e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2023; 15(4); 52-59

Original Research Article

A Randomised Controlled Trial to Compare the Efficacy of Levobupivacaine 0.5% and Ropivacaine 0.5% in USG Guided Supraclavicular Brachial Plexus Block for Upper Limb Orthopedic Surgery at Tertiary Care Centre

Pinal Vasani[1], Keta Patel[2], Hetal Sonawane[3], Jayendra C Makwana[4], Hina Shah[5], Shreya Popatiya[6]

[1]Consultant Anaesthetist, Ahmedabad
[2]Senior Resident, Department of Anaesthesia, GMERS Medical College Sola, Ahmedabad, Gujarat
[3]Assistant Professor, Department of Anaesthesia, GMERS Medical College Sola, Ahmedabad, Gujarat
[4]Associate Professor, Department of Anaesthesia, GMERS Medical College Sola, Ahmedabad, Gujarat
[5]Second Year Resident, Department of Anaesthesia, GMERS Medical College Sola, Ahmedabad, Gujarat
[6]First Year Resident, Department of Anaesthesia, GMERS Medical College Sola, Ahmedabad, Gujarat

Received: 20-01-2023 / Revised: 26-02-2022 / Accepted: 28-03-2023
Corresponding author: Dr Jayendra C Makwana
Conflict of interest: Nil

Abstract

Background and Aim: Clinical guidelines state that controlling postoperative pain requires long-term postoperative pain management. The best local anaesthetics are selected for peripheral nerve block. Levobupivacaine has been demonstrated to be safer, more effective, and more time-effective than ropivacaine for peripheral and neuraxial nerve blocks. The objective of the study was to compare the effects of 0.5% Ropivacaine and 0.5% Levobupivacaine in supraclavicular brachial plexus block in patients undergoing upper limb procedures.

Material and Methods: Present Prospective 1.5 year long randomise double blind comparison study was carried out in the Department of Anaesthesia, Tertiary Care Institute of India. The 70 patients were split into two groups of 35 each at random. 30 ml of intravenously administered 0.5% levobupivacaine were given to group L patients. Participants in group R got 30 ml of intravenous 0.5% ropivacaine. The length of the procedure, the length of post-operative analgesia based on the VAS score, and any side effects or issues were all monitored after the block was administered.

Results: The Onset Time of Sensory and Motor Inhibition in Group L Was Significantly Earlier Than in Group R. In contrast to Group R, which had analgesia for an average of 11.6 1.80 hours, Group L experienced analgesia for an average of 15.37 2.00 hours. The length of analgesia in Group L was substantially greater than in Group R.

Conclusion: Levobupivacaine 0.5% outperforms Ropivacaine 0.5% in terms of early commencement of sensory blockade, early beginning of motor blockade, extended duration of sensory blockade, and prolonged duration of motor blockade for supraclavicular brachial plexus block. Longer Period of Analgesia.

Keywords: Levobupivacaine, Ropivacaine, Supraclavicular Brachial Plexus Block, Upper Limb Orthopedic Surgery.

Introduction

A frequently used component of comprehensive anaesthesia care is regional blocks. Their duties now extend outside of the operating room and into the field of long-term and post-operative pain management. The expert placement of these blocks expands the anesthesiologist's options for offering the greatest anaesthetic care. [1,2]

Brachial plexus blocks are frequently used during upper limb surgery. Bupivacaine, a racemic combination of the two stereo enantiomers (dextrobupivacaine and levobupivacaine), is typically employed as the local anaesthetic for supraclavicular block because it has a longer duration of action and an adequate sensory-motor block profile. In reality, a small percentage of people have systemic adverse effects such cardiac toxicity while using the dextro-bupivacaine enantiomer of bupivacaine. This motivated researchers to create brand-new local anaesthetics that share all the advantages of bupivacaine without any of its drawbacks. [3,4]

Ropivacaine was one of the first local anaesthetics that had the potential to take the place of bupivacaine. The molecular structure of ropivacaine, an amino-amide local anaesthetic similar to bupivacaine, is similar. It is S-1-propyl-2, 6 pipecoloxylidide's senantiomer.[5]

Several studies contrasting the effects of ropivacaine and bupivacaine revealed that the former induced fewer negative CVS and CNS effects, less motor block, and an action that lasted roughly the same amount of time to suppress pain. Numerous clinicians shifted from utilising bupivacaine to ropivacaine for all sorts of neural blockades as a result of this useful clinical discovery. The latency of sensory analgesia for ropivacaine, however, was discovered via clinical use to be around two thirds that of bupivacaine, making it less effective for extending post-operative analgesia.[6-9]

Levobupivacaine, the S-enantiomer of bupivacaine, is the most recent local anaesthetic to be approved for clinical usage. The anaesthetic efficacy of bupivacaine's enantiomers, R-dextrobupivacaine and Slevobupivacaine, has been demonstrated in tests; however, the senantiomer demonstrated significantly fewer negative effects on the CNS and CVS than bupivacaine while still assuming a comparable duration of sensory blocking. Levobupivacaine has demonstrated to be more favourable than ropivacaine for neuraxial and peripheral nerve blocks in terms of safety and efficacy, as well as having a longer duration of analgesic effect.[10,11]

Levobupivacaine was widely accepted by medical professionals as the preferred local anaesthetic for neurological blockades, but there is still discussion about which substance—ropivacaine or levobupivacaine—is best for facilitating brachial plexus anaesthesia in the literature and in clinical settings. Several clinical trials assert that ropivacaine provides a sensory blockade similar to levobupivacaine, despite the fact that many doctors report varying findings in clinical practise. This argument is made more difficult by the lack of direct comparison studies comparing these 2 drugs in individuals receiving brachial plexus blocks. [9,11]

Clinical guidelines state that controlling postoperative pain requires long-term postoperative pain management. The best local anaesthetics are selected for peripheral nerve

block. Hence, using ultrasound guidance, we did this randomised prospective trial to examine the efficacy, duration, and quality of sensorimotor blocks as well as the postoperative analgesic effects of levobupivacaine and ropivacaine in patients having orthopaedic surgery procedures. [12,13] The objective of the study was to compare the effects of 0.5% Ropivacaine and 0.5% Levobupivacaine in supraclavicular brachial plexus block in patients undergoing upper limb procedures.

Material and Methods

Study Area: Department of Anesthesiology, GMERS Medical College and Civil Hospital.

Study population: All patients aged between 18 and 60 years as per inclusion criteria

Inclusion criteria:

- Patients posted for elective upper limb orthopedic surgeries.
- Age 18-60 years of either sex.
- ASA grade 1 & 2.
- With no known history of allergy, sensitivity or other form of reaction to local anesthetics of amide type.

Exclusion criteria:

- Patient's refusal
- Allergy to amide group of local anesthetic agent
- Contraindication to brachial plexus block
- Significant neurological disease in upper limb
- Inability to comply with study assessment
- Pregnancy & lactation

Study design: A Prospective Randomize double blind comparative study

Study duration: 1.5 years from July 2019 to January 2021.

We divided the 70 patients into two groups at random using a computer-generated randomization table and studied Grade 1 and Grade 2 patients according to the American Society of Anesthesiology (ASA) categorization. The research was interventional and prospective in design. All of the study participants gave a thorough explanation of the study's nature and goal in terms they could all comprehend. Only after receiving a signed written informed consent were they included in the study.

Allocation of Groups

The 70 patients were randomly allocated into two groups of 35 each.

Group L: Patients received 30 ml of 0.5% of levobupivacaine by supraclavicular route.

Group R: Patients received 30 ml of 0.5% of ropivacaine by supraclavicular route.

Each patient underwent a thorough pre-anesthesia evaluation that included a systemic exam, a general examination, and the gathering of their medical history. Thus, both common and uncommon investigations are carried out. A local examination of the block site was carried out to rule out any signs of infection, past harm, or prior deformity. A 0.25 mg Alprazolam tablet was given the night before the surgery, and the patient was instructed to abstain from meals and liquids for 6 to 8 hours. The patients were told about the block process and provided with a signed informed consent.

A multipara monitor was set up before the patient entered the operation room, and baseline measurements of the patient's respiration rate, pulse rate, noninvasive blood pressure, SpO_2, and ECG were made. According to the patients' needs, IV fluids were administered while an 18G cannula was used to secure the intravenous line.

Five minutes before supraclavicular brachial plexus block, intravenous doses of ondansetron 4 mg, ranitidine 50 mg, and midazolam 1 mg were given. The patient was instructed to lie face down with their shoulders down and their head turned away from the blocked side. The arm on the blocked side was kept in abduction. The neck and the area up to

the nipple were cleaned and coated with an antiseptic solution. The painted area was wrapped in a wound cloth to maintain strict aseptic and antiseptic care. A dish was used to prepare the medication for the block, and a syringe was used to draw up the medication. The brachial plexus trunks and the pulsatile subclavian artery may be seen by keeping the ultrasound probe parallel to the clavicle. Then, a supporter flushed a short, fine 22 G needle with a syringe containing 10 cc of medicine into a 10 cm extension line.

The centre of the probe was left in place and the needle was inserted out of plane. Between the subclavian artery and the needle was the advanced ulnar pocket of the first rib. The medicine was then slowly and repeatedly administered around the nerve bundle once the correct location had been found and a blood aspiration test had come back negative. The risk of the needle becoming loose and puncturing an artery or the pleura was carefully avoided. Following the administration of the drug, the following observations were made. After the block was administered, the length of the procedure, the length of the post-operative analgesia according to the VAS score, the side effects and complications, if any, as well as the onset time, peak effect time, total duration, and vital parameters of the Sensory and Motor block were all monitored (pulse, BP, SPO2, and R.R.).

This is how the sensory block was graded: [14]

Grade-0: Normal sensation (Sharp pain felt)

Grade-1: Blunted sensation (Dull sensation or slight heaviness),

Grade-2: No pain perception (State of anaesthesia).

The distribution of the Musculocutaneous nerve, the Ulnar nerve, the Radial nerve, and the thenar eminence on the back of the hand were all tested for sensory block (Lateral border of forearm over the site of radial artery). The time between a medicine injection and the first time a specific nerve region experienced diminished feeling was called the "time to sensory onset." The time to peak sensory effect was calculated once complete loss of sensation/pain to pin-prick was achieved in all of the aforementioned nerve areas. The duration of the sensory block is the period of time from the beginning of grade 2 block to the end of grade 1 block.

Motor block was assessed by Modified Bromage scale.[15]

Grade – 0: Normal muscle tone (full flexion and extension of elbow, wrist and fingers is possible).

Grade – 1: Decreased muscular tone (weakness of grip) i.e., Paresis.

Grade – 2: Complete loss of muscular tone (unable to move the fingers).

(a) Motor block onset: the time passed between injection of drug and attainment of grade 1 block.

(b) Peak motor block: when there was total loss of motor power or grade 2 motor block.

(c) Duration of motor block: the time from beginning of grade 2 block to return of grade 1 block.

Monitoring was done every 15 minutes for the first 60 minutes, then every 30 minutes for the following 120 minutes, to check for sensory and motor blockage, oxygen saturation, ECG, pulse rate, blood pressure, and respiration rate. Complications and adverse effects of local anaesthesia are closely watched.

The procedure's duration and residual effects were noted after it was finished. When the patient was brought to the ward, patients were seen for the evaluation of the postoperative analgesia, any problems, and other vital parameters at predefined intervals. a 10-point visual analogue scale for rating postoperative analgesia.

Duration of postoperative analgesia: Time from onset of sensory blockade to time when patient VAS score >/=3.

Results

Groups L (levobupivacaine) and R (ripivacaine), which are age-matched in both groups, are not statistically significant. Groups L (levobupivacaine) and R (ripivacaine) in both groups have gender-matched members. There are 09 females in Group L and 08 in Group R, as well as 26 and 27 males, respectively, in Groups L and R.

When compared to Group R, which had onset times for sensory blockage and motor blockade of 12.05 seconds and 15.51 seconds, respectively, in Group L, the mean onset times were 9.00 seconds, 18.7 seconds, and 16.7 seconds, respectively. (Table 1)

Table 1: Comparision of group l and group r on the basis of onset time of sensory and motor blockade

Variable	Group L	Group R	P value
SENSORY ONSET TIME	9.00±1.87	12.05±2.085	0.001
MOTOR ONSET TIME	13.71±1.67	15.51±2.40	0.001

Comparison of Mean Onset Time between the groups

In Group L, Sensory and Motor Blockade Onset Time was earlier than in Group R. Statistics show that the p value was 0.001, which is extremely highly significant. In comparison to Group R, which had a mean duration of analgesia of 11.6 1.80 hours, Group L had a mean duration of analgesia of 15.37 2.00 hours. When compared to Group R, Group L's analgesic duration was longer. Statistically speaking, the p value of 0.0001 is quite significant. (Table 2)

Table 2: Comparision of group L and group R on the basis of duration of analgesia

Variable	Group L	Group R	P Value
Duration Of Analgesia	15.37±2.00	11.6±1.80	0.001

Discussion

During limb surgery, regional anaesthesia, especially peripheral nerve blocking, is frequently utilised to provide both anaesthesia and postoperative analgesia. During procedures on the upper limb, brachial plexus block is preferable to general anaesthesia because to its sympathetic block, superior postoperative analgesia, and reduced side effects.

When a significant volume of the medicine is needed, the existing local anaesthetic bupivacaine is renowned for its propensity for neuro and cardiotoxicity, with possibly deadly arrhythmias. Levobupivacaine has less cardiac and central nervous system toxic effects than bupivacaine, while possessing same duration of sensory blocking. When compared to bupivacaine, ropivacaine is a long-acting amide local anaesthetic medication that may have a better safety profile. The use of ultrasound technology also provides a better block success rate with superior localisation and a better safety profile. The study involved 70 patients from ASA 1 and ASA 2 who were having elective upper limb orthopaedic surgery. It was a prospective, randomised study. There were two groups of 35 patients each.

In a USG-guided supraclavicular brachial plexus block, Group L received 30 ml of 0.5% Levobupivacaine, and Group R received 30 ml of 0.5% Ropivacaine. The following parameters were measured: the moment at which sensory and motor blocks first appeared, their durations, the length of analgesia, and any side effects.

Changes in the perioperative cardiovascular parameters: Regarding the pattern of variations in heart rate, systolic

blood pressure, diastolic blood pressure, and mean arterial pressure during surgery, there were no significant differences between the research groups. In the Shantanu B. Kulkarni *et al*. study from 2017 [16], it was discovered that heart rate (HR), systolic blood pressure (SBP), and diastolic blood pressure (DBP) were comparable during the course of the trial in both groups and that there was no statistically significant difference ($p > 0.05$).

Systolic, diastolic, and heart rate measurements were found to be comparable in both groups in the study done by Dr. Vikas Kumar Singh *et al*. in 2020. [17]

Onset time of Sensory and Motor block: In our study, we found that the Levobupivacaine group (Group L) had an earlier sensory block start time than the Ropivacaine group (Group R), which had a mean value of 12.05 ±2.08 minutes. This difference was statistically significant.

In our study, we found that the Levobupivacaine (Group L) group's motor block start time was earlier than the Ropivacaine (Group R) group's, with a mean value of 13.71 ±1.67 minutes compared to 15.51 ±2.40 minutes, which is statistically significant.

In the study conducted by V. Sai Dilip *et al* in 2015 [18] they found that onset of sensory and motor blockade was earlier with levobupivacaine when compared to ropivacaine.

In the study conducted by Shantanu B. Kulkarni *et al* in 2017 [16] 0.5% levobupivacaine provides rapid onset of sensory and motor blockade when compared to ropivacaine.

The findings of our investigation agreed with the aforementioned observations. Thus, we draw the conclusion that Levobupivacaine 0.5%, compared to Ropivacaine 0.5%, has an advantage of Early Onset of Sensory and Motor Blockade for Supraclavicular Brachial Plexus Block at Equal Volume.

Duration of Sensory block and Motor block: In our investigation, the duration of the sensory block was 9.22±1.57 minutes with ropivacaine and 12.14±1.91 hours with levobupivacaine. Levobupivacaine group's sensory block lasted longer than Ropivacaine group's, which is statistically significant.

Levobupivacaine group's motor block lasted 14.42±1.63 hours, while Ropivacaine group's lasted 11.51±1.65 hours. Levobupivacaine group's motor block lasted longer than Ropivacaine group's, which is statistically significant.

The duration of the sensory and motor block was substantially shorter for ropivacaine than for levobupivacaine (P 0.05) in Prerana P. Mankad *et al* study [19]'s comparing 0.5% Ropivacaine with 0.5% levobupivacaine for brachial plexus block.

The duration of the sensory and motor blockade was longer with levobupivacaine than ropivacaine in the study by Dr. V. Sai Dilip *et al*. in 2015 [18] comparing 0.5% Ropivacaine and 0.5% levobupivacaine for brachial plexus block.

The findings of our investigation agreed with the aforementioned observations. We therefore come to the conclusion that, when compared to Ropivacaine 0.5% for Supraclavicular brachial plexus block at identical volume, levobupivacaine 0.5% has the benefit of longer Duration of Sensory and Motor blockage.

Duration of Analgesia

Whole duration of analgesia was calculated as the mean interval between the start of block and the request for analgesics. In our study, the Levobupivacaine group (Group L) and the Ropivacaine group (Group R) had an analgesia duration of 15.37 2.0 hours and 11.6 1.80 hours, respectively. Levobupivacaine group's analgesia lasted longer than Ropivacaine group's, which is statistically significant.

In the study conducted by Prerana P Mankad *et al* in 2015 [19] comparing 0.5% Ropivacaine

and 0.5% levobupivacaine for brachial plexus block they noted Levobupivacaine has significantly longer duration of analgesia as compared to ropivacaine.

In the study conducted by Dr. V. Sai Dilip *et al* in 2015 [18] comparing 0.5% Ropivacaine and 0.5% levobupivacaine for brachial plexus block they noted Levobupivacaine has longer duration of analgesia as compared to ropivacaine.

In the study conducted Amit P Chauhan *et al* in 2020 [5] by comparing 0.5% Ropivacaine and 0.5% levobupivacaine for brachial plexus block they noted Levobupivacaine prolonged duration of anaesthesia as well as prolonged post-operative pain relief compare to Ropivacaine.

The above observation was similar to our study. As a result, we came to the conclusion that Levobupivacaine has a better profile in terms of analgesic duration and should be taken into consideration when postoperative analgesia is a concern, but not when an early return to motor activity is necessary.

Conclusion

Based on our research, we can say that with a supraclavicular Brachial Plexus block, Levobupivacaine 0.5% has an advantage over Ropivacaine 0.5% in terms of

- Early onset of Sensory blockade.
- Early onset of Motor blockade.
- Prolonged Duration of Sensory blockade.
- Prolonged Duration of Motor blockade.
- Prolonged Duration of Analgesia

References

1. Chitnis S. S., Tang R., Mariano E. R. J. K. J. O. A. The role of regional analgesia in personalized postoperative pain management. 2020; 73: 363-371.
2. Brodner G., Van Aken H., Gogarten W. J. A., Intensivmedizin, Notfallmedizin, Schmerztherapie: AINS. Regional anesthesia for postoperative pain control. 2007; 42: 32-41.
3. Cox C., Faccenda K., Gilhooly C., Bannister J., Scott N., Morrison L. J. B. J. O. A. Extradural S (-)-bupivacaine: comparison with racemic RS-bupivacaine. 1998; 80:289-293.
4. Albright G. A. J. T. J. O. T. A. S. O. A. Cardiac arrest following regional anesthesia with etidocaine or bupivacaine. 1979; 51: 285-287.
5. Chauhan A. P., Pandya J., Jain A. J. A. Comparison of block characteristics and postoperative analgesia of 0.5% Levobupivacaine with 0.5% Ropivacaine in ultrasound guided supraclavicular block for orthopedic forearm surgery-a prospective, comparative, randomized, clinical study. 2020; 5:14.
6. Casati A., Fanelli G., Cappelleri G., Beccari P., Magistris L., Borghi B., Torri G. J. E. J. O. A. A clinical comparison of ropivacaine 0.75%, ropivacaine 1% or bupivacaine 0.5% for interscalene brachial plexus anaesthesia. 1999, 16, 784-789.
7. Bertini L. J. R. A. P. M. 0.75% and 0.5% ropivacaine for axillary brachial plexus block; a clinical comparison with 0.5% bupivacaine. 2000; 25: 659.
8. Casati A. Fanelli G., Aldegheri G., Berti M., Colnaghi E., Cedrati V., Torri G. J. B. J. O. A. Interscalene brachial plexus anaesthesia with 0.5%, 0.75% or 1% ropivacaine: a double-blind comparison with 2% mepivacaine. 1999; 83: 872-875.
9. Cline E., Franz D., Polley R. D., Maye J., Burkard J., Pellegrini J. J. A. J. Analgesia and effectiveness of levobupivacaine compared with ropivacaine in patients undergoing an axillary brachial plexus block. 2004; 72: 339-346.
10. Sia A. T., Goy R. W., Lim Y., Ocampo C. E. J. T. J. O. T. A. S. O. A. A comparison of median effective doses of intrathecal levobupivacaine and ropivacaine for labor analgesia. 2005; 102: 651-656.
11. Egashira T., Fukasaki M., Araki H., Sakai A., Okada M., Terao Y., Hara T. J. P. P. Comparative efficacy of levobupivacaine

and ropivacaine for epidural block in outpatients with degenerative spinal disease. 2014; 17: 525.
12. Bosanquet D., Glasbey J., Stimpson A., Williams I., Twine C. J. E. J. O. V., Surgery E. Systematic review and meta-analysis of the efficacy of perineural local anaesthetic catheters after major lower limb amputation. 2015; 50:241-249.
13. Møiniche S., Kehlet H., Dahl J. B. J. T. J. O. T. A. S. O. A. A qualitative and quantitative systematic review of preemptive analgesia for postoperative pain relief: the role of timing of analgesia. 2002; 96: 725-741.
14. Kaygusuz K., Kol I. O., Duger C., Gursoy S., Ozturk H., Kayacan U., Aydin R., Mimaroglu C. J. C. T. R. Effects of adding dexmedetomidine to levobupivacaine in axillary brachial plexus block. 2012; 73 103-111.
15. Nallam S. R., Chiruvella S., Karanam S. J. I. J. O. A. Supraclavicular brachial plexus block: Comparison of varying doses of dexmedetomidine combined with levobupivacaine: A double-blind randomised trial. 2017; 61: 256.
16. Kulkarni S. B., Pimpare M., Govardhane B. T. J. I. J. R. M. S. Comparison of levobupivacaine with ropivacaine for supraclavicular brachial plexus block. 2016; 4:3789-3796.
17. Kant K., Salvi K. Department Anatomy. 1996.
18. Dilip V. S., Sekhar G. C., Murthy G. K., Rao A. K., Sivaji K., Benerji G. J. A. Supraclavicular block with 0.5% levobupivacaine and 0.5% ropivacaine-comparative study. 20, 70yrs.
19. Mankad P. P., Makwana J. C., Shah B. J. J. I. J. M. S. P. H. A comparative study of 0.5% ropivacaine and 0.5% levobupivacaine in supraclavicular brachial plexus block. 2016; 5: 74-79.