

**COMPARISON OF THE EFFECT OF EPIDURAL LEVOBUPIVACAINE 0.5%, 20ML
AND ROPIVACAINE 0.75%, 20ML IN LOWER LIMB SURGERIES.**

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Abstract

Introduction: Anesthesiologist play a main role in providing comfort to patient, monitor the patient and maintain normal physiological levels. With the advancement of anaesthesia different techniques are being used in combination with different drugs for providing pain relief. With introduction of levobupivacaine and ropivacaine, a new era of pain relief had begun.

Materials and Methods: A total number of 200 patients, 100 in each group were selected for study; patients were allocated randomly into groups by lottery method. Group LB, n=100: Consists of patients who received 20 ml of Levobupivacaine 0.5% in epidural route and Group R, n=100: Consists of patients who received 20 ml of Ropivacaine 0.75% in epidural route. After fulfilling the inclusion and exclusion criteria, the patients were enrolled into the study and informed written consent was obtained from all patients. The pulse rate, respiratory rate, blood pressure and SpO₂ were recorded before starting the case. Peripheral venous conflation was done with 18G IV cannula and all the patients were preloaded with 10ml/kg Ringer Lactate solution.

Results: On set time of sensory blockade is taken from the completion of injection of study drug till the patient does not feel the pin prick. The mean time of onset of sensory block to T10 level in group LB was 10.02 ± 3.21 min, in group R was 9.10 ± 2.20 min and is considered to be statistically not significant. The mean time to attain maximum sensory level 15.6 ± 3.70 min for group LB, 14.50 ± 2.80 min for group R, which is not statistically significant.

Conclusion: Our study has shown that two drugs were same in sensory block characteristics such as mean on set time of sensory blockade, mean time to attain maximum sensory level, maximum level of sensory blockade, two segment regression time, and duration of analgesia. Also motor parameters such as mean time of onset of motor block, and duration of motor block and quality of motor block were comparable between the groups with a statistically insignificant p value. With respect to haemodynamic parameters and side effect profiles, both Levobupivacaine and Ropivacaine were comparable. Both drugs could be better alternatives to Bupivacaine in epidural anaesthesia.

Key Words: Anesthesiologist, sensory blockade, duration of analgesia, Levobupivacaine and Ropivacaine.

INTRODUCTION

Anesthesiologist play a main role in providing comfort to patient, monitor the patient and maintain normal physiological levels. With the advancement of anaesthesia different techniques are being used in combination with different drugs for providing pain relief. With introduction of levobupivacaine and ropivacaine, a new era of pain relief had begun.¹

With the introduction of central neuraxial blockade, providing relief to patient from pain intraoperatively and postoperatively is in common practice now-a-days. Epidural anaesthesia provides effective anaesthesia and analgesia intraoperatively and also postoperative pain relief and lead to early mobilization with decreased side effects. Thus it has been used routinely in orthopedic surgeries considering all its advantages.²

Epidural anaesthesia is one of the regional techniques for lower abdominal, lower limb, pelvic and vascular surgery, it has some definite advantages over spinal anaesthesia like there is no limitation for the duration of surgery if an epidural catheter is in place. It can also be used as a modality for post-operative pain relief.³ Bupivacaine has been the drug of choice in providing effective epidural anaesthesia followed by post-operative analgesia for a considerable time. The recognition of acute life-threatening cardiotoxicity of bupivacaine. led to the search for a local anaesthetic agent comparable with bupivacaine but with lower cardiotoxicity resulting in development of a relatively new amide, ropivacaine, registered for use in 1996.⁴ but introduced in India only in 2009. Ropivacaine is a new, long acting local anaesthetic which is chemically homologous with Bupivacaine and Mepivacaine. It is similar to the 'S' enantiomer of Bupivacaine, except that a propyl group is present in place of butyl group on the piperidine ring's tertiary nitrogen atom. Ropivacaine exhibits less cardio toxicity and CNS toxicity. It produces effective analgesia as that of Bupivacaine and that motor block appears to regress considerably more rapidly than sensory block. This makes Ropivacaine potentially well suited for administration through epidural route for epidural anaesthesia.⁵

The aim of the present study is to compare the effectiveness of levobupivacaine 0.5% and ropivacaine 0.75% in a volume of 20 ml in epidural neuraxial blockade in 100 patients undergoing elective lower limb surgeries. The objectives of this study was to compare the time for onset of sensory blockade, time for onset of motor blockade, maximum level of sensory blockade, two segment regression time, quality of motor blockade, duration of analgesia, duration of motor blockade, hemodynamic parameters and any adverse effects.

MATERIALS AND METHODS

Study design: A prospective study.

Study location: Department of Anaesthesia, Balaji Medical College, Chennai.

Study duration: June 2013 to November 2013.

Sample size: 200 patients.

A total number of 200 patients, 100 in each group were selected for study; patients were allocated randomly into groups by lottery method. Group LB, n=100: Consists of patients who received 20 ml of Levobupivacaine 0.5% in epidural route and Group R, n=100: Consists of patients who received 20 ml of Ropivacaine 0.75% in epidural route.

Inclusion criteria: ASA grade I and II physical status, aged between 18-60 years, weighing between 50-70 kg, height within range of 150-170cm, of either gender undergoing lower limb surgeries were included.

Exclusion criteria: Patients not willing to participate in the study, patients with ASA grade III and IV, those with known sensitivity to local anaesthetics, patients with local infection at the site of injection, uncooperative patients, patients with coagulopathies, bleeding diathesis and raised intracranial tension were excluded.

After fulfilling the inclusion and exclusion criteria, the patients were enrolled into the study and informed written consent was obtained from all patients. The pulse rate, respiratory rate, blood pressure and SpO₂ were recorded before starting the case. Peripheral venous cannulation was done with 18G IV cannula and all the patients were preloaded with 10ml/kg Ringer Lactate solution.

The patients were placed in left lateral position and under strict aseptic precautions, after local infiltration with 1% Xylocaine the epidural space was identified with a 18/16G Tuohy needle at L3-L4 or L2-L3 interspace, by “loss of resistance” technique. 18/16G epidural catheter was threaded through the needle into the epidural space for 3-4cms and secured with adhesive tapes to the back.

After negative aspiration for blood and CSF, 3ml of 2 % Lignocaine with 15µgm of adrenaline was given as test dose and the patient was turned to supine position.

After 5mins if there is no adverse reaction for the test dose, intravascular and intrathecal placement were ruled out (heart rate \geq 100bpm, systolic blood pressure $<$ 90 mm Hg, or presence of sensory block) and the study drugs were administered incrementally over a 5 min period, after negative aspiration for blood and cerebrospinal fluid.

Group LB (n=100), were given 20ml of 0.5% levobupivacaine and Group R, (n=100) were given 20 ml of 0.75% ropivacaine epidurally. The level of sensory block was assessed by bilateral pin prick method using a blunt tipped 27 G needle at 0, 2, 5, 10, 15, 20, 25, 30 and 60 min post injection every 30 min thereafter until complete regression of sensory block was observed and quality of motor blockade assessed by Modified Bromage Scale at 0, 10, 20 and 30 minutes intervals post dose and subsequently every 30 minutes until the patient returned to a score of zero in both legs.

Continuously SpO₂, respiratory rate, heart rate, were monitored. Hemodynamic variables like SBP, DBP, MAP, pulse rate were recorded every 5 min until 30 min and at 10 min interval thereafter up to 90 min and then at 30 min interval till the end of surgery.

Statistical analysis: Descriptive data presented as mean \pm SD and Continuous data analyzed by paired or unpaired “t” test. Chi-square test and Fischer Exact Probability test to analyze incidence data and there by statistical difference between the two groups. P value<0.05 is taken as statistically significant.

RESULTS

Parameter	Group LB	Group R
Age (Mean \pm SD)	42.40 \pm 14.12	37 \pm 13
Height (Mean \pm SD)	155.13 \pm 3.20	156.12 \pm 6.00
Weight (Mean \pm SD)	56.12 \pm 4.10	57.13 \pm 3.50
Sex(M/F)	48/52	36/64
ASA grade I/II	44/56	40/60

Table 1: Demographics

Type of surgery	Group LB	Group R
Hernioplasty	28	24
Incisional hernia mesh repair	8	16
TAH(Total Abdominal Hysterectomy)	24	16
Open Prostatectomy	8	8
Ovariectomy	4	8
Appendectomy	28	28
Total	100	100

Table 2: Different type of surgeries in two groups

On set time of sensory blockade is taken from the completion of injection of study drug till the patient does not feel the pin prick. The mean time of onset of sensory block to T10 level in group LB was 10.02 \pm 3.21 min, in group R was 9.10 \pm 2.20 min and is considered to be statistically not significant.

Group	Group LB	Group R
Mean	10.02	9.10
SD	3.21	2.20

Table 3: Comparison of mean time of onset of sensory blockade

Maximum	Group LB	Group R	Total
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sensory level			
T4, (Count %)	12 (12%)	8 (8%)	20 (10%)
T6, (Count %)	80 (80%)	72 (72%)	152 (76%)
T8,(Count%)	8 (8%)	20(20%)	28 (14%)

Table 4: Comparison of maximum sensory level attained

Highest sensory levels attained in both groups were shown below. They are statistically not significant.

Group	Group LB	Group R
Mean	15.6	14.50
SD	3.70	2.80

Table 5: Comparison of mean time to attain maximum sensory level

The mean time to attain maximum sensory level 15.6±3.70 min for group LB, 14.50±2.80 min for group R, which is not statistically significant.

Group	Group LB	Group R
Mean	22.28	21.04
SD	3.91	3.70

Table 6: Comparison of mean time of onset of motor blockade

Modified bromage scale	Group LB	Group R	Total
0, Count%	20 (20%)	24 (24%)	44 (44%)
1, Count%	24 (24%)	28 (28%)	52 (52%)
2, Count%	36 (36%)	36 (36%)	72 (72%)
3, Count%	20 (20%)	12 (12%)	32 (32%)

Table 7: Comparison of quality of motor blockade

Adverse effects	Group LB	Group R	Total
Nil	48	56	104
Hypotension	24	20	44
Bradycardia	24	20	44
Nausea	16	12	28
Vomiting	8	4	12
Shivering	4	8	12

Table 8: Comparison of side effects

The intraoperative complications encountered in the present study were hypotension, bradycardia, nausea, vomiting and shivering. There is no significant difference between two groups in both cases.

DISCUSSION

In the present study the duration of analgesia in Group LB was 229.52 ± 11.32 minutes and in Group R was 233.48 ± 10.58 minutes. There is no statistically significant difference in the duration of analgesia between the groups.

In a study conducted by Concepcion et al, where they compared three different concentrations of Ropivacaine (0.5%, 0.75%, 1%), the duration of analgesia with 0.75% Ropivacaine is 255 ± 73 minutes which is similar to our result.⁶ In a study conducted by Simon et al, where they compared the clinical profile of levobupivacaine in epidural route in different age groups, the duration of analgesia with 0.75% levobupivacaine is 327 ± 69 minutes. The longer duration of analgesia here could be explained due to use of higher concentration of levobupivacaine.⁷

In a study by Brockway et al, where they compared different concentrations of Ropivacaine (0.5%, 0.75%, 1%) with Bupivacaine (0.5%, 0.75%), they stated that there is little difference between the groups with respect to speed of onset of sensory block.⁸ Duration of analgesia was increased by increasing the concentration of both drugs; this had minimal effect on onset time or extent of block. Increasing concentration of both drugs resulted in greater degree and longer duration of motor block.⁹

In a study conducted by Peduto et al, where they compared epidural levobupivacaine 0.5% with ropivacaine 0.75% for lower limb procedures, it was concluded same clinical profile is seen in both drugs. It was observed by Karz JA et al that, no significant difference was found in motor or sensory effects with 0.5% Bupivacaine and with 0.75% Ropivacaine given epidurally which proves their equipotency at different concentration.¹⁰

In a study conducted by Senard et al, it was concluded that the spread, quality and haemodynamic effects are also similar after equal doses of levobupivacaine and Ropivacaine, self-administered via postoperative patient controlled epidural analgesia, but ropivacaine receiving patients appear to ambulate earlier.

CONCLUSION

Our study has shown that two drugs were same in sensory block characteristics such as mean onset time of sensory blockade, mean time to attain maximum sensory level, maximum level of sensory blockade, two segment regression time, and duration of analgesia. Also motor parameters such as mean time of onset of motor block, and duration of motor block and quality of motor block were comparable between the groups with a statistically insignificant p value. With respect to haemodynamic parameters and side effect profiles, both Levobupivacaine and Ropivacaine were comparable. Both drugs could be better alternatives to Bupivacaine in epidural anaesthesia.

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