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Original Research Article

COMPARISON AND EVALUATION OF PERFUSION INDEX WITH TWO VOLUMES OF 0.75% ROPIVACAINE WITH 4MILLIGRAMS OF DEXAMETHASONE IN SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK FOR UPPER LIMB SURGERIES UNDER ULTRASOUND GUIDANCE: A RANDOMISED CLINICAL STUDY

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Abstract

Background: The Perfusion index (PI) is an objective tool used to assess successful nerve block. The blockade of sympathetic fibres after successful regional anaesthesia results in increased local blood flow and vasodilation, eventually increasing PI. The aim is to assess, compare and evaluate the Perfusion index of the limb before and after achieving complete motor block with 15ml and 20ml of 0.75% Ropivacaine with 4mg Dexamethasone in ultrasound guided supraclavicular brachial plexus block for upper limb surgeries. **Materials and Methods:** A randomized, single blinded study was conducted in Dept. of Anaesthesiology of BGS Global Institute of Medical Sciences from August 2022 to April 2023. Eighty ASA (American Society of Anaesthesiologists) I or II patients of either sex undergoing upper limb surgeries under US-guided Supraclavicular brachial plexus block were included. Patients were randomly divided into group I (n=40) administered with 15ml 0.75% Ropivacaine + 4mg Dexamethasone and group II (n=40) with 20 ml 0.75% Ropivacaine + 4 mg Dexamethasone. Perfusion Index (PI) was recorded at baseline (before block), at every 2 minutes till 10 minutes and then every 5minutes till 30 minutes after the block. PI ratio was calculated as the ratio between PI at 10minutes and baseline PI. The duration of analgesia and adverse effects if any were noted. Statistical analysis was performed using SPSS v21. Student's t test and Chi square test was performed where deemed necessary. **Result:** The mean age, sex ratio and BMI were comparable in both the groups. The mean Perfusion index at 0 minutes in Group I was 1.72 ± 0.58, in Group II was 1.59 ± 0.58, and at 10 minutes after procedure in Group I and II were 6.29 ± 0.67 and 7.17 ± 0.64, respectively. Mean Perfusion ratio in Group I and II was 4.17±1.54 and 5.21±2.16 respectively. The duration of analgesia was 8.48±0.88hours and 10±1.2hours in group I and II, respectively ($P < 0.001$). No adverse effects noted. **Conclusion:** Perfusion index can be used as a reliable tool to assess the success of supraclavicular brachial plexus block with a volume as low as 15ml of 0.75% Ropivacaine with 4mg Dexamethasone for upper limb surgeries. However, there was 15% decrease in analgesic duration when the volume of Local Anaesthetic drug was reduced from 20ml to 15ml.

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INTRODUCTION

Peripheral nerve blockade is a well-accepted concept for comprehensive anaesthetic care. From the operative suite, the role of peripheral nerve blockade is expanded for management of postoperative pain and chronic pain.[1] Peripheral nerve block administered with higher volume of local anaesthetics helps to prolong the length of analgesia, however, may also increase the risk of occurrence of local anaesthetic's systemic toxicity. The advent of ultrasonography in the field of regional anaesthesia aides in accurate placement of the drug in the perineural sheath by real-time visualization of the nerves, thus enabling lower volume of the drug to be administered.[2]

Ropivacaine is a long-acting local anaesthetic agent, that acts by preventing the influx of sodium, and blocking Brachial plexus block is a useful substitute for general anaesthesia for upper limb surgeries. It not only helps in avoiding the untoward effects of general anaesthetic drugs and upper airway instrumentation,[3] it also aides in achieving ideal operating conditions by producing complete muscular relaxation, maintaining stable intraoperative hemodynamics, and associated sympathetic block. The sympathetic block decreases postoperative pain, vasospasm and oedema.[4] Certain complications such as pneumothorax, accidental intravascular injection of the local anaesthetic drug, phrenic nerve injury presenting as elevated diaphragm,[5] Horner's syndrome, and neuropathy could be avoided with the advent of ultrasound and administration of lower volume of the local anaesthetic drug.[6] Sensory and motor function are typically used to evaluate the effectiveness of peripheral nerve blocks. Nevertheless, this method is subjective, time-consuming, needs patient's cooperation. Assessment of these parameters become futile in patients who are unconscious or those who are unable to provide input due to general anaesthesia, deep sedation, dementia or other conditions.[7]

A pulse oximeter perfusion index (PI) is a new simple, indirect and non-invasive measure of peripheral perfusion and used for assessment of the success of central neuraxial and peripheral nerve blocks.[8] It can be expressed as a percentage or an absolute value and is derived by dividing the ratio of arterial blood flow (pulsatile) to the venous, capillary, and tissue blood flow (non-pulsatile blood flow). It is employed to examine the dynamics of peripheral perfusion imposed by changes in vascular tone in the peripheral vessels. PI can precisely indicate the effectiveness of regional anaesthesia induced sympathetic block causing vasodilatation and increased blood flow.[9] Hence it can be used as an independent parameter to assess the success of the block. The present study aimed to assess whether smaller volumes were as sufficient as higher volumes of 0.75% Ropivacaine (15ml versus 20ml) with 4 milligrams dexamethasone for successful SCBPB under ultrasound guidance using PI as the parameter.

MATERIALS AND METHODS

A single blinded randomised clinical study was conducted in BGS Global institute of medical sciences, Bengaluru for a period of 9 months from August 2022 to April 2023. The study protocol was approved by Institutional Review Board/Ethical Committee (BGSGlMS/ ll C/App/Feh/2022/0 12-IEC) and registered under Clinical Trails Registry-India. (CTRI/2022/07/044159 [Registered on: 20/07/2022]). Written Informed Consent was obtained from all the patients.

Inclusion Criteria

80 Patients of the age group 20-40years, of either sex, with body mass index (BMI) between 18-30kg/m2 belonging to ASA physical status I and II, undergoing elective upper limb surgeries.

Exclusion Criteria

32 Patients with peripheral neuropathy, coagulopathy, local site infection, hypersensitivity to the study drug, respiratory insufficiency, pregnant lady and lactating mothers were excluded from study.

Sample Size Calculation

For seed outcome variable on incidence of success rate derived from previous literature [1] for a comparative two group clinical study with minimum success rate of 15.0%, 90% statistical power and 5% level of significance, the sample size 80 (40 in each group) is adequate. The sample size was estimated using the formula:

$$N = \frac{Z\alpha/2\sqrt{2p\,(1-p)} + Z1-\beta\, p1\sqrt{(1-p1)p2\,(1-p2)}}{(p1-p2)^2}$$

Where p1 and p2 are the proportion of event of interest (outcome) for group I and group II, and p is $p=\frac{(p1-p2)^2}{2}$, $Z_{\alpha/2}$ is normal deviate at 1-β power with β% of type 2 error, normally type 2 error is considered 20% or less.

Method of Randomisation: Computer generated randomisation.

Procedure

After obtaining ethical committee approval, written and informed consent from 80 ASA I and II patients belonging to the age group of 20-40 years undertaking upper limb surgeries were included in this study. They were randomly divided in to two groups by computer randomization of 40 each 10.

The patients alone were blinded to the volume of drug used. All patients were kept fasting for 8 hours. Tab Alprazolam 0.25mg was given night before the day of the surgery. Inj. Pantoprazole 40mg and Inj. Ondansetron 4mg intravenously was given on the day of the surgery preoperatively. On arrival to the operating room, intravenous access was secured. Non-Invasive Blood Pressure, Pulse oximetry and electrocardiogram was connected. The baseline Systolic and Diastolic blood pressures, Heart Rate and Oxygen Saturation was recorded. A scout scan was performed using linear high frequency probe (12

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MHz- ANO36 Portable Ultrasound) over the supraclavicular area to rule out anatomical abnormalities including aberrant vasculature. Under aseptic precautions, an anaesthesiologist who was experienced in performing US-guided supraclavicular brachial plexus block performed the procedure using high frequency (12 MHz) linear probe through in-plane approach with an echogenic needle. The corner pocket between the brachial plexus and subclavian artery was targeted for needle tip placement.

Group I- 15ml of 0.75% Ropivacaine + 4mg Dexamethasone 14

Group II- 20ml of 0.75% Ropivacaine + 4mg Dexamethasone 1

Half the drug was injected into the nerve plexus, other quarter portions into the cords on either side of the nerve plexus.

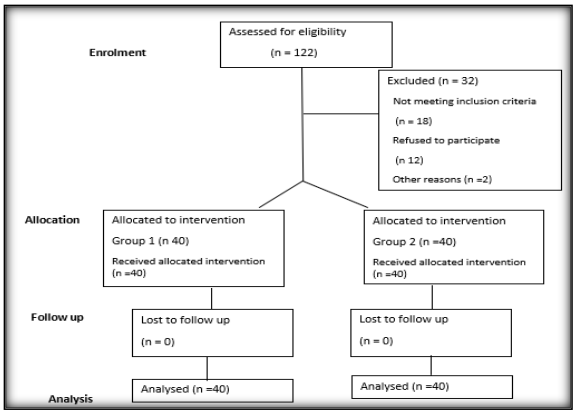

Figure 1: Consort Diagram for the Study

Outcomes: The primary outcome of the study was to assess the Perfusion index of the limb before and after achieving complete motor block. The secondary outcome was to assess the duration of analgesia / the time to post-operative rescue analgesic and to assess the safety profile of the drug and complications if any.

After the completion of SCBPB, PI was measured using Masimo radical-7 SET pulse oximeter applied on the middle finger of the ipsilateral arm. PI was recorded at baseline (before block) and 10 minutes following completion of SCBPB. PI ratio was calculated as the ratio between PI at 10 minutes and baseline PI.

The PI value is calculated from pulse oximetry data and is derived from the extent of absorption of red and infrared light. As a marker of peripheral perfusion, the PI is expressed as the ratio of the pulsatile component of light (i.e., the arterial compartment (AC)) to the non-pulsatile component of light (i.e., the direct current (DC) in other tissue) reaching the pulse oximetry sensor, and this value is independent of patient oxygen saturation.[11]

The PI can be expressed by the following formula: PI = (AC/DC) x 100%.[12]

Based on a study done in 2021 by Jatin Lal et al,[9] a PI of >3.03 is considered as an indicator of successful ultrasound-guided supraclavicular brachial plexus block.

The proposed surgery was carried out. Patient was monitored throughout the surgery and the PI and PI ratios in both the group were recorded and compared. Following successful completion of surgery, the patient was shifted out to post-operative anaesthesia care unit.

Statistical Analysis

All the data collected were compiled and entered into Microsoft excel worksheet. Descriptive statistics like mean, median, mode, standard deviation, Interquartile range, proportions were calculated. The data was analysed using statistical software (SPSS version 20.0 or 22.0). Students T test and Chi square test was used where deemed necessary.

RESULTS

In Group I mean age was 32.25±9.33 years, in Group II mean age was 28.33±11.88 years. The mean age in the two groups were comparable (p=0.270) [Table 1] The total number of male patients in both the groups were 28, while the female patients were 12 in each group. The sex ratio of the two groups was comparable (p= 0.806). [Table 1] In Group I mean BMI was 24.14±2.93 Kg/m², in Group II mean BMI was 24.10±3.44 Kg/m². The mean BMI of the two groups were comparable (p=0.964). [Table 1]

The mean PI at 0minutes (prior to procedure) in Group I was 1.72±0.58, and in Group II was 1.59±0.58. The mean PI at 0 minutes of the two groups were comparable (p=0.340). No significant difference in mean PI at 0minutes between the two groups was noted. The mean PI achieved at 10miuntes after procedure in Group I and II were 6.29±0.67 and 7.17±0.64, respectively, and the difference was statistically significant (p<0.001). [Table 2]

Perfusion Ratio is calculated by dividing PI at 10minutes by the baseline PI (0 minutes). Mean Perfusion ratio in Group I and II are 4.17±1.54 and 5.21±2.16 respectively, and the difference is statistically significant (p=0.016). [Table 2]

A PI ratio of <3.03 is noted in 25% patients in Group I and 7.5% in Group II, while a PI ratio of >3.03 is noted in 75% in Group I and 92.5% patients of Group II. [Table 3]

The mean duration of analgesia achieved in group I and II was 8.48±0.88 hours and 10±1.2hours, respectively, and the difference was statistically significant (p<0.001). There was a 15% decrease in the duration of analgesia with a decrease in volume of 0.75% ropivacaine from 20 ml to 15 ml. [Table 4]

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Table 1: Demographic Data

Demographics	Variables	GROUP I	GROUP II	Total
Age groups	<20	0 (0%)	0 (0%)	0 (0%)
	20-30	11 (27.5%)	21 (52.5%)	32 (40%)
	>30	29 (72.5%)	19 (47.5%)	48 (60%)
Sex	Female	12 (30%)	12 (30%)	24 (30%)
	Male	28 (70%)	28 (70%)	56 (70%)
BMI	<18.5	0 (0%)	1 (2.5%)	1 (1.3%)
	18.5-24.9	25 (62.5%)	23 (57.5%)	48 (60%)
	25.0-29.9	15 (37.5%)	16 (40%)	31 (38.8%)
	>30.0	0 (0%)	0 (0%)	(0%)

Table 2: Perfusion Index and Perfusion Ratio

Variables	GROUP I	GROUP II	P Value
Perfusion index (0 minutes)	1.72±0.58	1.59±0.58	0.340
Perfusion index (10 minutes)	6.29±0.67	7.17±0.64	<0.001**
Perfusion Ratio	4.17±1.54	5.21±2.16	0.016*

Table 3: Perfusion Index (p<0.016* using Student's t test)

Perfusion Ratio	GROUP I	GROUP II	Total
<3.03	10(25%)	3(7.5%)	13(16.3%)
>3.03	30(75%)	37(92.5%)	67(83.8%)
Total	40(100%)	40(100%)	80(100%)
Mean ± SD	4.16±1.54	5.20±2.15	4.68±1.93

Table 4: Mean duration of analgesia (p<0.001 using student t test)**

Variables	GROUP I	GROUP II	P Value
Duration of Analgesia (hours)	8.48±0.88	10±1.2	<0.001**

No adverse effects noted with respect to the drug and the procedure during intra-operative and post-operative period in both the groups.

DISCUSSION

The PI is an objective tool used to assess successful nerve block. The blockade of sympathetic nerve fibres after successful nerve block results in increased local blood flow and vasodilation, eventually increasing the PI.[9] The PI measures the pulsatility of blood, and not a measure of blood flow.[10] Every vasoconstrictor stimulus or sympathetic nervous system activity lowers the PI because it lowers the height of the pulsatile portion of the curve. Contrarily, every vasodilator stimulation, parasympathetic nervous system activation, or sympathetic nervous system inhibition raises the PI because it increases the height of the pulsatile section of the curve. When regional anaesthesia is administered to patients, a sympathetic block occurs initially, then a sensory and motor block. Due to peripheral vasodilatation in the extremity brought on by sympathetic block, PI increases. Our study population comprised of individuals of either sex with 30% females and 70% males in both the groups (P=0.806) with an age group ranging from 20 to 40 years with the mean age in groups I and II were 32.25±9.33 years and 28.33±11.88 years respectively (P=0.270). Patients had a mean BMI of 24.14±2.93 Kg/m² in group I and 24.10±3.44 Kg/m² in group II respectively (P=0.964). There was no significant difference noted among the groups with respect to the age, gender and BMI of the patients.

Perfusion Index

The mean PI at 0minutes (prior to procedure) in Group I was 1.72 ± 0.58, in Group II was 1.59 ± 0.58. The mean PI at 0minutes of the two groups were comparable (P=0.340). No significant difference in mean PI at 0minutes between the two groups was noted. The mean PI achieved at 10miuntes after procedure in Group I and II were 6.29 ± 0.67 and 7.17 ± 0.64, respectively, and the difference was statistically significant (P<0.001). Perfusion Ratio is calculated by dividing PI at 10minutes by the baseline perfusion index (0 minutes). Mean Perfusion ratio in Group I and II are 4.17±1.54 and 5.21±2.16 respectively, and the difference is statistically significant (P=0.016). In the present study, a PI ratio of <3.03 is noted in 25% patients in Group I and 7.5% in Group II, while a PI ratio of >3.03 is noted in 75% in Group I and 92.5% patients of Group II.

In the study conducted by Lal J et al. which included 65 individuals who were having arm surgery under supraclavicular block, the baseline mean of PI was 1.19 ±0.7. After the block, mean PI continued to rise from the starting point and peaked at 10 minutes. When a block was successful, the median PI began to rise two minutes after the block and rose linearly until 10 minutes had passed; when a block was unsuccessful, the mean PI barely rose at all. The median PI ratio was 7.50 in this study. It was 8.3 in blocks that were successful and 1.28 in blocks that weren't. This difference between successful and unsuccessful blocks' PI ratios was statistically significant (P< 0.001). This study is comparable to study wherein the mean PI and PI ratio proved a successful block in both the groups and the difference was statistically significant 9. In a study conducted

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on 33 ASA I and II patients by Bozdag et al.[7] In 32 of 33 patients who underwent brachial plexus block, our block was successful, and perfusion index measurements in the applied limb increased continuously from the 5th min over the 20-min observation period. In one patient who failed the block and in the arm group without block, no statistically significant difference was detected in the 5^{th}, 10^{th}, and 20^{th} min perfusion index measurements. The findings of the present study are consistent with their study in terms of achieving adequate block with using PI as the primary parameter indicating the success of sympathetic blockade post administration of the local anaesthetic.

Duration of Analgesia

The mean duration of analgesia achieved in group I and II were 8.48 ± 0.88 hours, and 10 ± 1.2 hours, respectively. The difference was statistically significant ($P < 0.001$). There was a 15% decrease in the duration of analgesia with a decrease in volume of 0.75% ropivacaine from 20 ml to 15 ml. Mamta Chadha et al,[1] performed a study based on 40 patients undertaking upper extremity surgery. Each group of 20 participants received 20 ml and 35 ml 0.5% ropivacaine, respectively, in US-guided SCBPB. The duration of analgesia achieved in group 20 and 35 was 575.56 ± 104.39 and 730.75 ± 102.09 min, respectively, and the difference was statistically significant. The duration of analgesia was 21% lesser in the patients receiving 20 ml of 0.5% ropivacaine. Similarly, our study depicts that, 15ml of 0.75% Ropivacaine with 4mg Dexamethasone provided adequate duration of analgesia and comfort to the patient postoperatively. Sangwan Pushpender et al,[14] conducted a prospective clinical study on 29 patients to estimate the minimum effective Volume of 0.5% Ropivacaine in US-guided SCBPB. The study being started with 30ml of 0.5% Ropivacaine, using step-up/step-down technique, concluded that 15ml of LA provided adequate duration of analgesia of 7.6 ± 1.18 hours. The study also stated that the block duration did not differ between patients with successful blocks at 15ml and those who required >15 ml was 7.10 ± 0.74 and 7.95 ± 2.22 hours, respectively; $P = 0.25$). In the present study, adequate duration of analgesia was achieved but with a 15% reduction in duration of analgesia in Group I compared to Group II.

In the study conducted by Avci et al. 30 volunteer orthopaedics and traumatology patients with American Society of Anaesthesiologists (ASA) I-II, 18-70 years posted for hand, wrist, forearm, elbow and arm surgery, were included. In this prospective study; after ultrasound guided supraclavicular block with local anaesthetic solution that consisted of prilocaine 12.5 ml + bupivacaine 12.5 ml to all patients, sensory block was checked with pin-prick test every 3-minute, motor block was checked by using modified Bromage scale every 2-minute, hemodynamic parameters and PI values were recorded on 0^{th}, 5^{th}, 10^{th}, 15^{th}, 20^{th}, 25^{th}, 30^{th} minutes. When the measured perfusion index values were compared, the differences were significant. When the PI measurements were compared in pairs, the differences between basal and 5th min,10 min,15 min,20 min,25 min and 30 min were significant. Positivity time for pin-prick test was 8.83+-2.70 minutes, motor block onset time was 6.7+-2.89 minutes, total motor block onset time was 10.83+-3.07 minutes. In the 5th minute PI values, an average increase of 148% was observed compared to basal PI values. Hence, they concluded that supraclavicular block provided faster sensory-motor block than other upper extremity blocks. It was concluded that perfusion index was faster, more objective and simpler than traditional methods on assessment of block success, because of vasodilatation that occurred before sensory and motor block.[9]

Adverse Reactions

No adverse reactions or complications noted with regards to the procedure or drug during our study Peripheral nerve blocks work well for providing good analgesia as well as can be used as sole anaesthetic. These are currently the anaesthesiologists' go-to clinical tactics for avoiding the airway manipulation during the coronavirus pandemic for any procedures that can be done with regional anaesthesia.[15] A block failure is an unpleasant stress both for the patient and the anaesthesiologist. Early diagnosis of failed blocks enables the quicker use of rescue treatments like block augmentation or general anaesthesia. PI is described as a reliable, quick, and remote method for block evaluation.[9]

Limitations

PI value is subject to manufacturer's error of pulse oximeter as well as variations in operation room temperature.

CONCLUSION

Perfusion Index can be used as an independent, non-invasive parameter to assess the success of a peripheral nerve block. Ultrasound guided SCBPB for surgeries below the shoulder joint can be performed using 15ml of 0.75% Ropivacaine with 4mg Dexamethasone. PI is a quicker, more effective, reliable and objective approach for assessing the performance of US-guided SCBPBs than traditional methods.

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