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Comparison of Ropivacaine and Levobupivacaine in Supraclavicular Brachial Plexus Blocks-A Double Blinded Randomized Control Study

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Abstract

Background: Brachial plexus anaesthesia has been an indispensable tool in the anaesthesiologist's armamentarium. Clinical studies have shown that levobupivacaine and ropivacaine have fewer adverse effects on the cardiovascular and central nervous system making them more advantageous in regional anaesthesia techniques. Less information is available regarding their comparable clinical data. Only a few studies have compared levobupivacaine and ropivacaine for brachial plexus blocks; hence, this study was aimed to compare the analgesic effectiveness and nerve block characteristics of ropivacaine and levobupivacaine in supraclavicular brachial plexus blocks in upper limb surgeries.

Methods: Patients with American Society of Anaesthesiologists physical status I or II coming for elective upper limb surgeries were included in the study. Total numbers of 62 patients were randomly allocated into two groups, group A and group B. Group A received 25 mL of 0.75% ropivacaine, and group B received 25 mL of 0.5% levobupivacaine. The duration of analgesia, onset of block, duration of sensory, and motor blockade were studied and compared.

Results: The mean duration of analgesia in group ropivacaine was 8.33 hours and in group levobupivacaine was 10.23 hours which was statistically significant. Ropivacaine had a faster sensory onset compared to levobupivacaine (5.22 vs. 6.88 minutes). The duration of sensory and motor blockade was longer with levobupivacaine than ropivacaine (sensory—8.64 vs. 10.29 hours, motor—8.32 vs. 9.8 hours).

Conclusion: Levobupivacaine had longer duration of analgesia. The sensory and motor blockade was also longer with levobupivacaine.

Keywords: Supraclavicular block, analgesia, ropivacaine, levobupivacaine

Introduction

Peripheral nerve blocks are often considered to be one of the best choices for procedures limited to the extremities with relatively less complications when good technique and reasonable precautions are employed. They are advancing as a well-accepted component of comprehensive anaesthesia care, expanding outside the operating rooms for postoperative pain relief and control of chronic pain. The use of regional anaesthesia techniques has increased over the past decade, while patients who previously received a regional block often prefer regional anaesthesia for subsequent surgery.[1,2]

While administering peripheral nerve blocks, newer local anaesthetics like levobupivacaine and ropivacaine have fewer adverse effects on the cardiovascular and central nervous system when compared with bupivacaine making them more advantageous in regional anaesthesia techniques.[3–6] These drugs when used for upper or lower limb surgery may be effective in providing good nerve blockade characteristics, but little information is available regarding their analgesic effectiveness and comparable nerve block characteristics. Only a few studies have compared levobupivacaine and ropivacaine for brachial plexus blocks.[7–10] Hence, this study was aimed to compare the analgesic effectiveness as primary

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outcome and nerve block characteristics of ropivacaine and levobupivacaine as a secondary outcome which includes onset and duration of sensory and motor nerve block.

Methods

This study was performed at a tertiary care hospital after getting ethics committee approval from the Sri Ramachandra Institute of Higher Education and Research and obtaining an informed written consent from all the patients. Patients of American Society of Anesthesiologists (ASA) I or II physical status, aged between 16–65 years posted for elective upper limb surgeries, were included in the study. Patients allergic or sensitive to local anaesthetics, having infection at site of block, injury to nerves of upper limb, coagulation disorder, neurological or neuromuscular or psychiatric illness, patient refusal to consent, change of anaesthesia plan or conversion to general anaesthesia were excluded from the study.

Patients were allocated into two groups-group ropivacaine (group A) and group levobupivacaine (group B) by randomly allotted chit system. Randomisation was done by a single trained anaesthetist not involved in the study. Patients were allocated into their respective groups in the operation complex holding area.

Double blinding was done by drawing lots labelled group A and group B and documenting their hospital number on the lot assigned. The lots were retrospectively used to find out the group to which the patient was allocated. Clinician assessing the outcomes was blinded to the groups to which they were allocated. After securing an intravenous access—baseline heart rate, non-invasive blood pressure and oxygen saturation were monitored and recorded. All patients were premedicated with IV midazolam 0.03 mg kg^{-1}. Patients were positioned supine with face turned towards the contralateral shoulder, and a pillow was placed underneath the head to provide adequate space for the probe and needle manipulation for performing the block.

The supraclavicular fossa and the surrounding area were prepared under strict aseptic precautions. A high-frequency linear probe (Sonosite S-ICU, 13-6 MHz) was sited close to the angle formed at the junction of first rib and subclavian artery. The needle was introduced vertically at this specific landmark and a nerve stimulator with setting of a current of 2 mA and a frequency of 2 Hz was used. As the plexus was approached, movements of the wrist or fingers were identified and the current was gradually reduced to 0.5 mA. The end point taken was when hand twitches could be elicited at a current of 0.5 mA. According to the group, 5 mL of local anaesthesia drug was given after aspiration before every bolus to avoid intravascular injection. Group A received 25 mL of 0.75% ropivacaine, and group B received 25 mL of 0.5% levobupivacaine. Drugs were prepared by an anaesthesiologist who was not involved in the study.

The syringes with patient's name were given to the anaesthesiologist who was giving the block. Patient was monitored closely after completing the local anaesthesia injection. The onset of sensory and motor blockade and the duration were noted. Block was considered to have failed if sensory anaesthesia was not achieved in 30 minutes. Subsequently, general anaesthesia was given to these patients and was excluded from the study. Complications associated with brachial plexus blocks and local anaesthetics, such as pneumothorax, haematoma, nausea, vomiting, tinnitus, circumoral numbness, dizziness and seizures, were monitored for possible occurrence. Surgery was allowed to begin 30 minutes after successful block. End of performing the injection will be taken as time zero. Sensory blockade was checked by ice packs every minute till 10 minutes and every 5 minutes till 30 minutes and post-operatively.

Pain was assessed using visual analogue scale (VAS), graded from 0 to 10 which will be explained to the patient preoperatively. VAS 0 represents no pain and 10 represents worst pain. When VAS score was ≥ 4, IV tramadol 1 mg kg^{-1} was given as rescue analgesia. Onset of sensory blockade was defined as loss of cold sensation. Onset time is the time taken from the completion of drug injection to loss of sensation in any of the C5 to T1 dermatomes. Onset of motor blockade was defined as the time required from completion of drug injection to loss of motor power. Motor block at the shoulder was assessed by asking the patient to elevate the arm while keeping the elbow straight (superior trunk function) and at the hand was assessed by grip strength and thumb movement (middle and inferior trunk function).

Duration of sensory blockade was defined as the time between onset of sensory block and return of dull pain and VAS < 4. This was assessed every 30 minutes postoperatively in at least three major nerve distributions. Duration of motor blockade was defined as the time between onset of motor block and regained ability of the patient to move fingers. Total duration of analgesia was defined as the time between onset of action and onset of pain (VAS ≥ 4) and the time when patients received the first dose of rescue analgesic. For statistical analysis, complete failure and unsatisfactory block was considered as failures and was excluded from the study. Patients were monitored for any signs of cardiovascular or central nervous system toxicity (changes in BP, heart rate, rhythm, signs or symptoms of CNS stimulation), hypersensitivity reaction for the drug and any evidence of pneumothorax.

Statistical Analysis

A pilot study was done, which showed the difference in pain scores between ropivacaine group and levobupivacaine group as 1.5 hours. Assuming the standard deviation in levobupivacaine group as 2 and standard deviation in ropivacaine group as 1.5, for 5% α error and 90% power the

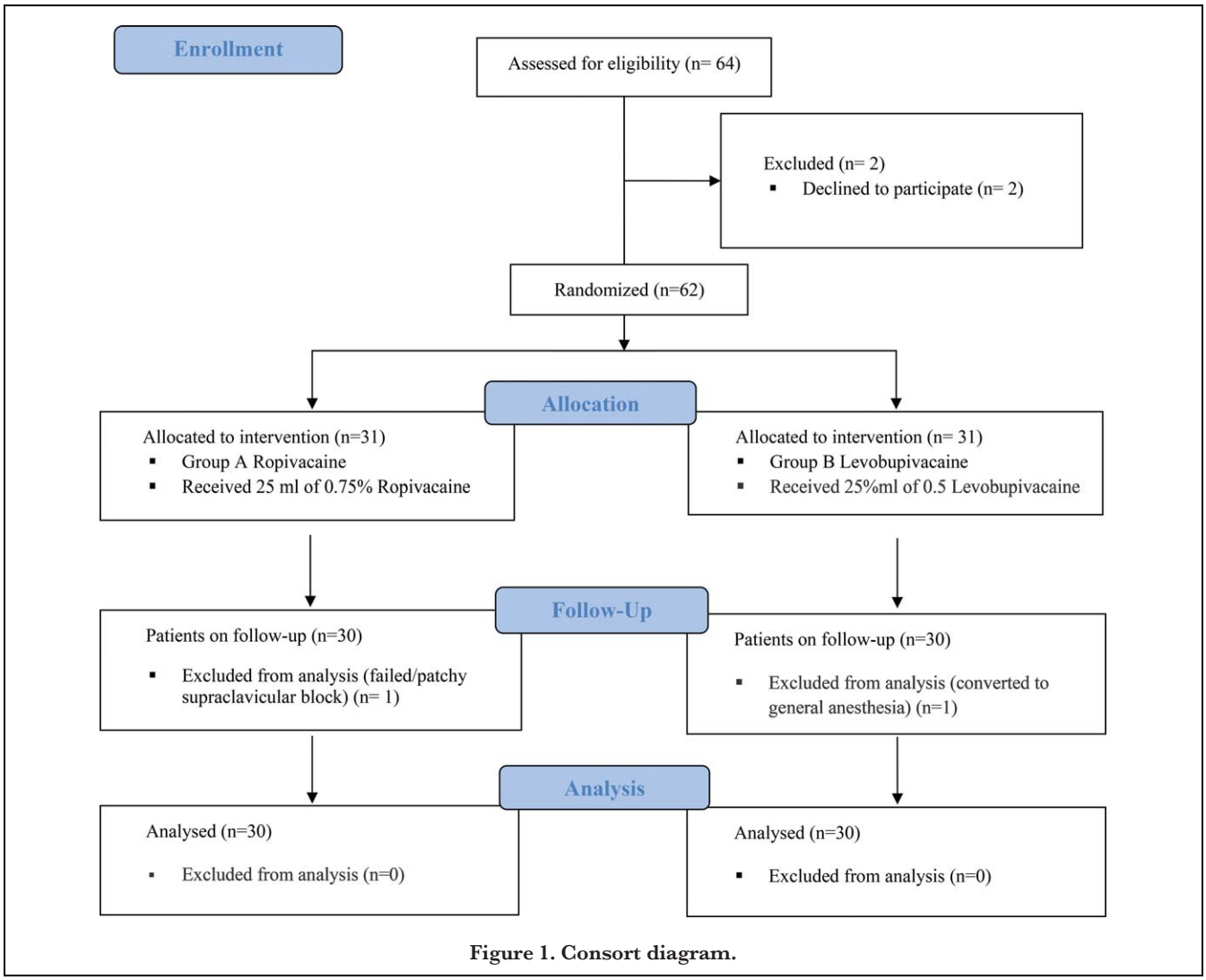

Figure 1. Consort diagram.

minimum sample size was arrived as 29 in each group. Hence, we planned to analyse 32 patients in each group.

Data was analysed using Statistical Package for the Social Sciences (SPSS) version 17.0 (IBM SPSS Corp., Armonk, NY, USA) software. Numerical variables were presented a mean with standard deviation, and categorical variables were presented as frequency (%). The difference between the two groups with regard to continuous variables was assessed by Student's t-test, and categorical variables were assessed by Chi-square test. For all the tests, $P \leq .05$ was considered statistically significant.

Results

A total number of 64 patients belonging to ASA physical status I and II were enrolled in this study. Four patients were excluded from the study (two patients refused to consent, one patient had patchy block, and one patient were converted into general anaesthesia). Hence, a total of 60 patients were analysed (Figure 1). The mean age in group A was 36 years and in group B was 35 years. In group A, 76.7% were males and 23.3% were females and in group B 66.7% were males and females constituted 33.3%. Other demographic and hemodynamic data were comparable and were not statistically significant (Table 1).

The duration of analgesia in group A was 8.33 hours and in group B was 10.23 hours. Duration of analgesia was longer in levobupivacaine group, and it was found to be statistically significant (Figure 2).

The mean duration for onset of sensory blockade was 5.22 minutes and 6.88 minutes for ropivacaine and levobupivacaine, respectively, with a P value of .0001. The mean duration of onset of motor blockade was 7.90 minutes in ropivacaine group and 8.94 minutes for levobupivacaine group. Both groups were comparable with respect to onset of motor blockade and were not statistically significant. The

Table 1. Demographic Parameters of Study Groups

Patient characteristics		Group A (N = 30) (mean ± SD)	Group B (N = 30) (mean ± SD)	*P*
Age distribution (years)		36.43 ± 14.86	35.47 ± 12.80	.78
Gender distribution (%)	Male	76.7	66.7	.39
	Female	23.3	33.3	
ASA class distribution (%)	ASA I	53.3	80	.075
	ASA II	46.6	20	
Base line HR (beats min^{-1})		84.57 ± 12.51	85.97 ± 9.85	.63
Base line systolic BP (mm Hg^{-1})		122.47 ± 14.88	126.77 ± 15.11	.058
Base line diastolic BP (mm Hg^{-1})		69.53 ± 10.47	73.83 ± 12.54	.069
Base line SpO_2 (%)		99 ± 0.9	99.2 ± 0.8	.38

N, number of patients; SD, standard deviation.
P was obtained with student's t-test.

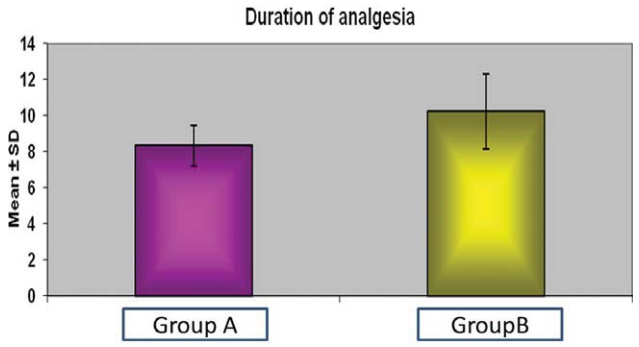

Figure 2. Duration of analgesia.

duration of sensory blockade in ropivacaine group was 8.64 hours and in levobupivacaine group was 10.29 hours. Levobupivacaine group had statistically significant longer duration of sensory blockade. The mean duration of motor blockade in group A was 8.323 hours and in group B was 9.837 hours. Duration of motor blockade was found to be longer in levobupivacaine group, and it was statistically significant (Table 2).

Two (3.3%) patients in ropivacaine group had vomiting while no adverse events were observed in levobupivacaine group (Figure 3).

Discussion

The present prospective randomized double blinded study compared 60 patients fulfilling the inclusion criteria. All patients tolerated the procedure well and remained comfortable. The blocks were given taking into account the maximum dose limit of toxicity which was 3 mg kg^{-1} for both the drugs. Previous studies were performed with higher doses and volume of local anaesthetics ranging from 30 to 40 mL.[9,10,11] With the effective use of ultrasound and nerve stimulator, we were able reduce the volume of local anaesthetics and thereby bringing down the drug related side effects without compromising on the quality of the block.

The duration of analgesia in this study was higher with levobupivacaine than ropivacaine. On reviewing the literature, we found few studies comparing ropivacaine and levobupivacaine for supraclavicular blocks; however, their results were varied.[8,12] In the study done by Watanabe et al.,[8] there was no significant difference in duration of analgesia between the two local anaesthetics. The study done by Mageswaran and Choy[9] also showed no differences in effectiveness of analgesia. The results with Cline et al.[10] were similar to our study which showed a longer analgesic effect with levobupivacaine. Brachial plexus blocks were performed in the above described studies by various approaches (interscalene/supraclavicular/axillary approach) with varied doses.

More randomized controlled trials with similar approaches and drug doses will throw more light in the present scenario. A pilot study done in our centre and the study by Mageswaran and Watanabe et al.[8] showed no major differences in postoperative analgesia with a concentration of 0.5%. Hence, we chose a higher concentration of ropivacaine 0.75% to test the duration of analgesic effectiveness. In our study, the mean onset of sensory block was faster with ropivacaine. This might be probably due to the higher concentration of ropivacaine and an ultrasound guided approach.

The onset time for motor block with ropivacaine and levobupivacaine in this study was not statistically significant. The duration of sensory blockade was more in levobupivacaine group than in the ropivacaine group. Similar results have

Table 2. Characteristics of Blockade and Duration of Aanalgesia Between Groups

	Group A (N = 30) (mean ± SD)	Group B (N = 30) (mean ± SD)	*P*
Onset of sensory blockade (minutes)	5.22 ± 1.2	6.88 ± 1.9	.001
Onset of motor blockade (minutes)	7.9 ± 1.6	8.9 ± 2.6	.75
Duration of sensory blockade (hours)	8.64 ± 1.3	10.29 ± 2.3	.001
Duration of motor blockade (hours)	8.32 ± 1.2	9.8 ± 2.03	.001
Duration of analgesia (hours)	8.33 ± 1.13	10.23 ± 2.0	.0001

N, number of patients; SD, standard deviation.
P was obtained with student's t-test.

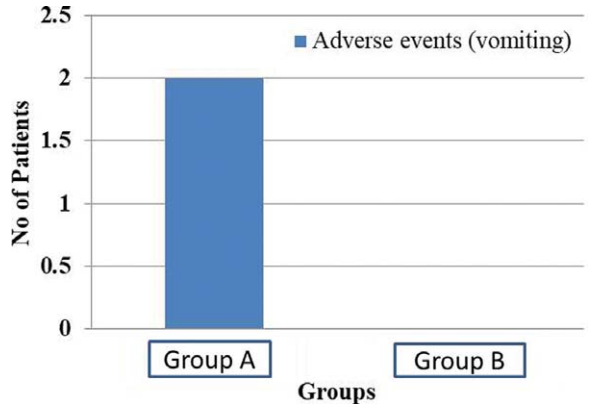

Figure 3. Comparison of adverse events.

been obtained by Cline et al.[10] As for levobupivacaine, the duration of motor blockade was shorter in comparison with the study done by Ilham et al.[13]

However, in comparison with the present study and study done by Biswas et al. the duration of motor block was longer in the levobupivacaine group probably because a targeted approach of ultrasound and nerve stimulator was used.[12] The duration of motor block in the study done by Cho et al. had similar results to the present study with a longer duration of motor block with levobupivacaine, although they used a different approach.[14]

The incidence of adverse effects was probably low in our study due to the decreased amount of local anaesthetic and the usage of ultrasound, nerve stimulator for guiding the deposition of the drug at the correct anatomical location.

The limitations of this study were the inclusion of only patients with ASA I and II physical status. The study of high risk patients to justify the safety of these drugs has to be carried out. The addition of adjuvants in the block along with the drugs of interest for prolongation and enhancing the analgesic effect could have been studied.

Conclusion

The duration of post-operative analgesia was better with levobupivacaine in elective upper limb surgeries.

Sensory and motor blockade was also longer in levobupivacaine without any major hemodynamic changes.

Ethics Committee Approval: Ethical committee approval was received from Sri Ramachandra Institute of Higher Education and Research, Chennai, India—2014 (No. CSP-MED/14/APR/14/101. dated 14/14/2014).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - D.T.; Design - K.G.S.; Supervision - R.B.K., M.V.; Resources - K.G.S.; Materials - R.K.K.V.; Data Collection and/or Processing - D.T.; Analysis and/or Interpretation - K.G.S.; Literature Search - D.T.; Writing Manuscript - K.G.S.; Critical Review - K.G.S.

Conflict of Interest: The authors have no conflicts of interest to declare.

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