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Research Article

The efficacy of epidural ropivacaine 0.75% and levobupivacaine 0.5% in abdominal and lower limb surgeries- a comparative study

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ABSTRACT

Background: Both levobupivacaine and ropivacaine are relatively new long acting amide local anaesthetics. Both are pure S-enantiomers of the parent drug racemic bupivacaine. Little is known about the comparative efficacy of epidural levobupivacaine with this another widely used long-acting local anaesthetic, ropivacaine.
Methods: We compared the efficacy of levobupivacaine 0.5% with ropivacaine 0.75% in epidural route in a volume of 20ml in 100 adult patients who were divided into two groups of 50 patients each, belonging to ASA grade 1and 2, of either gender, between the age group of 18-60 years undergoing lower abdominal surgeries.
Results: Our study has not shown statistically significant difference between the drugs 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.
Conclusions: The present study concludes that 0.5% levobupivacaine and 0.75% ropivacaine were clinically similar with respect to sensory block characteristics and duration of analgesia, quality of motor blockade with minimal side effects in both the groups. Both drugs could be better alternatives to bupivacaine in epidural anaesthesia.

Keywords: Levobupivacaine, Ropivacaine, Epidural anaesthesia, Lower limb surgeries, Abdominal surgeries

INTRODUCTION

Epidural anaesthesia is the anaesthesia of choice in various surgeries where in general or spinal anaesthesia carries a risk. It is a type of regional anaesthesia in which spinal nerves are blocked in the epidural space as they emerge from Dura. Epidural techniques are widely used for operative anaesthesia, obstetric analgesia, post-operative pain control and chronic pain management. Epidural anaesthesia and analgesia are most often performed in the lumbar region. Central neuraxial blockade is the commonly used anaesthetic technique for Lower abdominal surgeries. Bupivacaine, a highly lipophilic long-acting local anaesthetic has been the most commonly used anaesthetic agent in its class to date. Unfortunately, like all amide-type anaesthetics, Bupivacaine has been associated with high rate of cardiac and local toxicity. An important aspect of this toxicity is that it involves stereo-specificity with the S (-) enantiomer showing significantly less cardio depressant effects than R (+) enantiomer.[1]

Based on investigations of the etiological mechanisms of local anaesthetic-induced cardio toxicity, the search for less toxic alternatives to Bupivacaine was concentrated, an amide linked agents comprised of a single

enantiomer.[2] As a result of these efforts, the long-acting local anaesthetic Ropivacaine was found, which has been recently introduced in India. Ropivacaine is a long acting regional anaesthetic that is structurally related to Bupivacaine. Thus, Ropivacaine represents the monohydrate of the hydrochloride salt of 1-propyl-2,6-pipecoloxylidide. Ropivacaine has similar potency to Bupivacaine at doses higher than ED50 for pain relief.[3]

Various studies have compared the clinical efficacy of Levobupivacaine with Bupivacaine and Ropivacaine with Bupivacaine. Very few studies are there in literature comparing these two new drugs, Levobupivacaine and Ropivacaine.[4] So we have selected to compare the clinical efficacy of Levobupivacaine and Ropivacaine in Epidural anaesthesia.

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 abdominal and 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.

METHODS

The study was prospective randomised, double blind controlled study to evaluate the efficacy of Levobupivacaine 0.5% and Ropivacaine 0.75% in epidural route in adult patients undergoing lower abdominal surgeries. It was carried out in the Department of anaesthesiology, Mamata Medical College, Khammam, India from December 2013 to August 2015. The study was approved by the institutional ethical committee.

A total number of 100 patients, 50 in each group were selected for study; patients were allocated randomly into groups by lottery method. Group LB, n = 50: Consists of patients who received 20 ml of Levobupivacaine 0.5% in epidural route and Group R, n = 50: 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 abdominal 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 SpO_2 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 ≥100bpm,systolic blood pressure <90mm 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=50), were given 20ml of 0.5% levobupivacaine and Group R, (n=50) 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 there-after 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 SpO_2, 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 upto 90 min and then at 30 min interval till the end of surgery.

Statistical analysis

At the end of the study all the data is compiled and statistically analyzed using tatistical software namely Graphpad Quickcalc, vassar stats net was used for analysis of data and Microsoft word and Excel have been used to generate graphs, tables etc.

Descriptive data presented as mean ±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

There is no significant difference between the two groups with regards to the age, ASA grades, sex, height, weight. The demographic details were given in Table 1. The surgeries done were similar in both the groups and statistically comparable shown in Table 2.

Table 1: Demographic data.

Parameter	Group LB	Group R
Age (Mean±SD)	42.44±14.44	37.00±13.38
Height (Mean±SD)	156.44±4.20	157.16±6.10
Weight (Mean±SD)	57.44±4.68	58.32±4.74
Sex (M/F)	24/26	18/32
ASA grade I/II	22/28	20/30

Table 2: Different type of surgeries in two groups.

Type of Surgery	Group LB	Group R
Hernioplasty	14	12
Incisional hernia mesh repair	4	8
TAH (Total Abdominal Hysterectomy)	12	8
Open Prostatectomy	4	4
Ovariotomy	2	4
Appendicectomy	14	14
Total	50	50

Sensory and motor parameters

Onset of sensory blockade

Onset 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 10.0±3.22 min, in group R was 9.0±2.29 min and is considered to be statistically not significant (Table 3).

Highest sensory level achieved

Highest sensory levels attained in both groups were shown below. They are statistically not significant (Table 4)

Time to maximum sensory level

The mean time to attain maximum sensory level 15.8±3.80 min for group LB, 14.52±2.83 min for group R, which is not statistically significant (Table 5).

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

Group	LB (n=50)	R (n=50)
Mean	10.00	9.00
SD	3.22	2.29

Table 4: Comparison of maximum sensory level attained.

Maximum sensory level	Group L (n = 50)	Group R (n =50)	Total
T4, (Count %)	6 (12%)	4 (8%)	10 (10%)
T6, (Count %)	40 (80%)	36 (72%)	76 (76%)
T8, (Count %)	4 (8%)	10 (20%)	14 (14%)

Onset of motor blockade

It is taken from the completion of epidural injection of study drug to the time Bromage Grade 0 changed to Grade 1.The mean duration of onset of motor blockade in group LB was 22.28±3.90, in group R was 21.04 ± 3.72 mins . The statistical analysis by unpaired t test showed that there is no statistically significant difference in the two groups (Table 6).

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

Group	LB (n=50)	R (n=50)
Mean	15.8	14.52
SD	3.80	2.83

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

Group	LB (n=50)	R (n=50)
Mean	22.28	21.04
SD	3.90	3.72

Table 7: Comparison of two segment regression time.

Group	LB (n=50)	R (n=50)
Mean	111	106.60
SD	12.95	11.73

Two segment regression time

The two segment regression time in group LB was 111± 12.95 mins, in group R 106.60±11.73mins.The statistical analyses by unpaired t test showed that there was no statistically significant difference between the two groups (Table 7).

Quality of motor block

The quality of motor blockade was similar in Group LB compared to Group R.52% of patients in Group R had a

motor block less than grade 2 (Modified bromage scale) compared to 44% of patients in Group LB. 20% of patients in Group LB had motor block of grade 3 while 12% patients in Group R had motor blockade of grade 3 (Table 8).

Table 8: Comparison of quality of motor blockade.

Modified bromage scale	Group LB (n = 50)	Group R (n = 50)	Total
0, Count %	10 (20%)	12 (24%)	22 (44%)
1, Count %	12 (24%)	14 (28%)	26 (52%)
2,Count %	18 (36%)	18 (36%)	36 (72%)
3,Count %	10 (20%)	6 (12%)	16 (32%)

Table 9: Comparison of side effects.

Adverse effects	Group LB	Group R	Total
Nil	24	28	52
Hypotension	12	10	22
Bradycardia	12	10	22
Nausea	8	6	14
Vomiting	4	2	6
Shivering	2	4	6

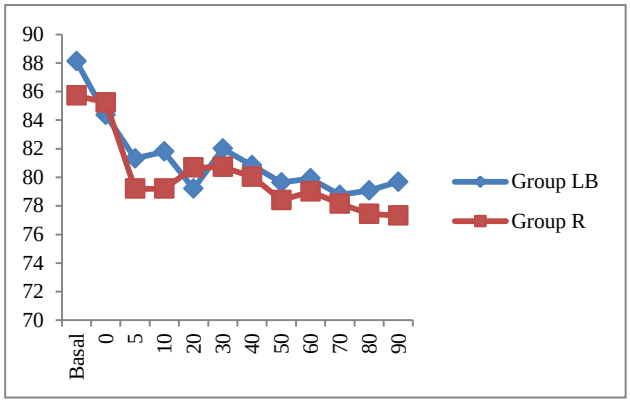

Figure 1: Comparison of changes in mean arterial pressure.

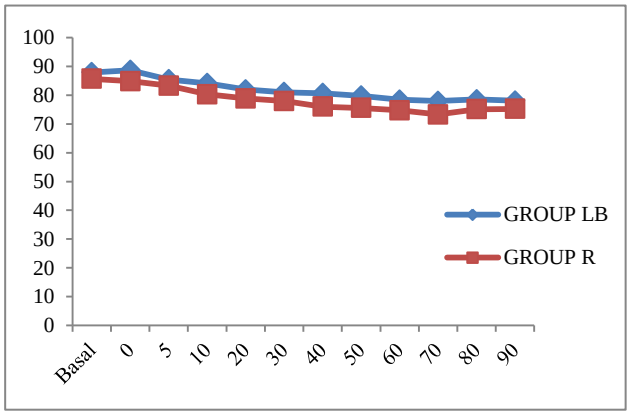

Figure 2: Comparison of changes in pulse rates.

Duration of motor blockade

The mean duration of motor blockade in group LB 117.5±20.42 was mins, in group R was 125.6±21.08mins. The statistical analysis by unpaired t test showed that there is no statistically significant difference in the two groups.

Duration of analgesia

The mean duration of analgesia in group LB was 229.52±11.32, in group R was 233.48±10.58, that there is no statistically significant difference between the two groups.

Haemodynamic parameters

The changes in mean arterial blood pressure were little more stable in Group LB than Group R. However there is no statistical significance in changes in mean arterial pressure in between groups and were comparable at various time intervals (Figure 1).There was no significant change in pulse rates in both groups at various time intervals. The pulse rates were comparable in both groups without any clinical or statistical significance (Figure 2).

Complications

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 (Table 9).

DISCUSSION

Ropivacaine and Levobupivacaine are relatively recently introduced amino amide local anaesthetics that are structurally similar to bupivacaine. Ropivacaine represents the monohydrate of the hydrochloride salt of 1-propyl-2,6-pipecoloxylidide.[1,5] Ropivacaine has a lower systemic toxicity than bupivacaine and has a shorter duration of action.[6]

Levobupivacaine, the isolated S (-) enantiomer of bupivacaine, has been shown to be less cardiotoxic than bupivacaine in preclinical studies.[7,8] Owing to the lower affinity of the S (-) isomer to the cardiac sodium channels compared to the R(+) isomer, it is associated with less cardiac side effects.[9] Although it has been already compared with racemic bupivacaine for spinal, epidural and peripheral nerve blockade, little is known about the comparative efficacy of epidural levobupivacaine with another widely used long-acting local anaesthetic, ropivacaine.

Both Ropivacaine and Levobupivacaine are pure S (-) isomers of the family of n-alkyl-substituted pipecholylxylidines. Their physicochemical properties are quite similar, but the question of their clinical profile has given rise to some controversy. Levobupivacaine, more lipophilic than ropivacaine, is theoretically more potent, but because Levobupivacaine has only a slightly greater protein binding than ropivacaine (95% vs 90%-92%), clinical studies do not consistently show a longer duration of action with the S-isomer of bupivacaine.

Ropivacaine (Naropin) and levo-(*S*) bupivacaine (Chirocaine) were formulated to exploit this stereo selectivity. 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. Conversely, it appears that the (*S*)-enantiomers of mepivacaine and bupivacaine are metabolized by the liver more slowly than the corresponding (*R*)-enantiomers, which would lead to somewhat greater systemic accumulation with prolonged infusions.[10]

There are various studies comparing Levobupivacaine with Ropivacaine stating that both agents have been proved to be associated with less CNS and cardiac toxicity relative to Bupivacaine when equal concentration were compared. There are very few studies which compared Levobupivacaine and Ropivacaine for epidural anaesthesia. This prospective clinical trial is intended to compare the clinical efficacy (onset, duration, intraoperative conditions) and safety of Ropivacaine with Levobupivacaine in epidural use.

Sensory and motor parameters

In the present study the mean time of onset of sensory blockade at T 10 in Group LB was 10±3.22 minutes and Group R was 9±2.29 minutes. In a study conducted by Cox et al where they compared the mean time of onset of sensory block for S (-) Bupivacaine is similar to the meantime of onset of sensory block with Levobupivacaine in the present study.[11] In a study by Cekman et al[12], where they compared epidural Ropivacaine and Bupivacaine in arthroscopic surgeries, the mean onset time to T10 for Ropivacaine was 13.6±5.1 as compared to 12.2±6.5 for Bupivacaine. Also the mean onset time of sensory block for Ropivacaine in our study was similar to the mean onset time of sensory block for Ropivacaine in a study conducted by David Brown et al, where they compared 0.5% Ropivacaine and 0.5% Bupivacaine for epidural anaesthesia (10.7± 5.6).[13]

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[14], 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. 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.[15] The longer duration of analgesia here could be explained due to use of higher concentration of levobupivacaine.

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.[16] 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.

In present study the time taken to attain maximum sensory level in two groups is similar, no statistically significant difference between the groups. In a study conducted by Kountoudi et al, where they compared epidural Levobupivacaine 0.5% with Ropivacaine 0.5% for inguinal hernia repair procedures in 30 patients, there was no difference as far as the level of sensory block is concerned.[17]

In a study conducted by Finucane et al, where they compared different concentrations of Ropivacaine (0.5%, 0.75% and 1%) and Bupivacaine in concentration of 0.5% in 25 ml volume in patient undergoing lower abdominal surgeries with epidural anaesthesia, they observed no difference between the groups in terms of maximum sensory block level.[12] However when duration of motor and sensory blocks were compared, as the ropivacaine dose was increased, they obtained a significant dose response effect.

In the present study there is no significant difference in mean time for onset of motor block in two groups. These results of quality of motor block were consistent with previous studies mentioned below. In a study conducted by Casati et al, where they compared epidural 0.5% Levobupivacaine with 0.5% Ropivacaine and concluded Levobupivacaine is having similar onset, quality,

duration and better motor blockade when compared to Ropivacaine.[19]

An increase in concentration resulted in a profound motor blockade. In a study by Finucane et al, in terms of motor block Bupivacaine group was observed to be significantly of better quality at certain times in comparison with Ropivacaine group. Olofsen, Erik et al noted that Ropivacaine had lower speed of onset and offset than Levobupivacaine. This may be due to lower lipid solubility of Ropivacaine.[18-21]

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.[22] It was observed by Karz J A et al that, no significant difference was found in motor or sensory effects with 0.5% Bupivacaine with 0.75% Ropivacaine given epidurally which proves their equipotency at different concentration. [21]

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.[22]

In lower concentrations and during labor analgesia, these anaesthetic agents have similar potency, with no difference in motor effects.[21] For spinal analgesia, bupivacaine had longer motor block duration and intensity as compared to levobupivacaine and ropivacaine.[25]

Ropivacaine provides satisfactory anaesthesia with minimal blockade of motor function at a concentration of 0.5%. This should be an asset in obstetrical analgesia and anaesthesia where prolonged sensory analgesia with minimal blockade is desirable. Levobupivacaine has a wider margin of safety and showed greater differentiation between duration of sensory and motor blockade similar to Ropivacaine and It can be safely used for regional anaesthesia for lower abdominal surgeries.[26]

Haemodynamic changes

There is no statistically significant difference in heart rate between the two groups at various time intervals. No patient in either group develops significant bradycardia. There was no statistically significant differences in systolic blood pressure, diastolic blood pressure, mean arterial pressure monitored at various intervals between the two groups.

However 12 patients (24%) in group LB and 10 patients (20%) in Group R developed hypotension which was treated with intravenous fluids and mephentermine. The requirement of vasopressor for maintenance of stable hemodynamic parameters did not reveal any significant difference between both groups on statistical comparison.

Complications

The intraoperative complications encountered in the present study were hypotension, bradycardia, nausea, vomiting and shivering. There was no statistical difference in incidence of complications between the groups. No episodes of headache, urinary retention and respiratory depression were noted. Levobupivacaine toxicity is intermediary to ropivacaine and bupivacaine.[6,23] It seems to have same cardiovascular and neurological effects as compared to Ropivacaine, when administered to volunteers.[22] Equal doses of Levobupivacaine and Ropivacaine provide similar onset of sensory block, maximum cephalic spread, and duration of analgesia but the onset of motor block is delayed and less dense in both drugs.

CONCLUSION

Both Levobupivacaine and Ropivacaine are relatively new long acting amide local anaesthetics. Both are pure S-enatiomers of the parent drug Racemic Bupivacaine. 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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