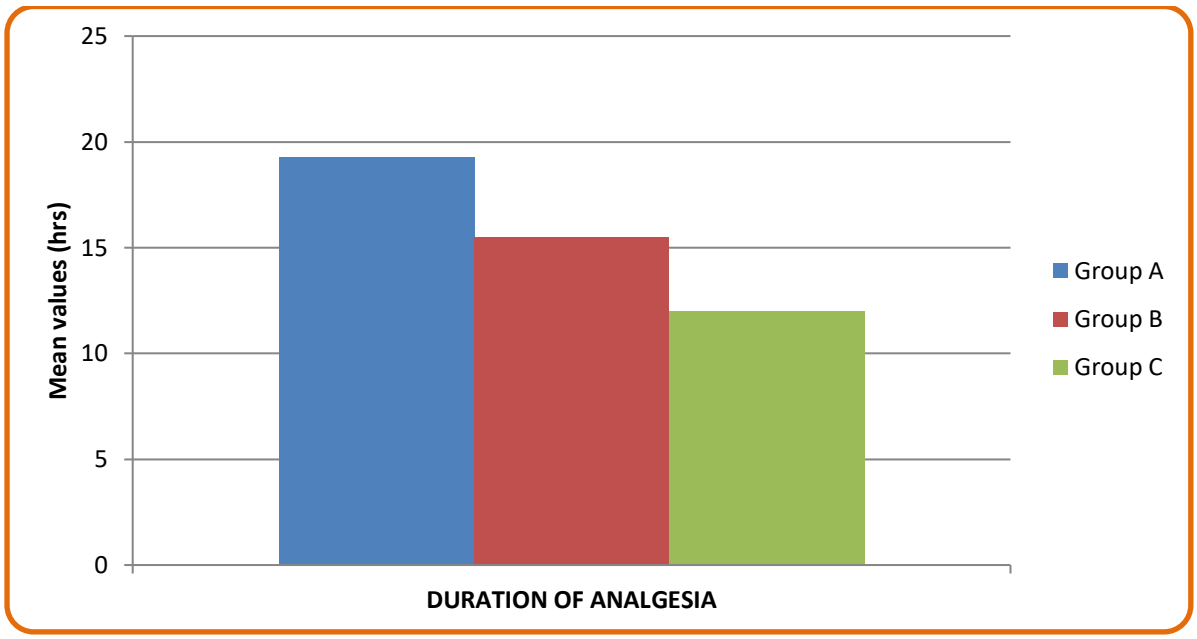
[Table 2] and [Figure 1], Sensory blockade onset time was sooner in Group A when compared to other groups (p value of 0.0001).

Figure 2: *Onset of Motor Blockade in 3 groups*



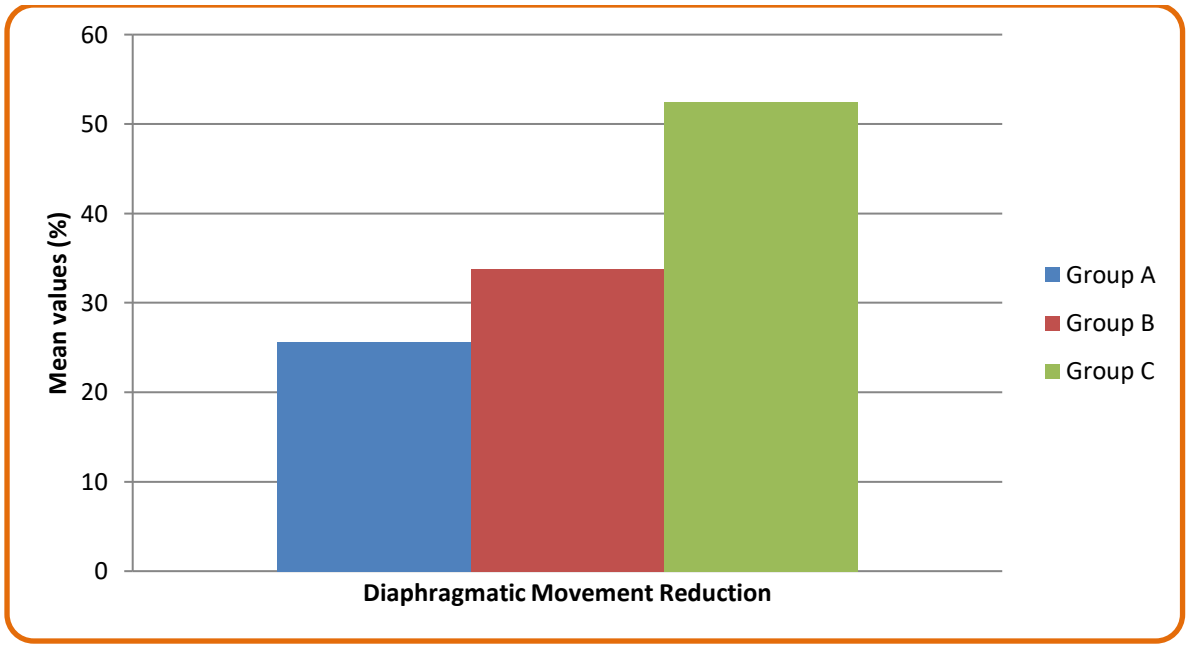
[Table 2] and [Figure 2], Motor blockade onset time was sooner in Group A when compared to other groups. (p value 0.0001)

Figure 3: Duration of analgesia in 3 groups



[Table 2] and [Figure 3], Duration of analgesia was prolonged in Group A when compared with Group B and Group C. (p value 0.0001)

Figure 4: Diaphragmatic movement reduction in 3 groups



[Table 2] and [Figure 4], Diaphragmatic movement reduction was lesser in Group A when compared with Group B and Group C. (p value 0.0001).

Discussion:

Ultrasound guided nerve block has an advantage of visualizing the plexus, needle and the administration of the drug. This allows reduction in local anaesthetic volume usage by administering it in to the nerve pocket and encircling the plexus. The reduction of the drug volume aids in reduction of the complications associated with higher volumes.

Zhai, Wang et al [7] (2016) compared Ropivacaine 0.75% (6.7mL), Ropivacaine 0.5% (10mL) and Ropivacaine 0.25% (20mL) in interscalene brachial plexus block with 99 participants. They exhibited a quicker initiation of complete sensory and motor block in the patients who were administered with the lesser volume (6.7mL) and higher concentration (0.75%) [$p < 0.05$]. In the same local anaesthetic dosage, hemidiaphragmatic paresis occurred in 58-70 % of patients, with no statistical difference [p=0.54].

Schoenmakers, Wegener and Stienstra,[1] (2012) compared 15mL and 40mL of mepivacaine 1.5% this resulted in the period to require pain medication for relief of pain after surgery was notably shorter in 15mL compared to 40mL population (p value lesser than 0.05).

Ultrasound provides an easier mode of visualizing the diaphragm which is precise and cost effective.

Lee et al,[8] (2018) carried out a study with 60 participants equally divided into two groups. Each received 5mL and 10mL of 0.75% Ropivacaine to identify if ISBPB using ultrasound was enough to produce adequate analgesia for shoulder surgery – arthroscopy. The period of pain relief was no different in both. They showed that both groups had similar efficacy but the incidence of diaphragm involvement was lesser in the 5ml group compared to the 10ml. group

Oliver et al,[9] 2021 performed a study with forty – eight participants who were undergoing shoulder arthroscopy, which was expected to be very painful post procedure. They were divided into two groups of 20 mL and 10 mL of Levobupivacaine 0.25% each who would undergo ISBPB. It was identified that the lower volume of the drug showed lesser diaphragm involvement with superior block characteristics.

Hence, higher the volume there is a higher incidence of diaphragmatic involvement. This involvement of diaphragm acts as a threat to the patients with pre-existing compromised pulmonary reserve. Although other studies have used pulmonary function tests to quantify the reduction in diaphragm movement in our study we have used ultrasound to elicit the involvement of the diaphragm.

One limitation of our study is that the participants who had patchy analgesia and failed blocks were excluded from the study. Rather, it should have been studied so as to estimate the success rate. Even with the 15mL volume, the diaphragmatic involvement was 25.61%. Therefore, further studies are needed to evaluate the minimum effective volume of local anaesthetic to SCB which provides earlier onset of blockade, adequate analgesia with no incidence of hemidiaphragmatic paresis.

Conclusion

Based on the current study undertaken by us, it shows there is involvement of phrenic nerve even with lesser volume in ultrasound guided supraclavicular block. It shows the onset of the blockade and duration of analgesia are concentration dependent and involvement of diaphragm is volume dependent. Overall, the onset of sensory and motor blockade was earlier, duration of analgesia was longer and incidence of diaphragmatic involvement is lesser when higher concentrations (0.75%) with lesser volumes(15mL) of local anaesthetic are used.

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