



Original Research Article

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

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ABSTRACT

Background and Aims: Levobupivacaine is relatively new drug and studies in supraclavicular blocks are limited. Our Primary aim was to evaluate and compare block characteristics and post operative analgesia of Levobupivacaine with Ropivacaine in supraclavicular block.

Secondary aim was to compare systemic toxicity profiles of both drugs.

Materials and Methods: Totally 60 adult patients were randomly allocated to two equal groups (n = 30). Patients in Group-R received 20 ml 0.5% ropivacaine and Group-L received 20 ml 0.5% Levobupivacaine in ultrasonography guided supraclavicular block.

The main objective was to evaluate block characteristics and the duration of analgesia and other were hemodynamic variables, sedation score, and adverse effects.

The data were interpreted with the help of t-test and Chi-square test.

Results: Onset time, Peak effect time and total duration of sensory block was 90.33 ± 35.43 sec, 379.67 ± 201.21 sec and 428.5 ± 94.19 min in Group L while it was 192.33 ± 65.21 sec, 484 ± 202.05 sec and 345.17 ± 104.59 min in Group-R respectively. (P value < 0.05).

Onset time and total duration of motor block was 265.67 ± 117.9 sec and 331 ± 93.13 min. in Group L while it is $283. \pm 122.73$ sec and 310 ± 99.83 min in Group R (p $\geq .05$)

The duration of post-operative analgesia was 12 ± 2.12 hr in group L and 7.7 ± 1.9 hr. in group R (p value < .001).

Conclusion: Levobupivacaine (0.5% 20 ml) can be safely and effectively used in ultrasound guided supraclavicular block and it has early onset with prolonged duration of anaesthesia as well as prolonged post-operative pain relief compare to Ropivacaine.

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1. Introduction

Regional blocks are well accepted part of comprehensive anesthesia care. Their role has expanded from operation theatre to the field of post-operative and chronic pain management. Skillful application of these blocks broadens the anesthesiologist's range of options in providing optimal anesthetic care.¹

Brachial plexus blocks are frequently used for upper limb surgery. Bupivacaine, a racemic combination of the two stereo-enantiomers (dextrobupivacaine and levobupivacaine) frequently employed as the local anesthetic for supraclavicular block as it has many advantages viz. longer duration of action and a acceptable sensory-motor block profile. But, practically, the use of racemic mixture of bupivacaine results in systemic side-effects like cardiac toxicity in few patients which were due to the dextro-bupivacaine enantiomer. This encouraged researchers to create novel local anesthetic agents with a

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characteristics which contained all of the desirable aspects of bupivacaine without any untoward effects.^{2–4}

Ropivacaine was one of the first local anesthetic agents that came as a probable substitute for bupivacaine. Ropivacaine, the S-enantiomer of S-1-propyl-2, 6 pipecoloxylidide is an amino-amide local anesthetic agent with a chemical formula similar to that of bupivacaine. Many comparative studies between ropivacaine and bupivacaine proved that ropivacaine produced less CVS and CNS related adverse effects, less motor block, and a almost equal duration of action of sensory block and pain free hours. This advantageous clinical discovery prompted many clinicians to move from bupivacaine to ropivacaine for all types of neural blockades. However, with clinical use, it was discovered that ropivacaine's latency of sensory analgesia was approximately two thirds that of bupivacaine; therefore, it was less effective in prolonging post-operative analgesia.^{5–14}

Levobupivacaine, the S-enantiomer of bupivacaine is the newest local anesthetic agent to enter into clinical practice. Research studies have shown that the enantiomers (R-dextropropivacaine and the S-levobupivacaine) of bupivacaine possess anesthetic activity, but the S-enantiomer had significantly lower CVS and CNS related toxic effects than bupivacaine, while still implying a similar duration of sensory blockade. Levobupivacaine has proved to be safer and effective with a longer duration of analgesic effect compared with ropivacaine for neuraxial and peripheral nerve blocks.^{15–19}

Many clinicians began using levobupivacaine as the local anaesthetic of choice for neural blockades, but a controversy exists in the literature and in clinical practice regarding which agent (ropivacaine or levobupivacaine) is ideal for facilitating brachial plexus anesthesia. Some clinical trials state that ropivacaine provides a sensory blockade equal to that of levobupivacaine, while in clinical practice, many practitioners report dissimilar findings. This controversy is aggravated by the fact that no direct comparative trials have been performed between these 2 agents in patients receiving brachial plexus blocks.¹⁵

Clinically, prolonged post-operative pain-relief is essential for postoperative pain management. Most suitable local anesthetics agents are selected for peripheral nerve block. So we undertook this randomized prospective trial to compare effectiveness, duration, and quality of sensorimotor block and the postoperative analgesic effects of levobupivacaine and ropivacaine when used for brachial plexus nerve blocks, performed with ultrasound guidance in patients undergoing orthopedic surgery procedures.

Our Primary aim was to evaluate the local anaesthetic characteristics and post-operative analgesia produced with Levobupivacaine and to compare with Ropivacaine in ultrasound guided supraclavicular block.

Secondary aim was to compare toxicity profiles of both drugs in terms of cardiovascular toxicity, CNS toxicity and safety profile.

2. Materials and Methods

Current study of 60 cases posted for upper limb orthopedic surgery was conducted in the Department of Anaesthesiology, Parul institute of medical science and research (PIMSR), Vadodara, during the period of December 2018 to December 2019.

It was a prospective randomized clinical study.

The selection criteria were Patients between 20 to 60 years of age of either sex with ASA I and II status, posted for Both elective and emergency surgeries of upper limb - around elbow, forearm and hand and Patient able to give informed and written consent.

The exclusion criteria were: Patients with history of hypersensitivity to local anaesthetic agent, bleeding disorder or on anticoagulant therapy, neurological and neuromuscular diseases, Pregnant patient, major cardiovascular, respiratory, renal and liver disease and patients taking opioids medicine.

All the patients underwent a thorough pre-anaesthesia check up which included history taking, general examination and systemic examination. Routine investigations like Hemoglobin, urine examination, blood sugar, blood urea, serum creatinine, bleeding time and clotting time were carried out for all patients. Special investigations like ECG, Chest X-Ray were done in patients above 40 years of age. Other specific investigations were done depending upon the history and examination. All the patients were kept nil by mouth for at least 6 hours.

Premedication was given as Injection Glycopyrolate 0.2 mg IV, Injection Ranitidine 50 mg IV and Injection Ondansetron 4 mg IV.

Patients were allocated randomly in two groups. In Group L: (n = 30) Patients received Inj.levobupivacaine 0.5% 20ml. And Group R: (n = 30) Patients received Inj.ropivacaine 0.5% 20 ml in USG guided supraclavicular block.

After taking the patient in operation theatre, vital sign multi para monitor (Concept Integra) was attached. Baseline pulse rate, blood pressure, respiratory rate and oxygen saturation (SPO₂) were recorded. An IV line was secured with a wide bore cannula (20G) and Injection DNS was started at 80ml/hr. The patient was made to lie in supine position, head turned away from the side to be blocked and shoulder dropped. The arm of the side to be blocked was kept adducted. The neck and the area upto the nipple was cleaned and painted with antiseptic solution. The painted part was draped with a wound towel thus maintaining strict aseptic and antiseptic precautions.

2.1. Method of giving supraclavicular block

The selected drugs for giving the block were drawn up in a syringe and were kept ready in a bowl. Ultrasound probe was kept parallel to clavicle and pulsatile subclavian artery and trunks of brachial plexus were identified. Then a short fine needle of 23 G $1\frac{1}{2}$ " was attached to 10 cm extension line flushed with syringe filled with 10 ml drug by assistant. While probe still in the place the needle was introduced in out of plane fashion from midpoint of probe. The needle was advanced between subclavian artery and 1st rib known as ulnar pocket. After proper point location, negative aspiration test for blood was done and drug was then injected slowly in real time around the nerve bundle. Care was taken so that the needle did not get displaced and arterial and pleural puncture avoided. After injecting the drug following observations were noted.

The various parameters were monitored after giving the block like Sensory & Motor block-onset time, Peak effect time, Total duration, Vital parameters (pulse\BP\SPO2\R.R) Duration of surgery, Post-operative analgesia as per VAS score, Side effects and complications if any.

Sensory block was confirmed using pin-prick technique with a 23G hypodermic needle, every minute till peak effect achieved.

Sensory block was graded as shown: -Grade-0: Normal sensation (Sharp pain felt), Grade-1: Blunted sensation (Dull sensation or slight heaviness), Grade-2: No pain perception (State of anaesthesia).²⁰

Assessment of sensory block was done along the distribution of Radial nerve (Lateral side of dorsum of hand), Median nerve (Thenar eminence), Ulnar nerve (Little finger), Musculocutaneous nerve (Lateral border of forearm over the site of radial artery).

Time to sensory onset was considered as the time duration between injection of drug to time for blunted sensation over any one of the nerve territories.

Time to peak sensory effect was noted when complete loss of sensation/pain to pin-prick was achieved, along with all the above mentioned nerve territories.

Sensory block duration: the time from the onset of grade 2 block to the return of grade 1 block.

Motor block was assessed by Modified Bromage scale.²¹

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.

Pulse rate, Blood pressure, Respiratory rate(RR) and oxygen saturation (SpO₂) were monitored regularly before giving the block, 5 minutes after the block then every 5 minutes till 15 minutes and every 15 minutes till the end of surgery and the same parameters again recorded immediately post-operatively before shifting the patients. These were again checked when we visited the patients at regular intervals for noting VAS score in recovery area.

In the post-operative period, patients were examined first at 30 and 60 minutes, then every 1 hourly till 12 hours then 2 hourly till rescue analgesia needed. The post-operative pain relief was assessed using visual analogue scale (VAS)

When VAS score was ≥ 4 rescue analgesia with Inj. Diclofenac Sodium 1.5 mg/kg intramuscularly was injected.

All the subjects were monitored for any untoward effects and complications like hypotension, bradycardia, respiratory depression, excessive sedation, nausea, vomiting, dry mouth, allergic reactions, pneumothorax, hematoma formation and any neurological sequel in the intra and post-operative time frame.

Bradycardia was taken as the fall in heart rate of greater than 20 % from baseline or less than 50bpm. Likewise, hypotension was considered as decrease in systolic blood pressure of more than 20 % from preoperative value or less than 90 systolic.

Respiratory depression was defined as fall in SpO₂ less than 90% or respiratory rate less than 10 per minute.

All the patients were observed for recovery of neurological function on 2nd post operative day as well as at the time of discharge so as to judge safety profile of the drug.

2.2. Statistical analysis

All the collected data was tabulated methodically. Qualitative data was analysed by applying chi square test while quantitative data was analysed using unpaired t-test respectively with help of Graphpad (prism 8) and microsoft excel 2010. Results were tabulated as Mean $\pm$ SD. 'P' values < .05 were considered as statistically significant and values < .001 were considered as highly significant respectively.

3. Results

Demographic Data, ASA status and Type of surgery are as shown in Tables 1, 2 and 3.

Majority of the surgeries were planned surgeries and duration of surgeries was ranging from 60 – 80 minutes.

Onset of sensory blockade was 90.33 ± 35.43 seconds and 192.33 ± 65.21 in Gr-L and Gr-R respectively. (P value <.001)

Table 1: Demographic data

Parameter	Group L	Group R	P value
Number of patients	30	30	
Age (in years, Mean±SD)	36.13±12.44	41.43±12.88	>0.05
Sex (Male: Female)	21:9	21:9	>0.05
Weight (in kg, Mean ± SD)	56.83±4.22	57.06±3.75	>0.05

Table 2: ASAphysical status of patients

ASA Status	Group L	Group R	P value
I	27(90%)	25(83.33%)	>0.05
II	3(10%)	5(16.67%)	>0.05

Table 3: Types of surgery

Type of surgeries	Group – L	Group – R
Open reduction and internal fixation	18(60%)	10(33.33%)
Closed reduction with or without internal fixation	10(33.34%)	19 (63.34%)
Implant extraction	01(3.33%)	0
Excision (Radial head)	01(3.33%)	01(3.33%)

Peak effect time of sensory block was 379.67 ± 201.21 & 484 ± 202.05 seconds in Gr-L and Gr-R respectively. (P value < .05) The difference in total duration of sensory blockade was highly significant between group L and Group R (428.5 ± 94.19 in Gr-L and 345.17 ± 104.59 in Gr-R) Table 4.

Onset of Motor block in most of the patients of both groups occurred within 5 minutes (300 sec) and showed no statistical difference. (265.67 ± 117.9 in Gr-L and $283. \pm 122.73$ in Gr-R) Table 5.

Peak effect time of motor block was 705 ± 212.24 & 956 ± 284.47 sec in Gr-L and Gr-R respectively. The difference was highly significant. (P value < 0.001).

The final duration of motor blockade was 331 ± 93.13 min. in group L and 310 ± 99.83 min. in group R (p value being > .05). Thus the final duration of motor block was comparable in both groups.

The total duration of postoperative pain relief was 12 ± 2.12 hr in group L and 7.7 ± 1.9 hr. in group R (p < .001). Thus total duration of post-operative pain relief was very significantly longer in group L patients compared to group R patients.

None of the patients from either group presented with any adverse reaction \ complications.

4. Discussion

Regional anaesthesia is almost always preferred over general anaesthesia (GA) for orthopedic limb surgeries because it ensures early mobilization and faster rehabilitation. Brachial plexus block is commonly used mode of regional anesthesia for upper limb surgeries.

We considered supraclavicular route of brachial plexus block as it provides durable anaesthesia for upper limb surgery without tourniquet pain which may not be possible

in axillary block. And complications like diaphragmatic paralysis, Horner's syndrome in interscalene brachial plexus block can be omitted.^{10,14}

Our study proved that mean time for Onset and peak effect of sensory block was drastically reduced and the total duration of sensory block was effectively prolonged in Group L patients. Mean onset time and the total duration of motor block was comparable in both groups. In a similar study done by Cline et al, it was shown that the duration of sensory block was longer in the Levobupivacaine group than in the Ropivacaine group.¹⁵ The statistically significant mean onset of sensorimotor blockade was observed earlier in group of patients received levobupivacaine compared to patients received ropivacaine. Similar results were observed by Mageswaran and Choy.²² On the contrary, Nodulus et al found that both 0.5% Levobupivacaine and 0.5% ropivacaine had similar onset of action.²³ These differences were mostly due to use of ultrasound guidance in our study.

Pulse rate, blood pressure, respiratory rate and SpO₂% were recorded regularly throughout the period of study and post operatively. There was no difference statistically in pulse rate, BP, RR and SpO₂% when values were compared perioperatively.

VAS score was 0 up to 5 hours in group L and 2 hours in group R. The VAS score of ≥ 4 was attained in 4 hours in Group R and by 9 hours in group L. The rescue analgesia was started by 4 hours in group R patients and from 9 hours in group L patients respectively.

Most of the patients in group L were given rescue analgesia by 6th hour while in group L patients rescue analgesia was considered around 9th hour. All the patients in group R were given rescue analgesia by 12th hour while in group L by 12th hour majority of patients required rescue analgesia but all the patients were given rescue analgesia by

Table 4: Sensory block characteristics

	Group L Mean $\pm$ SD	Group R Mean $\pm$ SD	P value
Time of Onset (in seconds)	90.33 $\pm$ 35.43	192.33 $\pm$ 65.21	<0.001
Peak Effect Time (in seconds)	379.67 $\pm$ 201.21	484 $\pm$ 202.05	<0.05
Total Duration (Minutes)	428.5 $\pm$ 94.19	345.17 $\pm$ 104.59	< 0.01

Table 5: Motor block characteristics

	Group L Mean $\pm$ SD	Group R Mean $\pm$ SD	P value
Time of Onset (in seconds)	265.67 $\pm$ 117.9	283. $\pm$ 122.73	P >0.05
Peak Effect (in seconds)	705 $\pm$ 212.24	956 $\pm$ 284.47	P<0.001
Total Duration (In minutes)	331 $\pm$ 93.13	310 $\pm$ 99.83	P>0.05

15th hour.

Total duration of post-operative pain-relief was 12 $\pm$ 2.12 hours in group L and 7.7 $\pm$ 1.9 hours in group R (P<.001). This difference was highly significant statistically. Thus our study shows that levobupivacaine gives longer pain relief than ropivacaine. Similarly in the study conducted by Deshpande et al, demonstrated that sensory-motor blockade was significantly early with levobupivacaine 0.5%. The duration of sensorimotor blockade and post-operative analgesia was prolonged with l-bupivacaine as compare to 0.5% ropivacaine in supraclavicular block.²⁴

There were no complications or side effects noted in our study in either groups using 100 mg of the drugs. Majority of the studies in dose of 175 mg have not reported any significant incidence of complication in either groups. Casati et al reported Horner's syndrome in 1 patient. Altintas et al observed Horner's syndrome 7 patients, hoarseness in 2 patients, respiratory distress in 2 patients.^{25,26}

Thus levobupivacaine and Ropivacaine when used in dose of 100mg (0.5% 20 ml are safe to use.

5. Conclusion

We conclude from our study that 20 ml of 0.5% Levobupivacaine can be safely used in ultrasound guided supraclavicular block and it has early onset and prolonged duration of anaesthesia as well as analgesia when compared to same dose of Ropivacaine.

6. Source of Funding

Nil.

7. Conflicts of Interest

Nil.

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