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COMPARATIVE STUDY BETWEEN 0.5% LEVOBUPIVACAINE AND 0.5% ROPIVACAINE USING NERVE STIMULATOR FOR INFRACLAVICULAR BRACHIAL PLEXUS BLOCK.

Anaesthesiology

Saloni Sahni* Senior resident, Department of Anaesthesiology, Government Medical College, Kota *Corresponding Author

S. C. Dulara Professor and Head of the department, Department of Anaesthesiology, Government Medical College, Kota

Loveleena Gupta Senior resident, Department of Anaesthesiology, Government Medical College, Kota

ABSTRACT

To challenge the neuro and cardiotoxic properties of racemic 0.5% bupivacaine, newer drugs like levobupivacaine and ropivacaine have come. An attempt has been made to compare efficacy and post-operative analgesia of 0.5% levobupivacaine and 0.5% ropivacaine for below elbow surgeries using infraclavicular brachial plexus block.

Sixty subjects undergoing upper limb surgery were randomized into 2 groups (groups L and R) of 30 each receiving levobupivacaine and ropivacaine. The major concerns were to study the onset and duration of sensory and motor blockade, and duration of analgesia. Onset of sensory and motor block was faster in Group L. Duration of sensory and motor blockade was longer in Group L.We found that both drugs are having the desirable blocking properties of bupivacaine with a greater margin of safety due to their reduced toxic potential.

KEYWORDS

Bupivacaine, Infraclavicular block, Levobupivacaine

Introduction

Regional anaesthetic techniques are often used to provide not only anaesthesia but also post-operative analgesia after limb surgery.[1] We have used infraclavicular approach as it causes less discomfort to the patient as positioning of the arm is not required and there is a lower incidence of pneumothorax.[2] and has a higher incidence of successful musculocutaneous nerve block.[3]

Bupivacaine 0.5% is one of the most popular drugs used because of its higher potency and prolonged duration of action.

Ropivacaine and levobupivacaine the newer local anaesthetic agents have shown to produce less cardiac and neurotoxic effects when compared to bupivacaine.[4]

In our study we have compared the onset, duration of sensory and motor blockade, postoperative analgesia and hemodynamic changes with 0.5% levobupivacaine and 0.5% ropivacaine for below elbow surgeries.

Methods

After obtaining an approval from the Ethics Committee and written informed consent from 60 patients of either sex, aged between 18 and 60 years, weight 50 to 100 kgs belonging to ASA physical status I or II, undergoing elective orthopaedic, plastic and reconstructive below elbow surgeries having duration lasting more than 30 minutes were included in the study. Patients with failure of block, receiving anticoagulants and coagulation disorders, history of peripheral neuropathy, known hypersensitivity to local anesthetic agents, infection at site of block or pregnant women were excluded from the study.

All patients underwent a preanaesthetic evaluation and were randomized into two groups with 30 patients each; group L-using 0.5% Levobupivacaine 30 ml and group R-using 0.5% ropivacaine 30 ml in a double blind fashion. All drug solutions were prepared by an anaesthesiologist who was not involved in administration of anaesthesia, patient care and data collection.

In the operating room standard monitors were attached and intravenous (IV) access obtained and an IV infusion was started. The baseline hemodynamic data was charted. All infraclavicular brachial plexus blocks were performed using coracoid approach using a 22G 50 mm insulated blunt Stimuplex needle and a nerve stimulator.

As the nerve was approached, movement of the wrist or fingers elicited was identified and the current was gradually reduced to 0.4 mA. The end point taken was when hand twitches could be elicited at a current of 0.4 mA. Once this was achieved, the appropriate local anaesthetic was given in 5 ml increments, aspirating before each bolus to avoid intravascular injection. Group L received 30 ml of 0.5% levobupivacaine and group R received 30 ml of 0.5% ropivacaine. The concentrations of the local anaesthetic drugs used in the study are kept considering the toxic level of respective drugs.

The effects of the anaesthetic agents on the following parameters were observed:

1. Onset time of sensory blockade:

Time between injection and total abolition of pinprick response and temperature testing using spirit-soaked cotton on skin, was evaluated in 4 nerve areas (median, ulnar, radial and musculocutaneous) at every 3 minutes until 40 minutes after the injection. The block was judged to have failed if anaesthesia is not present in 2 or more peripheral nerve distributions and such patients were excluded from the study.

2. Onset of Motor blockade:

Motor block was assessed by Bromage three-point score. (appendix 1) The time when motor block achieved was noted at an interval of every 3 minutes until 40 minutes after the injection.

3. Duration of sensory blockade:

Time between onset of action and return of pinprick response, was assessed every 30 minutes in at least 3 major nerve distributions.

4. Duration of motor block:

Assessed every 30 minutes till the return of complete muscle power in three major nerve distributions. Complete muscle power was denoted by lifting of arm against gravity.

5. Duration of analgesia:

Time between onset of action and onset of pain, is the time when patients received the first dose of analgesic. Postoperatively, the pain score was recorded by using visual analogue pain scale (VAS) [5]. (appendix 2) Initially pain was accessed every 2 hourly for first 12 hours and then 4 hourly for next 12 hours. Inj diclofenac sodium 75 mg was given intramuscularly as a rescue analgesic when VAS > 4.

6. Heart rate, non-invasive blood pressure and oxygen saturation: were also monitored every 15 min during procedure and every 60 minutes postoperatively.

Statistical data

In our study considering the drop out rate of 5% and taking power of study as 90% (alpha error of 5% and beta error of 95%), we calculated the sample size as 30 in each group. For statistical analysis the unpaired t-test was used for comparison of mean between two groups. The chi-square test was used for qualitative data. A p - Value of < 0.05 was considered to be statistically significant and ** $P <= 0.001$ i.e. highly significant. The statistical data was analyzed using Stat Cal software-SPSS version 17.0.

Results

Demographic data included variables of gender, age and weight which were comparable between the two groups(Table 1).

Parameters	Group L	Group R	P value
AGE (years)	34.24+11.10	30+10.47	0.13 (NS)
Gender(M/F)	23/7	24/6	0.75(NS)
Weight(kgs)	64+7.80	64.17+8.25	0.93(NS)

Onset of sensory blockade was faster in group L (11.16 ± 1.18 min) compared to group R (13.5 ± 0.95 min). This difference was statistically significant (P<0.001).

Onset of motor blockade was faster in group L (17.33 ±0.86 min) compared to group R (19.66 ± 0.87 min). This difference was statistically significant (P<0.001).

Duration of sensory blockade was longer in group L (640 ± 45.74 min) compared to group R (582 ± 36 min). This difference was statistically significant (P<0.0001).

Duration of motor blockade was longer in group L (467.33 ± 33.25 min) compared to group R (415.33 ± 25.65min). This difference was statistically significant (P<0.001).(table 2)

Table2: Sensory and motor block parameters

PARAMETERS	Group L	Group R	P value
Onset of sensory block(min)	11.16+1.18	13.5+0.95	<0.001
Onset of motor block(min)	17.33+0.86	19.66+0.8	<0.001
Duration of sensory blockade (min)	640.66+45.74	582+36	<0.001
Duration of motor blockade	467.33+33.25	415.33+25.65	<0.001 (HS)

NS = Not significant, S = significant, HS = Highly significant

Duration of analgesia was longer in group L (730+ 33.17 min) compared to group R (605 + 36.30 min).This difference was statistically highly significant (P<0.001). Significantly prolonged duration of analgesia was observed in levobupivacaine group (p value 0.0001). (Figure 1)

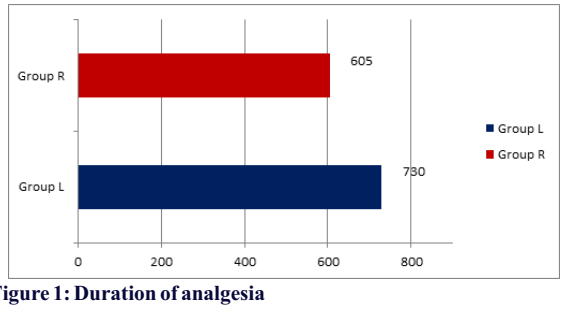

Figure 1: Duration of analgesia

Heart rate, non-invasive blood pressure and oxygen saturation: were also monitored every 15 min during procedure and every 60 minutes postoperatively. Nausea, vomiting, drowsiness or any other adverse effects and complications were noted.

The statistical analysis showed that there was no significant difference in the pulse rate, mean blood pressure and oxygen saturation between the two groups (P > 0.05).

Appendix 1
Bromage three-point score.
0= normal motor function with full flexion and extension of elbow, wrist and fingers,
1= decreased motor strength with ability to move fingers and/or wrist only,
2= complete motor blockade with inability to move fingers.

Appendix 2
Visual analog scale

Pain Intensity	Word Scale
0	No pain
1-2	Least pain
3-4	Mild pain
5-6	Moderate pain
7-8	Severe pain
9-10	Excruciating pain

DISCUSSION

Bupivacaine is a racemic mixture of (*R*) - and (*S*) - stereoisomers. In response to the problem of cardiovascular toxicity as a result of accidental intravenous injection of bupivacaine, single enantiomers were developed in the hope that they would be potentially safer local anesthetics. Ropivacaine and levo-(*S*)-bupivacaine were formulated to exploit this stereoselectivity. Ropivacaine is a single (*S*)-stereoisomer that differs from levobupivacaine in the substitution of a propyl for the butyl group on the piperidine ring. With these designed changes in molecular structure, it was hoped that ropivacaine and levobupivacaine would be less intrinsically cardiotoxic. [6]

The onset of sensory and motor block is related to the physicochemical properties of the individual drugs, namely the mass of the injected local anaesthetic (mass = concentration X volume), the dissociation constant (pKa) of the drug, pH of the tissues and the presence of frequency dependent blockade.[7]

Levobupivacaine, the S- enantiomer of bupivacaine (racemic mixture) which has been formed by removing R-enantiomer from the racemic mixture of bupivacaine has shown to have a higher margin of safety index. The dissociation constant (pKa) of levobupivacaine (8.1) is similar to that of bupivacaine (8.1) and ropivacaine (8.1); but higher than that of lignocaine (7.7) .Its higher lipid solubility makes it more potent than lower lipid-soluble agent ropivacaine and results in longer duration of action.[8]

Ropivacaine has a high pKa and low lipid solubility that block nerve fibres involved in pain transmission (A delta and C fibres) to a greater degree than those controlling motor function (A beta fibres).The drug is less cardiotoxic than equal concentrations of racemic bupivacaine but more than lignocaine; it has a significantly higher threshold for CNS toxicity than racemic bupivacaine.[9]

In our study, significant differences were found in the onset of sensory and motor blockade (p<0.001) between two groups. Group L had a faster onset of sensory blockade (11.16 minutes) and motor blockade (17.33 minutes) as compared to group R which has sensory and motor blockade of 13.5 minutes and 19.66 minutes respectively.

Similar results were found in a study by R. Mageswaran and Y.C. Choy using 0.5% ropivacaine and 0.5% levobupivacaine .They had found that the onset of sensory blockade was faster with levobupivacaine (11.1 minutes) as compared to ropivacaine (13.5 minutes, p=0.003) which was statistically significant. When compared the onset of motor blockade, levobupivacaine had faster onset (17.1 minutes) as compared to ropivacaine (19.0 minutes, p=0.013) .[10]

In another randomized study by C. Piangatelli and co-workers comparing 0.5% levobupivacaine with 0.75% ropivacaine showed that the onset of sensory block for levobupivacaine was 13.46 minutes and for ropivacaine 14.2 minutes. The onset for motor block for levobupivacaine was 19.33 minutes and for ropivacaine 20.2 minutes, which were similar to the results found by us.[11]

In our study, the duration of sensory blockade for levobupivacaine and ropivacaine was 640.66 minutes and 582 minutes respectively, which was statistically significant (p<0.001), the duration of motor blockade for levobupivacaine was 467.33 minutes and for ropivacaine 415.33 minutes (p<0.001).

Similar results were found in C.Piangatelli's study ,the duration of sensory block for levobupivacaine and ropivacaine was 684 minutes and 615 minutes respectively, which was statistically significant (p<0.05).The duration of motor blockade for levobupivacaine and ropivacaine was 504 minutes and 499 minutes respectively, which was statistically significant (p<0.05).In another study by Cline ,the duration of motor block for levobupivacaine was 1047 minutes while for ropivacaine was 778 minutes(p=0.005).[12]

In our investigation the duration of analgesia produced by Group L was 730 minutes and by Group R was 605 minutes. The duration of post-operative analgesia was statically significant (p<0.001).

In a study done by Cline E. et al comparing 0.5% levobupivacaine with 0.5% ropivacaine, the pain score was taken as verbal numerical rating scale (VNRS), the ropivacaine group had higher VNRS scores at 8th (P= .001) and 10th (P = .003) hours post-operative as compared to levobupivacaine. The duration of sensory analgesia was significantly longer in levobupivacaine group (831 minutes; p=0.013) as compared to 642 minutes for the ropivacaine.[13] This was in accordance with our study too.

Similar result regarding post-operative analgesia was found by Casati and co-workers [14].They compared 30 ml each of 0.5% levobupivacaine with 0.5% ropivacaine in interscalene block, post-operative rescue analgesia time was higher with levobupivacaine with less number of patients demanded the same (47%).

In our study, hemodynamic changes were not statistically significant between the two groups. In a study by Cacciapuoti and co-workers using 0.5% levobupivacaine, 0.5% bupivacaine and 0.75% ropivacaine, there were no significant hemodynamic changes seen between the three drugs[15].

CONCLUSION

In our study, comparing 0.5% levobupivacaine with 0.5% ropivacaine the following can be concluded: onset of sensory and motor block is faster with 0.5% levobupivacaine, the duration of sensory blockade, motor blockade and post-operative analgesia is longer with 0.5% levobupivacaine as compared to 0.5% ropivacaine and there were no statistically significant differences seen in hemodynamic between the two groups.

Thus, when considering levobupivacaine and ropivacaine for brachial plexus anaesthesia, levobupivacaine can be considered when postoperative analgesia is a major concern and ropivacaine can be considered when an early return of motor activity is required.

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