

A COMPARATIVE STUDY OF EFFICACY OF INRATHECAL ROPIVACAINE 0.5% (PLAIN) VERSUS BUPIVACAINE 0.5% (PLAIN)

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ABSTRACT: BACKGROUND: Bupivacaine is the most commonly used drug for spinal anesthesia. Ropivacaine is a relatively new enantiomerically pure isomer of bupivacaine with a low pKa and low lipid solubility as well as less cardiotoxicity with a possibility of shorter duration of sensory as well as motor block compared to bupivacaine. The shorter duration of block could be helpful in early ambulation and early discharge particularly in day care settings. **AIMS AND OBJECTIVES:** The aim of the study were to evaluate the onset and duration of sensory and motor block, the maximum height of sensory block as well as the degree of motor block and haemodynamic stability of ropivacaine in comparison with bupivacaine. **METHODS AND MATERIALS:** Eighty ASA I or II patients undergoing lower abdominal and lower limb surgeries were randomly divided into two groups, Group R(n=40) received 3ml (15mg) of isobaric ropivacaine intrathecally and Group B(n=40) received isobaric bupivacaine 3ml(15mg) intrathecally. The onset and duration of sensory and motor block, height of sensory block and degree of motor block and haemodynamic stability were noted. **RESULTS:** Onset of sensory block and motor block were similar in both the groups. Onset time of sensory block in group R was 7.49±3.05min and in group B was 6.75±2.01min (p value 0.2). Onset of motor block in group R was 2.23±1.63min and in group B was 2.27±1.34 min(pvalue0.16). The highest level of sensory block (T₄) obtained in group R was n=3(7.5%), and in group B n=8(20%) (p<0.01) The duration of sensory block in group R was 181.93±46.87min and in group B was 247±51.77min (pvalue<0.001). The duration of motor block in group R was 158.49±42.7min and in group B was 222±48.53min (p<0.001). The degree of motor block was complete in both groups. There was no significant difference in haemodynamic stability between the groups. **CONCLUSION:** Intrathecal isobaric ropivacaine 15mg is similar to isobaric bupivacaine 15mg with respect to onset of sensory and motor block as well as degree of motor block. However a shorter duration of both sensory and motor block was seen in ropivacaine group compared to bupivacaine group. **KEYWORDS:** Spinal anaesthesia, intrathecal isobaric bupivacaine, isobaric ropivacaine, sensory block, motor block.

INTRODUCTION: Spinal anesthesia, defined, as 'the regional anesthesia obtained by blocking nerves in the subarachnoid space' is a popular and common technique used worldwide.

The advantages of an awake patient, simplicity of the procedure, rapid onset of action, minimal drug cost, relatively less side effects and rapid patient turnover has made this the technique of choice for many a surgical procedure.¹

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Subarachnoid block is the anesthetic technique of choice for surgical procedures involving lower limbs, pelvis, and lower abdomen, as the technique is simple and provides for all the requirements of surgery like analgesia and motor block with a single drug.²

Various drugs have been used to produce spinal anesthesia. Lidocaine was the widely used drug to produce anesthesia. It was associated with a very rapid onset and a shorter duration of action and also a high incidence of transient neurological symptoms.³

Presently, Bupivacaine is the widely used drug, but has a prolonged duration of action, prolonged motor blockade and also cardiotoxicity.

Ropivacaine is a relatively new amino amide local anesthetic agent which is long acting and a enantiomerically pure isomer of Bupivacaine(s isomer). It has a low pka and low lipid solubility, and is considered to block sensory nerves to a greater extent than motor nerves⁴ and having similar local anaesthetic properties and chemical structure to that of bupivacaine.⁵

Because of sensorimotor dissociation, ropivacaine should be a favourable local anesthetic for day care surgery and could be associated with earlier post-operative mobilization than Bupivacaine.⁶

Ropivacaine was first approved for intrathecal use in the European Union in 2004⁷ and there are limited studies comparing plain bupivacaine solutions with plain ropivacaine. Hence the present study was undertaken to assess the duration of sensory and motor blockade of intrathecal ropivacaine and side effects if any compared to intrathecal bupivacaine.

METHODS: After obtaining institutional ethical committee clearance and informed written consent 80 adult patients of ASA Physical status I & II in the age group of 18-60 years of either sex, posted for elective lower limb, lower abdominal, gynecology and urology surgeries were enrolled for the study.

Patients were randomly divided into two groups of 40 each.

Group "B" Bupivacaine group - Receiving Intrathecal isobaric 0.5%
Bupivacaine 3ml (15 mg)

Group 'R" Ropivacaine group- Receiving Intrathecal isobaric 0.5%
Ropivacaine 3ml (15mg)

Patients belonging to ASA class III&IV, with comorbid medical conditions, coagulation disorders or on anticoagulant therapy, local infection at site of puncture for spinal anesthesia and with abnormalities of the spine like kyphosis and scoliosis were excluded from the study.

After a detailed preanesthetic evaluation done the day before surgery, patients were kept nil by mouth from 10 P.M. and were premedicated orally with tablet alprazolam 0.5mg and tablet ranitidine 150mg the night before surgery.

On the day of surgery after shifting to the operating table, intravenous access was obtained on the forearm with 18 Gauge intravenous canula and preloading was done with 10ml/kg of ringer lactate solution before performing the block.

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The monitors connected to the patient included non-invasive blood pressure, pulse oximeter and ECG monitors. Baseline Pulse rate, systolic blood pressure, diastolic blood pressure, and oxygen saturation was recorded.

Under strict aseptic precautions, lumbar puncture was performed in lateral position by midline approach by using disposable Quincke spinal needle (25-27 G) at L3-L4 intervertebral space and study drug was administered over 30sec

After the spinal block, pulse rate, respiratory rate and blood pressure were measured at 0, 1, 2, 3, 5, 10, 15, 20, 25, 30, 45, 60, 90, 120, 180 min

Hypotension was defined as 20% decrease in blood pressure from baseline values, and was treated with incremental intra venous boluses of ephedrine. Bradycardia was defined as pulse rate less than 60bpm and treated with intravenous atropine 0.6mg.

O₂ 4l/min via face mask and intravenous fluids at the rate of 10ml/kg/hr were administered throughout the period of surgery.

Assessment of sensory block:

- Sensory block was tested by pin-prick method.
- The time to obtain T₁₀ sensory block from the time of injection of drug into subarachnoid space was considered as the time of onset.
- The highest sensory level obtained was noted.
- The duration of sensory blockade was taken as time from onset to time of return of pinprick sensation to S1 (lateral aspect of foot) dermatomal area.
- Requirement of supplemental analgesics intra operatively was noted

Assessment of Motor Blockade: This was done using modified Bromage scale.⁸

- Grade 0- Full flexion of knees and feet.
- Grade 1- Just able to flex knees, full flexion of feet.
- Grade 2- unable to flex knees but some flexion of feet possible
- Grade 3- unable to move legs or feet.

The time interval between injections of drug into subarachnoid space, to the patient's inability to lift the straight extended leg was taken as onset time (grade 2).

The duration of motor block was taken from time of injection to complete regression of motor block. (ability to lift the extended leg, grade 0).

Quality of intraoperative analgesia: Was assessed on a four point modified Belzarena scale⁹

1. Unable to tolerate pain
2. Able to tolerate discomfort with additional analgesia
3. Some discomfort but no additional analgesia required
4. Completely satisfied

Side effects like nausea, vomiting, sedation and urinary retention were monitored in the recovery room and shifted to ward. Neurological examination was done to rule out any neurological deficits at the time of discharge.

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Data were analyzed by applying statistical test such as percentage, proportions, Student's t-test or Chi-square test where ever appropriate. All values were expressed as mean±standard deviation and $P < 0.05$ was considered statistically significant.

RESULTS: None of the patients were excluded from statistical analysis.

There was no statistically significant difference between the groups with respect to age, height, sex and weight of the patients.

Sensory block:

Time of Onset of Sensory Block: The mean time for onset of sensory block in Group R was 7.49 ± 3.05 minutes and in Group B was 6.75 ± 2.01 minutes, with p value 0.2, which was statistically not significant.

Highest level of sensory block: In Group R, 3(7.5%) of the patients achieved a level of T₄ while in Group B, 8(20%) of the patients achieved a level of T₄. 42.5%(17) of patients achieved a level of T₆ in group R while 62.5% (25) of patients achieved a level of T₆ in group B. There was a statistically significant difference in the number of patients achieving T₆ sensory block. (p 0.017).

Duration of sensory block: The mean duration of sensory block(regression of sensory block to S1) was 181.93 ± 46.87 minutes for group R and 247 ± 51.77 minutes for group B which was clinically and statistically significant (p value < 0.001)

Motor block:

Onset time of motor blockade: The mean time for onset of motor blockade was 2.23 ± 1.63 minutes for group R and 2.27 ± 1.34 minutes for group B (P value 0.9) and was statistically not significant.

Degree of motor block: Complete motor block was seen in all patients in both groups without any statistically significant difference.

Duration of motor block: Duration of motor blockade ranged from 125 min to 218 min in group R while it was between 180 min to 298 min in group B. The mean duration of motor block in group R was 158.49 ± 42.76 min, while in group B it was 222 ± 48.53 min (p < 0.001) which was statistically significant.

Haemodynamic changes: Both groups noted a fall in systolic blood pressure after the administration of spinal anaesthesia. Maximum fall was seen between 5th and 25th minute. The magnitude of fall was greater in group B compared to group R and was statistically significant.

Comparison of systolic blood pressure between two groups: There was fall in diastolic blood pressure in both the groups but was statistically not significant.

There was no significant difference in the pulse rate between the two groups.

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Side Effects: 2 patients in group R had hypotension while 4 patients in group B had hypotension. Bradycardia was seen in 2 patients in group B. No cases of nausea, vomiting and respiratory depression were reported in either of the groups.

DISCUSSION: Subarachnoid block is a commonly employed anaesthetic technique for surgeries of the lower abdomen and lower limb. It is a safe, inexpensive and easy to administer technique which produces anaesthesia, analgesia and relaxation with a single drug thus avoiding poly pharmacy, and also provides post-operative pain relief. The risks of general anaesthesia are avoided.

Bupivacaine is the local anaesthetic widely used for spinal anaesthesia because of its high potency and minimal neurological toxicity. Though cardiotoxicity is not a concern in subarachnoid block, the quality of sensory and motor blockade, hemodynamic changes and side effect profile are some considerations in selecting a drug for spinal anaesthesia.

Ropivacaine, a s-enantiomer¹⁰ of bupivacaine is being increasingly used for spinal anaesthesia in lower abdominal, perineal surgeries as well as lower limb surgeries. Advantages claimed are shorter duration of motor block with similar sensory block properties compared to bupivacaine,¹¹ thus minimising the psychological discomfort of being immobile for long time.

Low cardiotoxicity is also a major advantage. Hence this study was undertaken to assess the sensory and motor block characteristics of ropivacaine for spinal anaesthesia in patients coming for surgeries of lower abdomen and lower limbs. Bupivacaine 0.5%(H) 15mg is the commonly used drug in our institute. Hence a equivolume dose of 15mg (3ml of 0.5%) Ropivacaine was selected for the study. Since hyperbaric ropivacaine is not available commercially, we chose isobaric solutions of Ropivacaine and Bupivacaine.

Both the groups were similar with respect to demographic profile in order to avoid variations in intraoperative and post-operative outcomes.

Sensory block characteristics: The mean time for onset of sensory block in group R was 7.49 ± 3.05 min and in Group B was 6.75 ± 2.01 min ($p > 0.2$) which was statistically not significant.

This observation was comparable to the study done by C.O. Ogun et al¹² who compared intrathecal isobaric ropivacaine 15 mg with morphine 150 μ g and isobaric bupivacaine 15 mg with morphine 150 μ g for women undergoing caesarean section. The onset of sensory block was 7.2 ± 4 min for Ropivacaine with morphine group and 7.3 ± 4.2 min for the Bupivacaine with morphine group.

In another study by DA McNamee et al¹³ who compared 3.5ml of ropivacaine with 3.5ml of bupivacaine in patients undergoing Total hip replacement, the median onset time for sensory block was similar in both the groups, 2min (range 2-5min) in ropivacaine and 2min (range 2-9min) in bupivacaine group.

Highest level: In our study the highest level of sensory block achieved was T4 in both groups, with 3 patients (7.5%) in group R and 8 patients (20%) in group B ($p < 0.017$) and it was statistically significant.

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In the study done by C.O. Ogun et al¹², maximum level of sensory block attained in Ropivacaine group was T4 and Bupivacaine group was also T4 which was statistically not significant.

Malinovsky et al¹⁴ in their study comparing ropivacaine 15 mg and bupivacaine 10 mg in patients undergoing urology surgeries, found the highest level of sensory block in bupivacaine group to be T₇ while in ropivacaine group it was T₉ (p<0.001) which was higher in bupivacaine group and was statistically significant.

DA McNamee et al¹³ also found the level of sensory block to be higher in the bupivacaine group compared to ropivacaine group but this difference was not significant.

JB Whiteside et al¹⁵ who compared hyperbaric bupivacaine with hyperbaric ropivacaine found the level of sensory block to be significantly higher in bupivacaine group.

Findings of our study correlate with that of Malinovsky et al and TB White et al.

Duration of sensory block: J.B. Whiteside et al¹⁵ found the total duration of sensory block shorter with Ropivacaine (180min) compared to Bupivacaine (255min) group and this was statistically significant p< 0.0001.

Malinowski et al¹⁴ also found a significant difference in the duration of sensory block between bupivacaine and ropivacaine groups (105±29min and 127±41min respectively, pvalue <0.01)

C.O. Ogun et al¹² did not find any difference in the duration of sensory block between the two groups.

In our study there was a significant difference in the duration of sensory block between the two groups being 181.93±46.87min in group R and 247±51.77min in group B respectively.

Our findings correlate with that of JB Whiteside et al and Malinovsky et al.

Motor block characteristics: DA McNamee et al¹³ in their study found the median onset time for motor block of Bromage scale 2 to be 4min in both bupivacaine and ropivacaine groups.

J. M Malinovsky et al¹⁴ found no significant difference in the time of onset of complete motor block between ropivacaine and bupivacaine groups (25±12min vs 24±17min).

C. O Ogun et al¹² found faster onset of motor block in bupivacaine morphine group compared to ropivacaine morphine group (4±2min vs 5.9±3.3min, pvalue <0.05).

In our study time to onset of motor block Bromage 2 was 2.23±1.6 min in group R and 2.7±1.34min in group B (pvalue 0.16) and was statistically not significant. Our study correlates with that of DA McNamee et al and JM Malinovsky et al.

Degree of motor block: CO Ogun et al¹² found the degree of motor block to be 96% in bupivacaine morphine group and 88% in ropivacaine morphine group, and in the study by DA McNamee et al¹³ all the patients in both the groups developed complete motor block.

In our study also all the patients in both the groups developed complete motor block.

Duration of motor block: Mc Namee et al¹³ noted the duration of motor block to be significantly shorter in ropivacaine group (2.1hrs) compared to bupivacaine group (3.9hrs). Helena Kallio et al¹⁶ also noted the duration of sensory block to be significantly shorter in

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ropivacaine group (150min) compared to bupivacaine group (210 min). The findings of various studies correlate with our study where we found the time to recovery of complete motor block (Grade3 to Grade0) to be 158.49 ± 42.76 min in ropivacaine group compared to 222 ± 48.5 min in the bupivacaine group.

Quality of intra operative analgesia: There was no significant difference in the quality of intra operative analgesia between the two groups

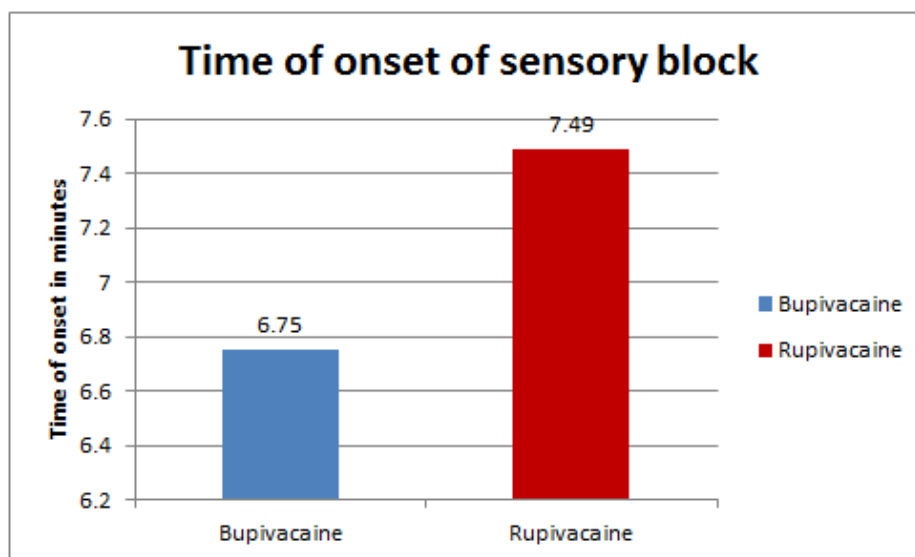
Haemodynamic parameters: In our study hypotension occurred in 3% of the cases in ropivacaine group and 10% of the cases in bupivacaine group and was easily managed with ephedrine boluses. The mean fall in systolic blood pressure was significantly greater in the bupivacaine group compared to ropivacaine group and was same as in the study by DA McNamee et al¹³

Where 12% of the patients in ropivacaine group developed hypotension compared to 26% of the cases in bupivacaine group.

Bradycardia was seen in 5% of cases in bupivacaine group and none in ropivacaine group.

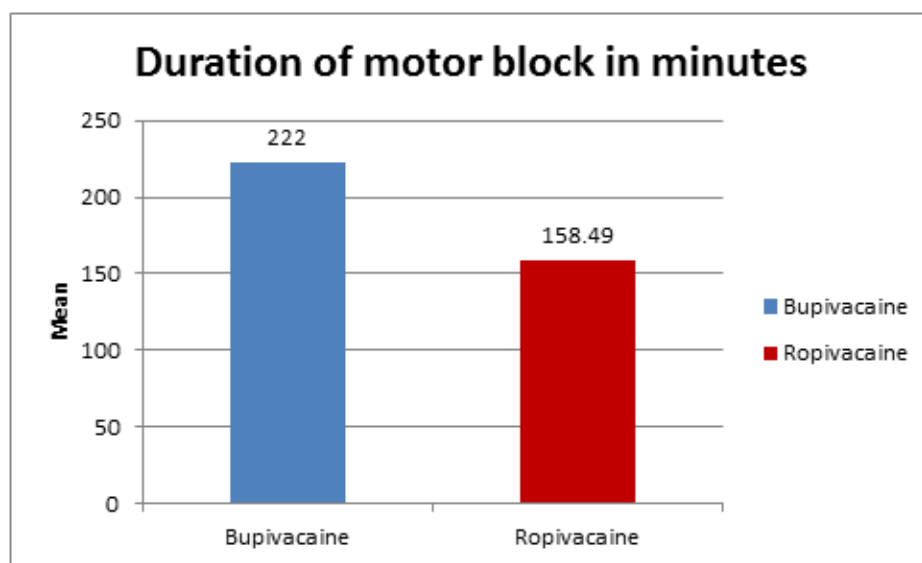
No adverse effects were seen in either of the groups.

CONCLUSION: In conclusion isobaric ropivacaine 15mg when administered intrathecally provides adequate anaesthesia for lower abdominal and lower limb surgeries. The onset time of sensory and motor block as well as the degree of motor block of ropivacaine is comparable to that of bupivacaine, but ropivacaine is associated with a shorter duration of both sensory and motor block compared to bupivacaine leading to early recovery and ambulation. Hence Ropivacaine is a safe alternative to bupivacaine for surgeries of lower limb when early ambulation and early discharge are needed as in day care anaesthesia.

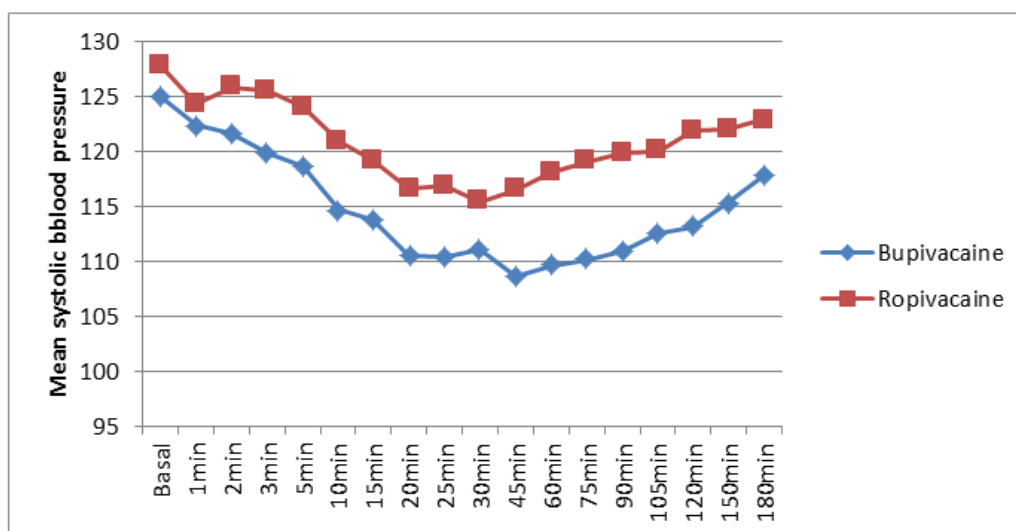


Graph 1: Time of onset of Sensory Block

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Graph 2: Duration of Motor Block



Graph 3: Hemodynamic Parameters

Parameter	Group R	Group B	P Value
Age (Years)	33.85±9.29	38.18±9.29	0.42 NS
Sex Male/Female	20:20	22:18	0.8 NS
Height (cms)	162.58±4.5	161.07±6.2	0.216NS
Weight (Kgs)	63.73±5.72	61.62±5.17	0.08 NS

Table 1: Demographic Profile

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Highest Level of Sensory block	Group R	Group B
T4	3 (7.5%)	8 (20%)
T6	17 (42.5%)	25(62.50%)
T8	18 (45%)	6 (15%)
T10	2 (5%)	1 (2.5%)
T12	0	0

Table 2: Highest Level of Sensory Block

	Group R	Group B	P Value
Duration of sensory block (min)	181.93±46.87	247±51.77	<0.001

Table 3: Duration of Sensory block

	Group R	Group B	P Value
Onset of Motor block (min)	2.23±1.63	2.27±1.34	0.16 NS

Table 4: Onset of Motor Block

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