

Comparison between Intrathecal isobaric Ropivacaine 0.75% with Hyperbaric Bupivacaine 0.5% in Lower Abdominal and Lower Limb Surgeries

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Abstract: Spinal anaesthesia is widely used for lower limb and lower abdominal surgeries. It has been the mainstay for regional anaesthesia in developing countries, especially in India. Bupivacaine is being extensively used and produces an adequate sensory and motor blockade. However, it has its own disadvantages and side-effects such as cardiac and central nervous system toxicity. Newer long-acting local anaesthetics (ropivacaine, levobupivacaine) have recently been introduced for clinical use. The claimed benefits of these are reduced cardiac toxicity on overdose and more specific effects on sensory rather than motor nerve fibres. In our study, we compared the efficacy of 22.5 mg (3ml) of 0.75% isobaric ropivacaine with a control group using 15 mg (3ml) of 0.5% hyperbaric bupivacaine. Ropivacaine for intrathecal anaesthesia in the lower abdominal and lower limb surgeries provided an adequate level of block for the surgery with lesser duration of motor blockade with good analgesia and more hemodynamic stability so it can be safely use for day care surgery.

Keywords: Spinal anaesthesia, Bupivacaine, Ropivacaine, lower limb surgeries, Lower abdomen surgeries

1. Introduction

Spinal anaesthesia, also called spinal analgesia or sub-arachnoid block (SAB), is a form of regional anaesthesia involving injection of a local anaesthetic into the cerebrospinal fluid (CSF) through a fine needle.

Spinal anaesthesia is widely used for lower limb and lower abdominal surgeries. It has been the mainstay for regional anaesthesia in developing countries, especially in India. Various local anaesthetics have been injected into the intrathecal space to achieve intrathecal blockade, starting with cocaine way back in 1898.

Bupivacaine is being extensively used and produces an adequate sensory and motor blockade. However, it has its own disadvantages and side-effects such as cardiac and central nervous system toxicity

The acute and most serious adverse effects of local anaesthetics involve the cardiovascular and central nervous system. They are usually because of accidental intravascular injections or a pronounced overdose. These adverse effects have prompted a search for drugs with lesser toxicity.

Newer long-acting local anaesthetics (ropivacaine, levobupivacaine) have recently been introduced for clinical use. The claimed benefits of these are reduced cardiac toxicity on overdose and more specific effects on sensory rather than motor nerve fibres.

Ropivacaine was developed after bupivacaine, ropivacaine was found to have less cardiotoxicity than bupivacaine in animal models. Unlike bupivacaine, ropivacaine has been developed and marketed as the pure S (-) enantiomer of ropivacaine. It is less lipophilic than bupivacaine. This property is associated with a decreased potential for CNS toxicity and cardiotoxicity.¹

Numerous experimental studies were conducted to identify the fine cellular mechanism of the local anaesthetic toxicity which refined the understanding of their action. The identification of optically active isomers of the mepivacaine family led to the selection of ropivacaine, a pure S(-) enantiomer, whose toxicology was selectively and extensively studied before its introduction on the market in 1996. During the rapid and extensive use of ropivacaine in the clinic, unwanted side-effects have been found to be very limited.

Besides being well tolerated and safe, ropivacaine has a short time to onset of anaesthesia and results in a sensory and motor blockade of duration appropriate for the indication or procedure.

In the present study, we compared the efficacy of 22.5 mg (3ml) of 0.75% isobaric ropivacaine with a control group using 15 mg (3ml) of 0.5% hyperbaric bupivacaine. The parameters that were observed are: duration of motor blockade, sensory and motor onset and duration of analgesia.

2. Literature Survey

Morrison SG et al (2000) A comparison study of the electrocardiographic cardiotoxic effects of racemic bupivacaine, levobupivacaine, and ropivacaine in anesthetized swine concluded that levobupivacaine and ropivacaine to be less cardiotoxic than racemic bupivacaine.

P. Gautier et al (2003) "Comparison of the Effects of Intrathecal Ropivacaine, Levobupivacaine and Bupivacaine for Caesarean Section," They observed longer duration of analgesia and motor block with bupivacaine as compared to levobupivacaine and ropivacaine.

Bhat SN, Himaldev, Upadya M. et al. (2013), Comparison of efficacy and safety of ropivacaine with bupivacaine for intrathecal anaesthesia for lower abdominal and lower limb surgeries. They conclude that use of ropivacaine for intrathecal anaesthesia in the lower abdominal and lower limb surgeries provided an adequate level of block for the surgery with faster onset of sensory and motor blockade, lesser duration of motor blockade with good analgesia and stable hemodynamic.

C. Radhika Rani et al (2014) "A Comparative Study of Intrathecal Hyperbaric Bupivacaine 0.5% & Intrathecal Isobaric Ropivacaine 0.5% for Quality and Duration of Anaesthesia and Post-Operative Analgesia in Patients Undergoing Lower Limb Surgeries." They found that Ropivacaine 0.5% is safe and effective with minimal intra-operative & post-operative side effects and provides lesser grade of motor blockade and shorter duration of both sensory and motor blockade.

Chari VRR, Goyal A, et al (2013) Comparison between intrathecal isobaric ropivacaine 0.75% with hyperbaric bupivacaine 0.5%: A double blind randomized controlled study found that Intrathecal plain ropivacaine might be superior to bupivacaine in terms of a longer sensory block, and a shorter motor block duration. Therefore 0.75% isobaric ropivacaine can be safely used in lower limb and lower abdominal surgeries, especially in cases where early ambulation is desired.

Nanavati DS, et al, (2015): Comparative Evaluation of Hyperbaric Bupivacaine versus Isobaric Ropivacaine in Spinal Anaesthesia in Lower Abdomen and Lower Limb Surgery. Conclude that administration of 0.75% isobaric ropivacaine in spinal anaesthesia is found to have shorter duration of motor blockade and similar duration of analgesia with hemodynamic stability and without significant side effects and complications as compared to bupivacaine.

Layek A, Maitra, et al. (2015): Comparison between intrathecal isobaric ropivacaine-fentanyl and bupivacaine-fentanyl in elective infraumbilical orthopaedic surgery: A randomized controlled study. It shows intrathecal isobaric bupivacaine-fentanyl combination produces a significantly longer duration of analgesia, sensory block and motor block than isobaric ropivacaine-fentanyl combination. As ropivacaine has a shorter duration of sensory and motor block, it may be preferred in day care surgery.

3. Methods/Approach

After obtaining institutional ethical committee approval and written informed valid consent, a study of 100 patients of either sex, ASA-I/II in the age group of 15-65 years was conducted in Civil hospital, Ahmedabad.

Study Design

- An open labelled randomized, prospective and controlled study was done.
- 100 patients were divided into two equal groups.

Inclusion criteria:

- Age between 18 years to 60 years
- Genders: Both
- ASA physical status I and II.
- Elective orthopaedic surgeries, gynaecologic surgeries, lower abdominal surgeries under Spinal anaesthesia.

Exclusion criteria

- ASA status III, IV
- Emergency surgeries
- History of seizure disorder
- Patient with contraindication for spinal anesthesia.
- Previous mild allergic reaction to Bupivacaine or Ropivacaine.

All the patients underwent a pre-anaesthetic check-up before surgery and all the routine and specific investigations were noted. The patients were kept electively nil per oral for 6 hours before surgery. On the day of surgery, written informed valid consent was taken and prior to operation patients were explained about the procedure. Standard monitors like ECG, NIBP, and pulse oximeters were applied and patient's baseline parameters like pulse, blood pressure, respiratory rate, SpO₂ were recorded. Intravenous line secured in all the patients and intravenous fluid started. Patients were preloaded with ringer lactate 15ml/kg body weight 15 minutes before subarachnoid block.

One hundred selected patients were divided into two equal groups of 50 patients each by a lottery method.

GROUP R ROPIVACAINE GROUP: In this group patients were given 0.75% isobaric ropivacaine 3 ml (22.5 mg) intrathecal.

GROUP B BUPIVACAINE GROUP: In this group patients were given 0.5% hyperbaric bupivacaine 3 ml (15 mg) intrathecal.

PREMEDICATION: INJ. ONDENSATRON (0.15% mg/kg) INJ. MIDAZOLAM (0.05-0.1 mg/kg) i.v. given.

Under all aseptic precautions, subarachnoid block was given with suitable small-bore spinal needle (23G Quinke) in sitting or lateral position through mid-line approach intrathecally. Bupivacaine Group was injected with 3 ml 0.5% of hyperbaric bupivacaine and Ropivacaine Group was injected with 3 ml of 0.75% of isobaric ropivacaine. Pulse, blood pressure and SpO₂ were measured every 5 minutes for half an hour and thereafter every 10 minutes.

Sensory Blockade:

Onset of Sensory block was assessed by atraumatic pin prick test until it reaches desired level, then surgical incision allowed.

Sensory blockade was graded as

Grade 0: No loss of sensation to pinprick

Grade 1: Analgesia (pt. feel touch but no pain on pin prick)

Grade 2: Anaesthesia (pt. even not feel touch sensation on pinprick)

Onset time was defined as time taken from drug injection to complete ablation of sensation (sensory score 2). Duration of sensory block was defined as time from onset of block to complete return of paraesthesia (sensory score 0).

Motor Blockade:

The degree of motor blockade was assessed by loss of antigravity movements of the legs by the Bromage scale.

Bromage criteria of motor movement after intrathecal anaesthesia:

0 = no impairment of movement of legs and feet

1 = barely able to flex knees no impairment of movement of feet

2 = unable to flex knees and barely able to move feet

3 = unable to move feet or knees

The following readings were noted for assessment of onset of blockade:

T0 – Time of Spinal anaesthesia

T1 – Time of onset of sensory block (loss of pinprick sensation)

T2 – Time of onset of motor block (inability to lift the extended leg)

T3 – Total duration of sensory block

T4 – Total duration of motor block

In the intra-operative period, patients were closely monitored for pulse rate, respiratory rate, SpO₂, blood pressure and blood loss. Any side effects such as nausea, vomiting, pain, shivering, pruritus, sedation, respiratory discomfort was noted and treated with appropriate drugs.

Subsequently, patient was transferred to the Post Anaesthesia Care Unit (PACU) where residual sensory blockade was monitored and wearing off time was noted (when sensation to pinprick regressed by two-dermatome segment), residual motor blockade was monitored and its wearing off time was noted (when patient started to lift legs against gravity). Patients were transferred from the PACU after recording the two-segment sensory regression and motor wear-off time.)

Post-Operative Analgesia: Intensity of post-operative pain was evaluated using VAS Score (visual analogue scale) with grade 0 (no pain) to 10 (worst pain). Pain score were noted post-operatively at 30 mins, 60 min and then hourly interval. Time noted when patient regain VAS score of 4. Analgesia was considered satisfactory if the score was 3 or less. If VAS score was more than 4, analgesia was judged unsatisfactory and RESCUE ANALGESIA was administered in form of inj. Diclofenac 2mg/kg im.

Evaluation was stopped and time for need of first analgesia was noted. Both groups were compared for duration of analgesia.

Duration of postoperative analgesia = Time from onset of sensory blockade to time when patient VAS score > 4 (four).

Comparison between two Groups

Both groups were compared for

- Onset of sensory block (time taken from drug injection to complete ablation of sensation (sensory score 2).
- Onset of motor block (Time taken from drug injection to complete motor block (motor grade score 3)
- Duration of sensory block (time from onset of block to complete return of paraesthesia (sensory score 0).
- Duration of motor block (Time taken from complete motor blockade to restoration of movements of forearm (grade 0)
- Duration of Post-operative analgesia (Time from onset of sensory blockade to time when patient VAS score > 4 (four).

4. Results and Discussion

After studying 100 cases, the observation and results were summarized in tabulated form and described below. All the patients were divided into two groups with 50 patients in each group (n= 50).

- 1) Group R: Inj. Isobaric Ropivacaine 0.75% 3cc (22.5 mg)
- 2) Group B: Inj. Hyperbaric Bupivacaine 0.5% 3cc (15 mg)

Table 1: Age distribution among study participants (N=100)

Variable	Group R, (n=50)	Group B, (n=50)
Age (in years)	3 (6.0)	5 (10.0)
<20-35	15 (30.0)	21 (42.0)
35-50	24 (48.0)	15 (30.0)
50-65	4 (8.0)	6 (12.0)
>65	4 (8.0)	3 (6.0)
Mean Age (Mean ± SD)	41.7 ± 12.4	37.9 ± 13.0

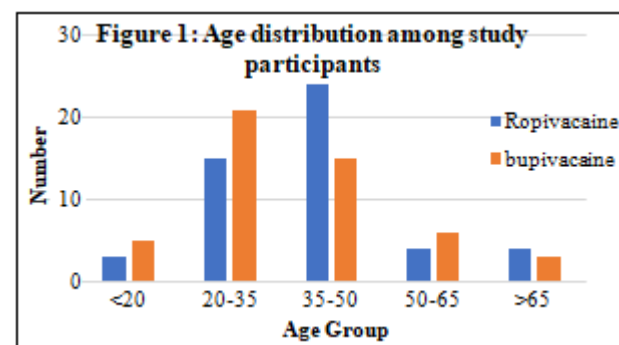


Table 1 and figure 1 suggest that 2 groups are comparable in respect to age of patients, there is no statistical difference between two groups.

Table 2: Gender distribution among study participants (N=100)

Gender	Group R, (n=50)	Group B, (n=50)
Male	20 (40.0)	25 (50.0)
Female	30 (60.0)	25 (50.0)
Male: Female ratio	01:01.5	1:01

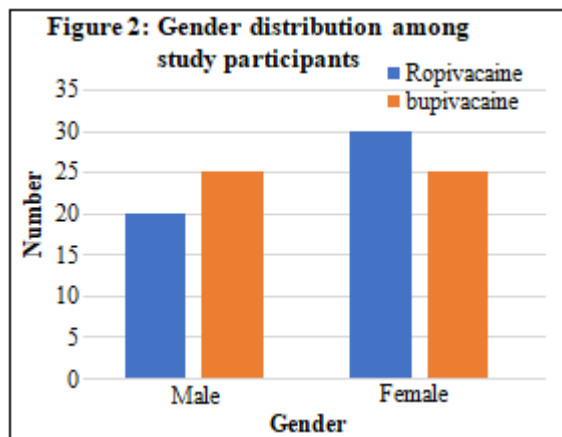


Table 2 and figure 2 suggest that two groups are comparable in respect to sex. There is almost equal male and female patients in both the group.

Table 3: Distribution of participants according to BMI classification (N=100)

BMI Classification	Group R, (n=50)	Group B, (n=50)
< 18.5	3 (6.0)	4 (8.0)
18.5 – 25.0	19 (38.0)	15 (30.0)
> 25.0	28 (56.0)	31 (62.0)
Mean BMI (mean ± SD)	27.1 ± 6.2	26.9 ± 5.9

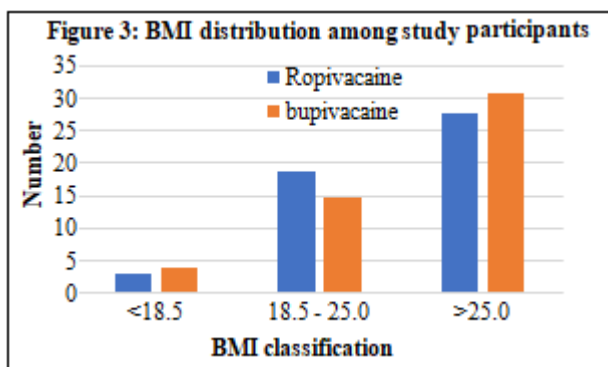


Table 3 and figure 3 suggest that patients in both the group are comparable in terms of BMI.

Table 4: Distribution of participants according to ASA grading (N=100)

ASA Grading	Group R, (n=50)	Group B, (n=50)
I	31 (62.0)	18 (36.0)
II	19 (38.0)	32 (64.0)

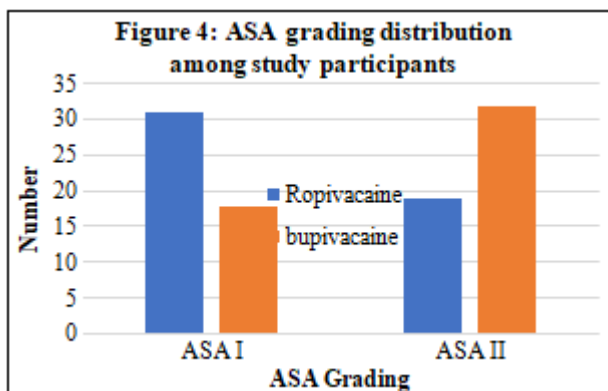


Table 4 and figure 4 suggest that patients in group R and group B are comparable in terms of ASA grading. Only patients with ASA Grade I and II are included in both the groups.

Table 5: Comparison of sensory and motor block parameters (N=100)

Parameter (in minutes)	Group R, (n=50)	Group B, (n=50)	p value*
Onset of sensory block (mean ± SD)	3.2 ± 0.33	2.5 ± 0.2	0.04
Duration of Sensory Block (mean ± SD)	135.8 ± 7.4	173.6 ± 7.8	0.001
Onset of motor block (mean ± SD)	3.9 ± 0.37	3.5 ± 0.21	0.01
Duration of motor block (mean ± SD)	130.1 ± 8.4	154.1 ± 7.1	<0.0001
Duration of Surgery (mean ± SD)	70.6 ± 16.4	76.0 ± 22.5	0.1
Duration of Analgesia (mean ± SD)	140.6 ± 7.4	178.0 ± 8.1	<0.001

- Table 5 shows mean onset time of sensory blockade and motor blockade with standard deviation in minutes in both groups.
- Sensory onset time was calculated from time taken from drug injection to complete ablation of sensation (sensory score 2).
- Motor onset time was calculated from Time taken from drug injection to complete motor block (motor bromage grade 3)
- According to data in table 5 suggest that sensory onset in ropivacaine group is significantly delayed than in bupivacaine group as p value is 0.04 (p<0.05).
- Motor onset in ropivacaine group is also significantly delayed than in bupivacaine group as p value is 0.01(p<0.05).
- Duration of sensory block is significantly shorter in ropivacaine group as p value is 0.001(p<0.05).
- Duration of motor block is significantly shorter in ropivacaine group as p value is 0.0001(p<0.05).
- There is no significant difference in duration of surgery in both the group.
- Also, there is significant difference in duration of post-operative analgesia in both the group, longer duration of post-operative analgesia in bupivacaine group as p value is <0.001(p<0.05).

Table 6: Mean Heart Rate (beats per minute) with standard deviation at various intervals

Time (in minutes)	Group R N=25	Group B N=25	P value	Inference*
Pre-op	73.2 ± 2.9	75.2 ± 3.5	0.07	Ns
2	70.6 ± 4.8	68.4 ± 4.1	0.13	Ns
10	68.8 ± 4.9	65.9 ± 2.5	0.09	Ns
15	67.4 ± 3.9	66.3 ± 3.7	0.12	Ns
30	68.6 ± 2.5	67.5 ± 3.4	0.18	Ns
45	72.2 ± 3.5	66.4 ± 3.3	0.05	Ns
60	69.7 ± 5.4	65.8 ± 3.8	0.06	Ns
75	68.8 ± 4.3	67.0 ± 3.7	0.15	Ns
90	67.8 ± 3.8	67.1 ± 2.7	0.11	Ns
120	71.6 ± 3.2	68.7 ± 3.5	0.20	Ns

*S = significant, Ns = non-significant

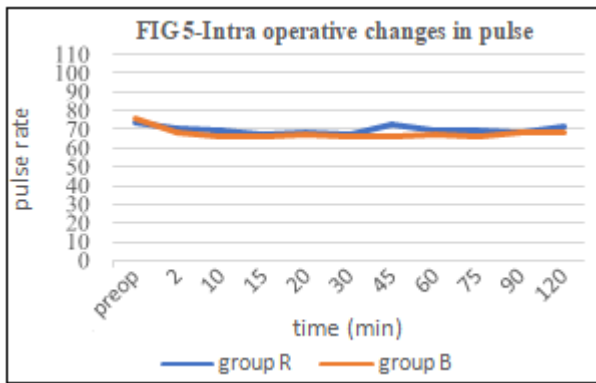


Table 6 and figure 5 suggest that there is no significant difference in intraoperative pulse rate changes.

Table 7: Mean systolic non-invasive blood pressure (mmHg) at various intervals

Time (in minutes)	Systolic blood pressure		P value
	Group R, N=50	Group B, N=50	
Pre-op	125.6 ± 8.4	123.2 ± 8.5	0.11
2	124.6 ± 12.1	120.3 ± 15.4	0.06
10	120.3 ± 8.0	116.1 ± 8.0	0.06
15	114.6 ± 5.8	110.8 ± 7.7	0.08
30	110.0 ± 14.0	104.1 ± 6.9	0.06
45	112.4 ± 14.1	102.4 ± 9.3	0.10
60	116.0 ± 5.4	109.3 ± 7.2	0.05
75	130.5 ± 4.9	122.2 ± 8.9	0.06
90	132.0 ± 3.5	120.0 ± 6.8	0.08
120	131.0 ± 4.2	126.0 ± 5.3	0.07

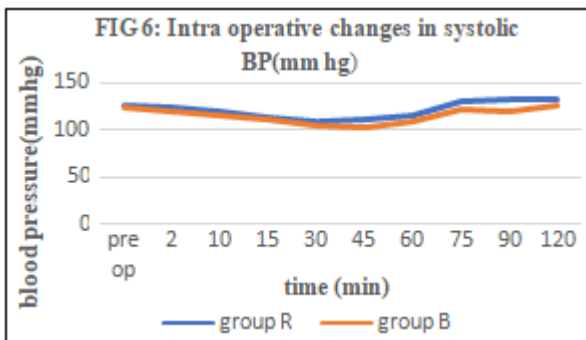
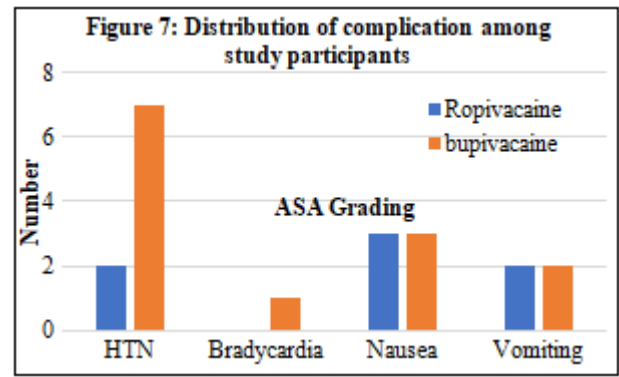


Table 7 and figure 6 shows that there is no significant difference in intraoperative changes in systolic BP in both the group.

Table 8: Distribution of complication among study participants (N=100)

Sign/symptoms	Group R, (n=50)	Group B, (n=50)
Hypotension	2 (4.0)	7 (14.0)
Bradycardia	0 (0.0)	1 (2.0)
Nausea	3 (6.0)	3 (6.0)
Vomiting	2(4.0)	2 (4.0)



- Bradycardia, hypotension and nausea vomiting were compared in both the groups.
- Seven patients in Bupivacaine Group experienced hypotension as compared to two patients in Ropivacaine Group.
- 2 patients in the Bupivacaine Group experienced bradycardia as compared to no patient in Ropivacaine Group, P-value <0.05.
- Incidence of nausea and vomiting were same in both the groups.

5. Conclusion

To conclude the study, we observed that ISOBARIC ROPIVACAINE 0.75% – a newer long acting anaesthetic agent provides shorter duration of both sensory and motor blockade for short duration orthopaedic surgeries and lower abdominal surgeries where prolonged motor blockade is quite undesirable and early mobilization can be planned.

6. Future Scope

Ropivacaine for intrathecal anaesthesia in the lower abdominal and lower limb surgeries provided an adequate level of block for the surgery with lesser duration of motor blockade with good analgesia and more hemodynamic stability so it can be safely use for day care surgery.

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