ORIGINAL RESEARCH PAPER

Anaesthesiology

LEVOBUPIVACAINE VS ROPIVACAINE FOR SUPRACLAVICULAR BRACHIAL PLEXUS BLOCKS IN PATIENTS UNDERGOING UPPER LIMB SURGERIES IN A TERTIARY CARE CENTRE

KEY WORDS:

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Regional anaesthesia techniques are gaining widespread popularity and are a well-accepted component of comprehensive anaesthesia care. They provide better regional analgesia as compared to other modalities like general anaesthesia and have been shown to decrease postoperative opioid requirements. Supraclavicular brachial plexus blocked, considered as the spinal anaesthesia of the upper limb, is easy to perform, safe, and provided excellent regional anaesthesia with almost no side effects when good techniques and proper precautions are employed. Bupivacaine is a commonly used and widely available since local anaesthetic that is frequently used in supraclavicular brachial plexus blocks due to its predictable profile and cost efficiency, but concerns have been raised over its potential cardiotoxicity and neurotoxicity.

Ropivacaine and levobupivacaine are both relatively newer local anaesthetics. Levobupivacaine is highly lipophilic along with vasoconstrictor properties. Ropivacaine is less lipophilic that levobupivacaine and therefore less likely to penetrate the large motor fibres resulting in a lesser degree is motor block but at the same time conferring a safer cardiac and CNS profile. There are very few studies comparing levobupivacaine and ropivacaine in supraclavicular blocks and even in these studies there are many conflicting findings. Hence, this study was carried out to compare the onset and duration of sensory motor block and duration of analgesia between levobupivacaine and ropivacaine in supraclavicular brachial plexus block for elective upper limb surgeries as primary outcome and to look for any side effects such as bradycardia or hypotension as secondary outcome.

METHODS

This study was performed at Assam Medical College and Hospital, a tertiary care hospital in rural India. Institutional ethics committee approval was obtained prior to conducting the study and informed written consents were obtained from all participants. Patients aged 18 to 65 years of all genders, belonging to American Society of Anaesthesiologists (ASA) grade 1 or 2 physical status admitted in Orthopaedics ward of Assam Medical College and Hospital and scheduled for elective upper limb surgeries feasible under supraclavicular brachial plexus block were included for the purpose of the study. Patients who refused to give consent, those allergic to either of the study drugs, pregnant or breastfeeding women, morbidly obese patients, those with coagulation disorders, infection at the site of injection, injury to nerves of upper limb, neurological or neuromuscular or psychiatric illness, those requiring a change of anaesthesia plan or conversion to general anaesthesia were excluded from the study.

Over the course of two months participants were allocated into two groups-group ropivacaine (group R) and group levobupivacaine (group L) randomly. Random allocation cards were made for 60 patients by an independent medical officer using computer-generated random numbers and they were divided into two equal groups of 30 each. Another independent medical officer used SNOSE (Sequentially Numbered, Opaque, Sealed and Stapled envelopes Method) method to conceal the allocation sequence from the researcher enrolling and assessing participants.

The envelopes were opened sequentially just before the injection by an independent nurse, who then prepared the injection as mentioned in the card inside for that particular patient and handed over the syringe to the anaesthesiologist performing the procedure. Input date, time, patient ID, results after the procedure, etc. were recorded by that anaesthesiologist on the envelope or another sheet inside of the envelope for that patient. The envelope was then sealed and preserved in a secured place for analysis by principal investigating officer and for future references.

Baseline heart rate, pulse, noninvasive blood pressure and oxygen saturation were monitored pre procedure and all throughout. Intravenous access using 18 G cannula was secured and all patients were premedicated with Inj Midazolam 0.05 mg kg -1 plus Inj Fentanyl 1ug kg -1 . Skin testing was done to determine sensitivity to the respective drug before the procedure.

The patient was placed in supine position with the head turned away from the side to be blocked. Sensory and motor functions were evaluated pre procedure to determine a baseline. The supraclavicular fossa and the surrounding area were prepared under strict aseptic precautions. The lateral border of the ipsilateral sternocleidomastoid muscle was identified and it followed to the point where it met the clavicle. The nerve stimulator was initially set to a current intensity of around 0.8 mA and a pulse width of 100 s. The needle was inserted around 2.5 cms lateral to the insertion of the lateral head of the sternocleidomastoid on the clavicle, at a point just above the clavicle and just lateral to the pulsation of the subclavian artery. Once appropriate response was obtained, group L received 30 ml of 0.5% Levobupivacaine and Group R received 30 mL of 0.5% of Ropivacaine, in 5 ml alliquots after negative aspiration. Drugs were prepared by an independent nurse who was not involved with the study.

The anaesthesiologist performing the block received the syringes filled with either of the drugs labelled with only the name, diagnosis and hospital number of the patient. After completion of the local anaesthetic injection the patient was monitored closely, and the onset of sensory motor block noted.

Assessment of sensory block was done via the pinprick method using a 22G hypodermic needle in the dermatomal areas of the median, radial, ulnar and musculocutaneous nerves every 3 minutes from completion of injection till complete sensory block was achieved upto a maximum time of 30 minutes and thereafter every 60 minutes. If onset of sensory block was not achieved within 30 minutes then block was considered to have failed and these patients were subsequently excluded from the study.

Sensory block was graded as:
Grade 0: Sharp pin felt

Grade 1: Analgesia, dull sensation felt, considered as the onset of sensory block

Grade 2: Anaesthesia, no sensation felt, considered as complete sensory block

Motor block was assessed using a modified Bromage Scale for the upper extremities that consisted of:

0 - able to raise the extended arm to 90o for a full 2 sec

1 - able to flex the elbow and move the fingers but unable to raise the extended arm, considered as the onset of motor block

2 - unable to flex the elbow but able to move the fingers

3 - unable to move the arm, elbow or fingers, considered as complete motor block.

The duration of sensory block was considered from the time of onset of sensory block to the reappearance of pinprick sensation and it was assessed every 60 minutes after complete sensory block. Duration of motor block was considered as the time interval between onset of motor block to the reappearance of finger movements of the operating limb which was also assessed every 60 minutes after complete motor block.

A 10 point Visual Analogue Scale (VAS) was used to assess the duration of analgesia in which a score of 0 indicated no pain a a score of 10 indicated the worst pain imaginable. The VAS was explained to the patient and it was assessed every 60 minutes till a VAS score of 6 at which point rescue analgesia in the form of Inj Paracetamol 1gm intravenously with/or Inj Tramadol 100 mg intramuscularly was provided as per departmental protocol.

Other factors such as hemodynamic fluctuations or any adverse events were looked for.

The resulting blocks were then compared based on onset and duration of sensory motor block, duration of analgesia, and any adverse events.

STATISTICAL ANALYSIS

Assuming the level of significance ( ) as 0.05 and the power of the study as 0.80 (= 0.20), and to detect an effect size of 0.7, concerning the primary study outcome variable i.e., evaluation of sensory block, motor block and duration of analgesia, we found that 26 patients will be needed to answer our research question. Considering a 10% chance of loss to follow-up, we included 60 patients, with 30 patients in each group, by rounding off our study population.

Data was analysed using Statistical Package for the Social Sciences (SPSS) version 21.0 (IBM SPSS Corp, USA) software. Numerical variables were presented a mean with standard deviation, Median (IQR), and categorical variables were presented as frequency (%). The difference between the two groups with regard to continuous variables was assessed by Independent t test and Mann Whitney subject to normality, and categorical variables were assessed by Chi-square test & Fishers Exact Test. For all the tests, a P value less than .05 was considered statistically significant.

RESULTS

A total of 63 patients belonging to ASA physical status 1 and 2 were recruited for the purpose of this study, out of which 1 patient refused to give consent and in 2 patients block was patchy. These patients were subsequently administered general anaesthesia and excluded from the study. A total of 60 patients were analysed, 30 in each group.

In group R, the mean age was found to be 34 years as compared to 39 years for group L. The percentage of males and females were similar in both the groups with 80% males and 20% females. Other demographic and hemodynamic variables were comparable in both the groups and were not found to be statistically significant, as shown in Table 1.

The mean duration of onset of sensory block was found to be 12.8 minutes for ropivacaine which was significantly longer than the 18 minutes it took for levobupivacaine. Complete sensory analgesia was obtained in around 18 minutes for ropivacaine whereas it took an average of 21.3 minutes for levobupivacaine, which was found to be statistically significant.

The mean duration of onset of motor block was 16.3 minutes for ropivacaine whereas it was found to be 20.4 minutes for levobupivacaine. Ropivacaine had a significantly shorter onset of motor block as compared to levobupivacaine.

Complete motor block took an average of 23.13 minutes for the ropivacaine group and 25.2 minutes for the levobupivacaine group, and these were again found to be statistically significant.

The mean duration of analgesia was 21 hours for levobupivacaine which was significantly longer than the mean duration of analgesia of ropivacaine which was 12.45 hours Duration of motor block was found to be statistically more for levobupivacaine with a mean of 14.33 hours as compared to ropivacaine which had a mean of 8.16 hours.

In our study, the mean duration of sensory block was 10.66 hours for ropivacaine whereas it was 17.43 hours for levobupivacaine which was statistically significant.

Two patients in the ropivacaine group had bradycardia whereas no adverse events were observed in the levobupivacaine group, but this was not found to be statistically significant.

Table 1 showing association between Group R and Group L using Chi square and Fishers Exact test(#)

Gender	Group R	Group L	Total	p value
Female	6(20%)	6(20%)	12(20%)	1
Male	24(80%)	24(80%)	48(80%)	
ASA				
1	19(63.3%)	16(53.3%)	35(58.3%)	0.432
2	11(36.7%)	14(46.7%)	25(41.7%)	
Side effects				
Bradycardia	3(10%)	0(0%)	3(5%)	0.237#
None	27(90%)	30(100%)	57(95%)	
Total	30(100%)	30(100%)	60(100%)	

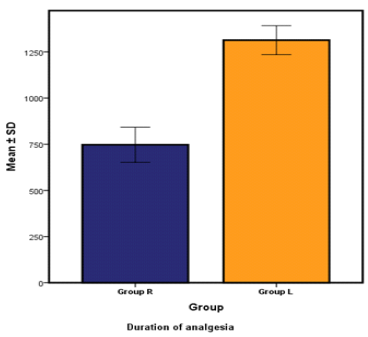
Table 2 showing comparison between Group R and Group L using independent t test

Independent t test	Group R	Group L	p value
Age	34.3±11.57	39.43±14.45	0.1340

Height	164.13±8.49	165.57±8.14	0.5070
Weight	67.43±12.4	70.97±11.16	0.2510
Baseline heartrate	77.1±6	75.1±4.48	0.1490
Baseline systolic bp	123.63±6.63	123.7±6.82	0.9690
Duration of Analgesia	747±95.09	1313.67±78.41	<0.001

Table 3 showing comparison between Group R and Group L using Mann Whitney test

Mann Whitney test	Group R		Group L		p value
	Mean±SD	Median (IQR)	Mean±SD	Median (IQR)	
Baseline diastolic bp	79.47±3.51	80 (77.5-80.5)	80.43±2.03	80 (80-80.5)	.386
Baseline spo2	100±0	100 (100-100)	100±0	100 (100-100)	1.000
Duration of Surgery	73.67±36.34	60 (40-112.5)	88.67±32.03	90 (60-120)	.108
Onset of sensory block	12.8±3.34	12 (9-15)	18±3.15	18 (15-21)	<0.001
Complete sensory block	18±3.43	18 (15-21)	21.2±3.04	21 (18-24)	.001
Onset of motor block	16.3±3.22	15 (15-18)	20.4±2.77	21 (18-24)	<0.001
Complete motor block	23.13±3.46	24 (21-27)	25.2±2.57	24 (24-27)	.035
Duration of sensory Block	640±82.38	630 (585-720)	1046±95.43	1020 (960-1140)	<0.001
duration of motor block	490±59.13	480 (480-540)	860±85.34	870 (780-960)	<0.001



DISCUSSION:

We compared 60 patients fulfilling the inclusion criteria in this randomised double blinded study. Patients were counselled beforehand about the temporary discomfort they would face during the procedure and proper consent obtained. All the patients tolerated the procedure well.

As ultrasonography facility was not available in our setup, we had to use a higher volume of local anaesthetic i.e., 30 ml, however the toxic dose of 3mg/kg was not exceeded in any patient.

In our study we found a statistically significant longer duration of analgesia with levobupivacaine as compared to ropivacaine. This is similar to the results of the studies done by Cline et al.,[1] and Thalamati et al.,[2] who performed brachial plexus blocks via various approaches. However this observation is contradictory to the findings of studies done by Watannabe et al.,[3] and Mangeswaran R et al.,[4] who did not find any statistically significant difference in the duration of analgesia or quality of analgesia for the two drugs. More studies are therefore required for this.

The onset of sensory block as well as the time required for complete sensory block with ropivacaine were significantly shorter than that required for levobupivacaine in our study. This is in tune with the findings of the study done by Thalamati et al.,[2] however it is worthwhile to note that unlike them we obtained these results using similar concentrations for both levobupivacaine as well as ropivacaine (0.5%).

The time taken for the onset of motor block as well as the time taken for complete motor block were also found to be significantly shorter for ropivacaine than with levobupivacaine in our study. This is contradictory to the findings of the study done by Thalamati et al.,[2] who did not find any significant difference. In another study done by C. Piangatelli et al.,[5] who compared 0.5% levobupivacaine with 0.75% ropivacaine for infraclavicular brachial plexuses block, they found that the onset time for motor block was significantly greater in the ropivacaine group. Perhaps the concentrations of the drugs used, their handling and storage as well as the transportation chain must be considered as well. Further studies are needed in this aspect.

The duration of sensory and motor block was found to be significantly longer for levobupivacaine than with ropivacaine. This is in concordance with the findings of Cline et al.,[1]. Cho et al.,[6] in their study did not find any difference in the duration of sensory block but the duration of motor block was increased after using levobupivacaine. Thalamati et al.,[2] also noted a longer duration of sensory blockade for levobupivacaine than with ropivacaine. In our study patients in the levobupivacaine group also had significantly longer duration of analgesia than the patients in the ropivacaine group. Perhaps people with a certain amount of motor block will also not be able to perceive pain and therefore the longer duration of analgesia.

Two patients in the ropivacaine group developed bradycardia intraoperatively, but it is worth noting that both patients were young athletic males who were involved with sports. No patient in the levobupivacaine group showed any hemodynamic fluctuation during the procedure. These differences are not statistically significant.

The inclusion criteria of this study were limited to ASA grade 1 and 2 patients only, therefore the effects of the two drugs as well as the safety profile of them in higher grade or frail patients were not studied. Due to unavailability of USG facility, higher volumes of drugs had to be injected. Also, we did not use any adjuvants in our study and therefore, we do not know how the addition of different adjuvants might change the pharmacodynamic and pharmacokinetic profile of these drugs. In a study done by Biswas S et al.,[7] they found that addition of dexmedetomidine to levobupivacaine in supraclavicular blocks significantly prolonged the duration of analgesia and the duration of block. Patil K N et al.,[8] found that clonidine as an adjuvant to ropivacaine significantly enhanced the quality of supraclavicular brachial plexus block and provided a faster onset as well as prolonged duration of sensory and motor block and also improved postoperative analgesia.

SUMMARY AND CONCLUSION:

Levobupivacaine had a slower onset of action but a longer duration of block. The duration of post-operative analgesia was also longer with levobupivacaine in elective upper limb surgeries. No major hemodynamic fluctuations were noted in either group. It seems from the findings of our study that levobupivacaine can be preferred over ropivacaine in cases where a longer duration of motor and sensory block is required. But in cases where a faster onset of block is required with a shorter duration of block as in day care surgeries, ropivacaine could be preferred. Levobupivacaine might also be better than ropivacaine in cases where we desire a longer duration of post operative analgesia.

ETHICAL CONSIDERATION: Institutional Ethics Committee(H) permission obtained prior to study commencement.

OTHER INFORMATIONS

Protocol: Passed by Institutional Ethics Committee(H) NO.AMC/EC/PG2498

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Conflict of Interest: None

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