Original Article

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Comparative Study of 0.75% Isobaric Ropivacaine and 0.5% Isobaric Bupivacaine in Epidural Anaesthesia in Lower Abdominal and Lower Limb Surgeries

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Abstract

Background: We did a study to compare the efficacy and side-effects of epidural 0.5% Bupivacaine with epidural 0.75% Ropivacaine in lower abdominal surgeries and lower limb surgeries. **Subjects and Methods:** The study was done on 60 patients with 30 patients in each group. Each group received 20 ml epidural drug either 0.5% Bupivacaine (group B) or 0.75% Ropivacaine (group R) in L2-L3 or L3-L4 interspace for elective lower abdominal or lower limb surgeries. The block characteristics, haemodynamic changes & side effects were observed and compared between the groups. **Results:** The time of onset of the sensory block at T10 was statistically insignificant between the groups B and R. [10.5 ± 1.68 and 10.87 ± 1.63 respectively]. 16 patients in group B and 15 patients in group R had maximum sensory level of T6. The time of onset of sensory block at T6 was 16.63 ± 1.93 (n=16) in group B and 16.07 ± 2.12 (n=15) in group R (p=0.4120). The time of onset of motor block was 16.63 ± 1.81, 15.9 ± 1.88 respectively for Grade 1 modified bromage score and 25.13 ± 2.01, 24.77 ± 1.85 for Grade 2 and 29.31 ± 3.1 (n=26) in B, 29.04 ± 2.65 (n=24) for grade 3 block. 26 patients in Group B and 24 patients in group R had maximum motor level of grade 3 (p>0.05). The time for two segment regression of the sensory block was 160.27 ± 31.01 and 162.93 ± 26.85 and statistically insignificant (p>0.05). 25 patients in group B and 23 patients in group R had excellent anaesthesia, 3 in each group had good or satisfactory anaesthesia whereas 2 in group B and 4 in group R had unsatisfactory anaesthesia (n=30). Bupivacaine had a statistically significant longer duration of motor block (284.27 ± 24.20 min) compared to Ropivacaine (240.1 ± 19.19 min) (p<0.0001). The duration of sensory block was statistically insignificant between the groups (317.47 ± 41.36 and 325.34 ± 37.96 min respectively). 6 patients in group B and 3 in group R had hypotension. 5 in group B and 3 in R had nausea/vomiting. The incidences of bradycardia and shivering were comparable between the groups (3:2 and 2:3 respectively). The haemodynamic parameters-heart rate, systolic blood pressure, diastolic blood pressure and mean blood pressure were comparable in between the groups. **Conclusion:** The duration of the motor block was significantly shorter in Ropivacaine compared to Bupivacaine which is desirable in the post-operative period. Also, Ropivacaine showed lesser incidences of side effects - hypotension, bradycardia, nausea/vomiting. Therefore, epidural ropivacaine is a safe alternative to epidural bupivacaine in lower abdominal and lower limb surgeries.

Keywords: Bupivacaine, Epidural Anaesthesia, Ropivacaine.

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Introduction

Spinal anaesthesia, epidural and caudal anaesthesia are also called neuroaxial anaesthesia. Neuroaxial anaesthesia is safer than general anaesthesia if managed well and can provide pain relief even in the post-operative period.[1]

The first epidural anaesthesia was given in 1901 independently by two French scientists-Jean Antanase Sicard and Fernand Cathelin by approach through the caudal epidural space. The first lumbar approach epidural anaesthesia was given twenty years later in 1921 by Fidel Pagés Miravé. The identification of the epidural space by 'loss of resistance. technique and 'hanging drop' method was discovered by Archille Mario Dogliotti. In 1931, a Romanian Obstetrician Eugene Aburel injected LA through a silk catheter. In 1949, the first lumbar continuous epidural was reported by a Cuban scientist Manuel Martinez Curbelo. In 1956 John J Bonica described the epidural approach by paramedian space.[2]

Bupivacaine was discovered in 1957.[3] It is an amino amide local anaesthetic and is cardiotoxic.[4]

Ropivacaine was developed after bupivacaine in view of cardiotoxicity associated with Bupivacaine. Ropivacaine has clinical (pharmacodynamic) effects similar to those of bupivacaine, but is associated with a lower potential for cardiovascular toxicity. Ropivacaine is available only as the (S)-stereoisomer, which has inherently less affinity for the cardiac sodium channel.[5]

The enantiomerically pure (S-enantiomer) amide local anaesthetic drug ropivacaine blocked nerve fibres responsible for transmission of pain (A delta and C fibres)

more completely than those that control motor function (A beta fibres) in in vitro studies.[6]
The potency of Ropivacaine is 60% of that of bupivacaine.[7] The dose-ratio ropivacaine:bupivacaine showing similar profiles of effects was 3:2, and, at equal doses, anesthesia was less intense using ropivacaine.[8] Ropivacaine blocks fibres responsible for transmission of pain (A delta and C fibres) more completely than those that control motor function (A beta fibres).[9]
In our study we compared the efficacy of 0.5% isobaric Bupivacaine and 0.75% isobaric Ropivacaine in epidural anaesthesia in lower abmominal surgeries and lower limb surgeries.

Aims And Objectives

The aim of our study was to observe and compare the efficacy of 20ml epidural 0.5% bupivacaine and 20ml epidural 0.75% ropivacaine in lower abdominal and lower limb surgeries. The primary objective of the study was to observe the sensory and motor block characteristics of the two study drugs by observing the time of sensory onset at T10 and T6; and motor onset of bromage scale grade of 1, 2 and 3; percentage of maximum sensory dermatomal level in each drug group; time for two segment sensory regression; quality of motor block, duration of motor block; duration of sensory block (time of first request for pain relief); quality of anaesthesia and side effects.

Subjects and Methods

After obtaining the institutional ethical committee and informed written consent, 60 patients of ASA 1 and 2, belonging to age group 18-60 years, posted for elective lower abdominal and lower limb surgeries of short and intermediate duration were taken for the study. The patients were divided into two groups - Group B and Group R. Group B received 20 ml 0.5% bupivacaine and group R received 20ml 0.75% ropivacaine in the epidural space. Patients posted for surgeries, of short and intermediate duration, of lower abdominal surgeries and lower limb were taken up for the study.

The inclusion criteria of the study were:

Age 18 – 60 years
Both gender
Lower abdominal surgery
Lower limb orthopaedic surgery
ASA physical status i and II

The exclusion criteria were

Patient unwilling
Any bleeding disorder or patient on anticoagulants
Neurological and musculoskeletal disease
Local infection at the injection site
History of allergy to local anaesthetic and signs of allergy to lignocaine test dose significant history of drug/alcohol abuse Patients with Cardiac arrhythmias Patients with any other contraindication for regional anaesthesia
In the pre-anaesthesia assessment clinic, after history and physical examination, the following investigations were done- Hb, TC, DC, Platelet count, BT, CT, ECG, CXR and RFT. Informed written consent was taken from all patients.
On the day prior to surgery, the patients were re-examined. Patients were kept nil orally after 10pm.
On the day of surgery, in the pre-operative room, intravenous cannulation was done and IV ringer lactate 500 ml was given. Randomisation was done by the anaesthesiologist who did not participate in the observation of the study parameters. Patients were then taken to the operating room. Multipara monitors were connected and the vitals - ECG, heart rate, SpO2, NIBP were recorded.
Under all aseptic precautions, after infiltration of 2% lignocaine 2ml of local anaesthesia, epidural space was identified by loss of resistance technique at L2-L3 for lower abdominal surgery and L3-L4 interspace of lower limb orthopaedic surgery preferably, in the left lateral position and epidural catheter was left in place. Injection lignocaine 2% with adrenaline test dose 3ml was given. Patient was then made to lie down supine. The study drug (20ml)-either 0.5 % bupivacaine or 0.75% ropivacaine was given. The time of injection of epidural bolus dose was noted as time zero. Surgery was started only when adequate surgical anaestheia was attained. Further epidural top-ups were given only in the post-operative period when the patient first complained of pain.
The sensory block characteristics were assessed by using pin prick method at the mid-clavicular line bilaterally. The motor block was assessed by modified bromage scale.

Modified Bromage Scale

Grade	Definition
0	No motor block
1	Inability to raise extended leg; able to move knees and feet
2	Inability to raise extended leg and move knee; able to move feet
3	Complete block of motor limb

The following block characterstics were noted:

1. Time of sensory onset at T10: Time from epidural drug injection to the loss of sensation at T10 dermatome level.
2. Time of sensory onset at T6: Time from epidural drug injection to the loss of sensation at T6 dermatome level.
3. Time of onset of motor block of grade1: Time form epidural drug injection to the attainment of Bromage score of 1.
4. Time of onset of motor block of grade 2: Time form epidural drug injection to the attainment of Bromage score of 2.
5. Time of onset of motor block of grade 3: Time form epidural drug injection to the attainment of Bromage score of 3.
6. Highest sensory dermatomal level achieved
7. Time for two segment sensory regression: Time taken from the epidural drug injection to the regression of the maximal sensory regression by two dermatomomes
8. Time of motor block duration: Time from epidural drug injection to the motor block recovery to Bromage 0.
9. Time of sensory block duration: Time from epidural drug administration to the time when the patient first requests for first pain relief medication.
10. Quality of motor block (Bromage grade 1, 2 or 3)
11. Quality of Anaesthesia assessed based on anaesthesiologists's judgement.

Definitions:

1. Hypotension: was defined as fall in MBP 20% below the baseline or SBP below 90 mm Hg
2. Bradycardia was defined as heart rate below 50 beats per minute.

Vital parameters were recorded every 5 minutes throughout the surgery and every 15 min in the post operative period.

Statistical analysis

The mean and standard deviation was obtained from each of the measured quantitative parameters. The data was analysed by independent T test between the groups. The P value of <0.05 was taken as significant.

Results

The demographic data compared were age, sex, height, weight and height and was found to be comparable (p>0.05)

Table 1: Demographic Data

Demographic Data	Group B (n=30)	Group R (n=30)	P value
Age (in years)	35.53±12.56	36.1±9.15	0.8424 [NS]
Sex (M:F)	16:14	17:13	[NS]
Weight (in kgs)	55.67±12.93	55.6±10.08	0.9823 [NS]
Height (in cms)	159±6.25	160±6.85	0.4936 [NS]

Table 2: Time of Onset of Sensory Block at T10

Time of Onset Sensory (min) at T10	Group B (n=30)	Group R (n=30)
Mean ±SD	10.5 ± 1.68	10.87 ± 1.63
Range	7-15	8-14
P value	0.3945	[NS]

Table 3: Time of Onset of Sensory Block at T6

Time of Onset Sensory (min) at T6	Group B	Group R
Mean ±SD	16.63 ± 1.93 (n=16)	16.07 ± 2.12 (n=15)
Range	12-18	13-19
P value	0.4487	[NS]

Table 4: Time of Onset of Motor block

Time of Onset Motor (min)	Group B	Group R	P value
Modified bromage score			
Grade 1 block	16.63 ± 1.81 (n=30)	15.9 ± 1.88 (n=30)	0.1294 [NS]
Grade 2 block	25.13 ± 2.01 (n=30)	24.77 ± 1.85 (n=30)	0.4656 [NS]
Grade 3 block	29.31 ± 3.1 (n=26)	29.04 ± 2.65 (n=24)	0.7463 [NS]

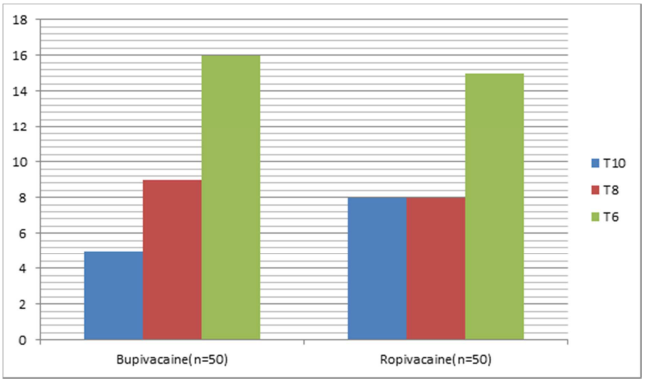

Chart 1: Maximum level of sensory block attained in each group

Table 5: Maximum level of sensory block achieved in each group

Maximum level achieved	Group B	Group R
T6	16	15
T8	9	8
T10	5	7

Table 6: Time for two segment sensory regression

Time of Two Segment Sensory Regression (min)	Group B	Group R
Mean ±SD	160.27 ± 31.01	162.93 ± 26.85
Range	135-210	107-218
P value	0.7231	[NS]

Table 7: Quality of motor block

Bromage Score	Group B (n=30)	Group R (n=30)
Grade 0	0	0
Grade 1	0	0
Grade 2	4	6
Grade 3	26	24

Table 8: Duration of motor block

Duration of motor block (min)	Group B (n=30)	Group R (n=30)
Mean ±SD	284.27 ± 24.20	240.1 ± 19.19
Range	232-332	197-263
P value	0.0001	[p<0.05, Significant]

Table 9: Duration of sensory block/Analgesia

Duration of senory block (min)	Group B (n=30)	Group R (n=30)
Mean ±SD	317.47 ± 41.36	325.34 ± 37.96
Range	262-390	264-389
P value	0.4459	[NS]

Table 10: Quality of Anaesthesia.

Quality of Anaesthesia	Group B (n=30)	Group R (n=30)
Excellent [2]	25	23
Good [1]	3	3
Not satisfactory [0]	2	4

Table 11: Side effects

Side Effects	Group B (n=30)	Group R (n=30)
Hypotension	6	3
Bradycardia	3	2
Nausea/Vomitting	5	3
Shivering	2	3

The changes in the heart rate, systolic blood pressure, diastolic blood pressure and the mean blood pressure were statistically insignificant between the two groups (p>0.05).

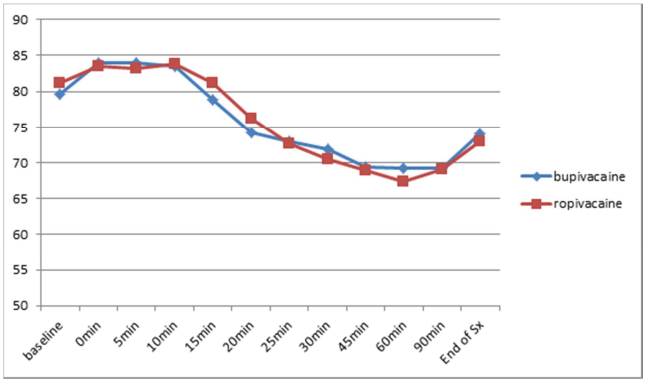

Figure 1: Changes in the Heart Rate

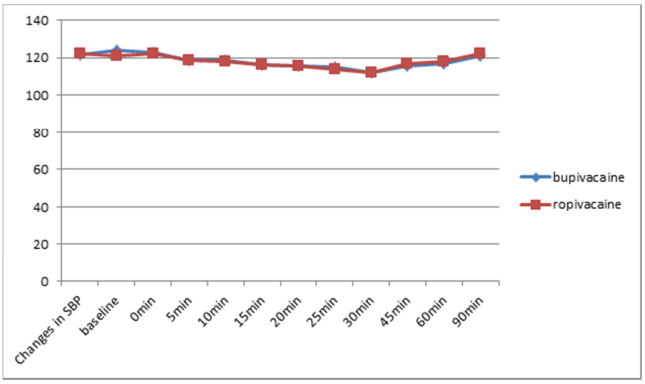

Figure 2: Changes in the systolic blood pressure

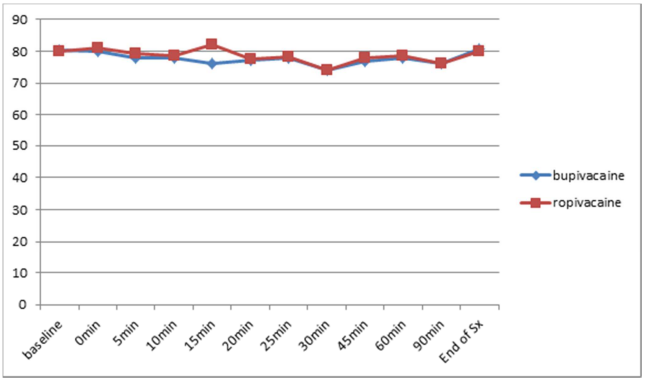

Figure 3 changes in the diastolic blood pressure

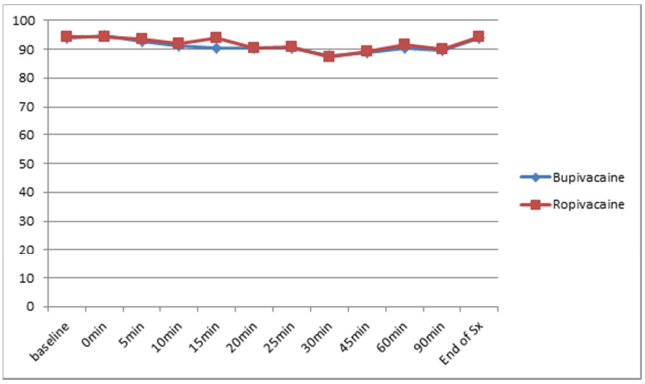

Figure 4: Changes in the mean blood pressure

Discussion

We did a study to compare the efficacy of 20ml epidural doses of 0.5 % Bupivacaine and 0.75% Ropivacaine in lower abdominal surgeries and lower limb surgeries in 60 patients, of ASA 1 and 2, of age from 18-60 years, in two groups of 30 patients in each group. All the patients completed the study.

The demographic data was comparable in between the groups ($p>0.05$).

The time of onset of the sensory block at T10 was comparable between the groups B and R. [10.5 ± 1.68 min and 10.87 ± 1.63 min respectively]. 16 patients in group B and 15 patients in group R had maximum sensory level of T6. The time of onset of sensory block at T6 was 16.63 ± 1.93 min (n=16) in group B and 16.07 ± 2.12 min (n=15) in group R (p=0.4120).

The time of onset of motor block was comparable between the two groups B and R [16.63 ± 1.81 min, 15.9 ± 1.88 min respectively for Grade 1 modified bromage score] and [25.13 ± 2.01 min, 24.77 ± 1.85 min for Grade 2 Bromage score]. 26 patients in Group B and 24 patients in group R had maximum motor level of grade 3 in modified bromage scale and the time of onset was [29.31 ± 3.1 min (n=26) in B, 29.04 ± 2.65 min (n=24) in R for Grade 3 Bromage score]. The difference was statistically insignificant ($p>0.05$).

The time for two segment regression of the sensory block was also comparable between the groups ($p>0.05$) [160.27 ± 31.01 min and 162.93 ± 26.85 min respectively]

26 patients in bupivacaine and 24 in ropivacaine had grade 3 block. Only 4 patients in group B and 6 in group R had maximum level of motor block of grade 2.

Bupivacaine had a longer duration of motor block (284.27 ± 24.20 min) compared to Ropivacaine (240.1 ± 19.19 min). The difference was statistically significant ($p<0.0001$).

However, the duration of sensory block was statistically insignificant between the groups (317.47 ± 41.36 min and 325.34 ± 37.96 min respectively). 25 patients in group B and 23 patients in group R had excellent anaesthesia, 3 in each group had good or satisfactory anaesthesia whereas 2 in group B and 4 in group R had unsatisfactory anaesthesia (n=30).

6 patients in group B and 3 in group R had hypotension. 5 in group B and 3 in R had nausea/vomiting. The incidences of bradycardia and shivering were comparable between the groups (3:2 and 2:3 respectively).

The haemodynamic parameters-heart rate, systolic blood pressure, diastolic blood pressure and mean blood pressure were comparable in between the groups.

McGlade et al,[10] compared 0.5% ropivacaine and 0.5% bupivacaine in 67 patients (32 patients in R and 35 patients in B) with 20ml of study drug in epidural anaesthesia at L-L3/L3-L4 interspacae for orthopaedic surgeries. The onset at T10 dermatomomal level was 10 min (5-15min) for Ropivacaine and 10min (6-15 min). The duration was 3.5 hrs (2.7-4.3 hrs) and 3.4 hrs (2.5-3.8 hrs) respectively. Maximum block height was T6 (T2-T12) and T6 (C7-T10) respectively. The motor and sensory block was judged satisfactory in 78% of patients in R and; 71% and 62% of patients in B. 9 patients in R and 8 in B showed no apparent motor block. Cardiovascular changes were comparable in both groups. No statistical differences were found in the study parameters in between R and B groups.

Peduto et al,[11] compared epidural 15ml 0.5% levobupivacaine and 0.5% ropivacaine in 60 patients (n=30) of ASA 1-3 in lower limb surgeries. The onset time of motor block was 29 ± 24 min, with ropivacaine it was 25 ± 22 min (P = 0.41). levobupivacaine took 105 ± 63 min for complete resolution of motor block took with levobupivacaine and ropivacaine took 95 ± 48 min with ropivacaine (P = 0.86). The time for regression of sensory block to T12 was 185 ± 77 min with levobupivacaine and 201 ± 75 min with ropivacaine (P = 0.46). The authors concluded that levobupivacaine 0.5% 15 ml produces an epidural block similar to ropivacaine 0.75% 15 ml.

Brendan et al,[12] compared 25ml epidural ropivacaine (0.5%, 0.75%, 1.0% and bupivacaine 0.5%) in patients undergoing abdominal hysterectomy in 120 patients. The most consistent

differences were noted between ropivacaine 1.0% and 0.5% and the least consistent between ropivacaine 0.5%, 0.75% and bupivacaine 0.5%. The main difference between ropivacaine 1.0% and bupivacaine was in sensory duration. No serious adverse events occurred in this study.

Tuttle et al,[13] conducted a study comparing 20 ml epidural 0.75% ropivacaine and 0.75% bupivacaine at L2-3/L3-4 interspace in 66, ASA I-III patients of 18-70 years age on patients undergoing elective gynaecological surgery.

The time for maximum and peak sensory block were similar in both groups (p>0.05). The complete sensory regression was significantly longer in B compared to R 9(458 +/- 77 vs. 404 +/- 62 minutes, P < .03). The motor onset of B was significantly faster than R ((9 +/- 3 vs. 12 +/- 3 minutes, P < .0013). The maximum motor block onset was significantly faster in B compared to R ((28 +/- 12 vs. 40 +/- 15 minutes, P < .0234). The duration of motor block was significantly longer with B compared to R (371 +/- 97 vs. 310 +/- 65 minutes P < .069).

A few differences noted from our study is because we used 0.5% Bupivacaine as it is considered equipotent to 0.75% ropivacaine. However, in our study the motor block was significantly prolonged in B compared to R.

Beilin et al,[14] compared ropivacaine and bupivacaine for labour analgesia. The authors found both ropivacaine and bupivacaine effective for labour analgesia with no statistical differences between in maternal satisfaction, mode of delivery or labor characterstics. Ropivacaine caused less motor block. Our study coorelates with this study.

Brockway et al,[15] compared Ropivacaine with bupivacaine in 110 patients in 5 groups with epidural 15ml of 0.5, 0.75 or 1.0% ropivacaine or 0.5 or 0.75% bupivacaine. There was little difference between the groups with respect to speed of onset or sensory block. The duration of analgesia was increased by increasing the concentration of both drugs, but 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. Ropivacaine produced a slower onset, shorter duration and less intense motor block than the same concentration of bupivacaine. The cardiovascular changes were similar in all groups. We used equivalent doses of both drug groups.

Conclusion

Epidural Ropivacaine is comparable to epidural bupivacaine in terms of the onset of sensory and motor block, maximum sensory level achieved, two sensory segment regression time, quality of the motor block, the duration of sensory block, and the haemodynamic effects. However, the duration of the motor block was significantly shorter in Ropivacaine compared to Bupivacaine which is desirable in the post operative period. Also, Ropivacaine showed lesser incidences of side effects like hypotension, bradycardia, nausea/vomiting compared to bupivacaine.

We therefore conclude that epidural ropivacaine can be safe alternative to epidural bupivacaine in lower abdominal and lower limb surgeries.

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