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A comparative study of efficacy of 0.5% intrathecal isobaric ropivacaine, ropivacaine heavy, and bupivacaine heavy for lower abdomen and lower limb surgeries

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ABSTRACT

Background: Lower abdomen and lower limb surgeries can be performed under spinal anesthesia. Ropivacaine is a local anesthetic, belonging to the amino amide group. It is a pure S-enantiomer and is considered to have a better safety profile than bupivacaine. **Aims and Objectives:** The aim of the study is to compare the efficacy of intrathecal isobaric ropivacaine (IR) 0.5%, ropivacaine heavy 0.75% and bupivacaine heavy 0.5% for lower abdomen and lower limb surgeries. **Materials and Methods:** This prospective randomized study was conducted in 120 patients scheduled for lower abdomen and lower limb surgeries under spinal anesthesia belonging to ASA Grade I or II. Patients were randomized into three groups of 40 each. Group IR-received 3 mL of 0.5% IR, Group hyperbaric ropivacaine (HR)-received 3 mL of 0.75% heavy Ropivacaine and Group Hemoglobin received 3 mL of 0.5% heavy bupivacaine. The parameters studied were the onset and duration of sensory and motor block, duration of analgesia, hemodynamic parameters, and side effects. **Results:** The onset of sensory and motor block was significantly faster in HR followed by hyperbaric bupivacaine (HB) followed by IR. The duration of sensory and motor block was significantly shorter in HR followed by IR followed by HB. Duration of analgesia was longest in HB. **Conclusion:** HR produced a rapid onset of the sensory and motor block with a shorter duration. HB produced a longer duration of motor and sensory block.

Key words: Spinal anesthesia; Ropivacaine; Bupivacaine

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INTRODUCTION

Spinal anesthesia, also referred to as sub-arachnoid block (SAB), is a type of regional anesthesia in which through a spinal needle, a local anesthetic is injected into the subarachnoid space in cerebrospinal fluid.[1]

Bupivacaine is a long-acting amide local anesthetic agent. It is a racemic mixture of both S- and R-enantiomers. Bupivacaine offers long-lasting and intense motor block. It has a higher incidence of cardiotoxicity and central nervous system toxicity. These factors have prompted researchers to look for a newer local anesthetic that can be used for SAB for daycare surgery and that can avoid bupivacaine's toxicity.[2,3]

Ropivacaine is a new local anesthetic that belongs to the amino amide category. It is pure S-enantiomer which is less cardiotoxic. Hence, ropivacaine has a better safety profile than bupivacaine. In comparison to bupivacaine, ropivacaine has a shorter half-life and reduced lipid solubility. It causes significantly less motor blockade because it penetrates the large myelinated motor fibers less deeply thus providing early ambulation and discharge with good-quality of post-operative analgesia.[4,5]

Because of insufficient block distribution, an intrathecal injection of isobaric ropivacaine (IR) produces a sensory block of variable extent. However, it provides adequate analgesia for surgical procedures.[6]

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Aims and objectives

1. To compare the onset and duration of sensory blockade of 0.5% IR, 0.75% heavy Ropivacaine, and 0.5% heavy bupivacaine
2. To compare the onset and duration of motor blockade of 0.5% IR, 0.75% heavy Ropivacaine, and 0.5% heavy bupivacaine
3. To compare the efficacy of 0.5% IR, 0.75% heavy Ropivacaine, and 0.5% heavy bupivacaine in the duration of analgesia
4. To observe undesirable effects and complications of drug used, if any.

MATERIALS AND METHODS

After approval from the ethical committee, a prospective comparative study was carried out, in 120 patients belonging to ASA grade I and II scheduled for lower limb and lower abdominal surgeries, in the Department of Anesthesiology, J.A. Group of Hospitals and G.R. Medical College, Gwalior (MP).

Patients were randomly divided into three groups (n=40 each) by envelope method as below:

1. Group IR (n=40)− 3 mL of 0.5% IR
2. Group hyperbaric ropivacaine (HR) (n=40)−3 mL of 0.75% heavy Ropivacaine
3. Group hyperbaric bupivacaine (HB) (n=40)−3 mL of 0.5% heavy bupivacaine.

Inclusion criteria

- Patients giving consent
- Age 18–60 years
- ASA grade I and II.

Exclusion criteria

- Patients not giving consent to participate in the study
- ASA grade III and IV
- Patients with respiratory, cardiovascular, renal diseases, obesity, and pregnancy
- Age below <18 years and above >60 years
- History of allergy or sensitivity or any other reaction to local anesthetic.

Pre-anesthetic assessment was done on all the patients. The purpose and protocol of the study were explained to patients and informed written consent was obtained. All patients were kept NPO for at least 8 h before surgery.

Upon arrival in the operation theatre, intravenous access with an 18-G cannula was inserted. All routine monitors were connected and observations were recorded. Pre-loading was done with 10 ml/kg Ringer lactate solution.

Under all aseptic pre-cautions, lumbar puncture was done in a sitting position at L2-L3 intervertebral space using a 25-G Quincke spinal needle. SAB was performed and the study drug was injected. The level was assessed and outcomes were recorded.

Primary outcome

1. Time for the onset of sensory block at T10
2. Time to achieve maximum motor block
3. Time for complete motor regression
4. Time for complete sensory regression
5. Visual Analog Scale (VAS) Score
6. Duration of analgesia
7. Observation and recording of side effects.

Secondary outcome

Assessment of hemodynamic parameters (PR, Systolic blood pressure, Diastolic blood pressure, Respiratory rate and SpO_2).

Statistical analysis

The observations were recorded in three groups and were tabulated using Excel and statistical analysis was carried out using independent Analysis of variance test, student "t" test, and "Chi-square " test by SPSS V.20 software. $P>0.05$ was taken to be statistically insignificant and $P<0.05$ was taken as statistically significant whereas $P<0.01$ was taken as highly significant.

RESULTS

The demographic profile was comparable in all three groups in terms of age, sex, weight, and ASA grade.

Table 1 shows the comparision of parameters of spinal anaesthesia including onset and duration of sensory and motor block and duration of analgesia among the three groups.

When the drugs were given, intrathecally there was a decrease in VAS score. VAS score increased till 3.5 h in the IR group then decreased due to rescue analgesia. Similarly in the HR group, it increased till 4 h and in the HB group, it increased till 4.5 h. The IR group needed an early rescue analgesia followed by the HR group followed by the HB group. The quality of analgesia was comparable among the three groups but the duration of analgesia was longer in the bupivacaine group than in the ropivacaine group as shown by the VAS score.

Figure 1 shows the Mean postoperative VAS score among the three groups.

Figure 2 shows comparison of complications among the three groups.

Table 1: Parameter of spinal anesthesia

Parameter	Group	No.	Mean±SD	P-value
Onset time of sensory blockade (min)	IR	40	04.03±02.75	<0.001
	HR	40	02.03±01.07	
	HB	40	02.28±02.09	
Duration of the sensory block (min)	IR	40	197.13±21.94	<0.001
	HR	40	194.53±20.90	
	HB	40	215.98±27.42	
Onset time of motor blockade (min)	IR	40	5.85±2.97	0.001
	HR	40	4.13±2.59	
	HB	40	3.83±1.69	
Duration of motor block (min)	IR	40	175.5±28.44	<0.001
	HR	40	153.1±24.81	
	HB	40	207.8205±27.72	
Duration of analgesia (min)	IR	40	192.36±25.17	<0.001
	HR	40	190.58±36.11	
	HB	40	233.46±33.05	

HR: Hyperbaric ropivacaine, HB: Hyperbaric bupivacaine, IR: Isobaric ropivacaine

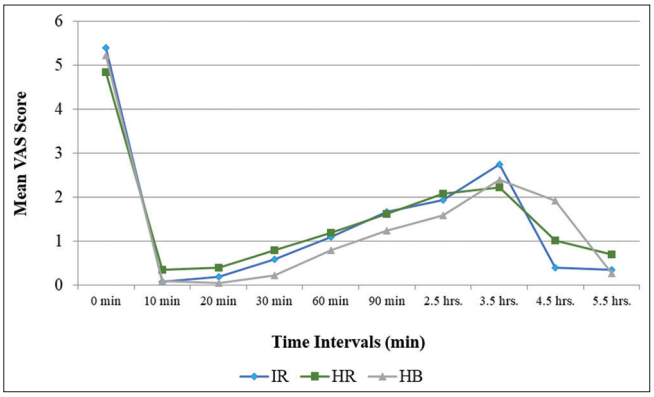

Figure 1: Mean post-operative Visual Analog Scale score

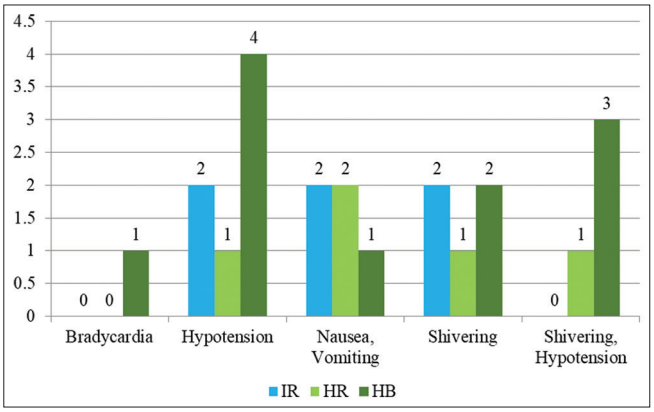

Figure 2: Post-operative complications

DISCUSSION

Bupivacaine, an amino amide molecule, is a long-acting local anesthetic drug for lower limb and abdominal procedures. Problems associated with bupivacaine are cardiovascular, central nervous system toxicity, and prolonged duration of sensory and motor blockade. Ropivacaine is a pure S-enantiomer; it has shown low cardiovascular and neurotoxic effects, good tolerability, and efficacy.[7]

Ropivacaine due to sensorimotor dissociation, perhaps leading to earlier post-operative mobilization compared to bupivacaine. HR is considered to produce more reliable and faster onset sensory and motor block with reduced potential for cardiotoxicity and neurotoxicity.[8]

In our study, the analysis of the onset of sensory analgesia revealed a statistically significant difference among these groups (P<0.001). Group HR demonstrated a significantly quicker onset of sensory blockade than HB and IR.

Our study is in accordance with study done by Padmavathi and Madhavi[9] in their study to assess the sensory and motor characteristics and side effects of intrathecal 0.5% HB 8 mg compared to intrathecal 0.75% IR 15 mg they found that the Onset of sensory block was faster with bupivacaine than with IR.

In our study, the difference in the duration of sensory block in the three groups was statistically significant (P<0.001), showing that Group HB has the longest average duration while Group HR has the shortest.

Our study is in accordance with a study done by Shujaat et al.,[10] in their study to compare the outcome of 0.5% HR with 0.5% HB they found that the duration of sensory block was statistically less in the Ropivacaine group as compared to Bupivacaine group with P=0.0001.

In our study, the time of onset of motor block was statistically significant among the three groups (P<0.001). Group HB has the fastest onset of motor blockade, while Group IR has the slowest onset.

Our study is in accordance with a study done by Olapour et al.,[11] they found that the onset of motor block in the bupivacaine group was significantly faster than the IR group (P<0.001).

In our study statistically significant difference was found among the three groups (P<0.001) in duration of motor block. Group HB has the longest average duration, while Group HR has the shortest.

Our study is in accordance with a study done by Kharat and Deopujari[12] in their study to compare the onset of action, intensity, and duration of motor block of 0.5% HR with 0.5% HB they found that the duration of motor blockade was significantly greater with bupivacaine group than ropivacaine group.

Our study is in accordance with a study done by Kordcal et al.,[13] in their study to compare sensory, motor effects and hemodynamic stability of 2 mL intrathecal IR (0.75%) with 3 mL HB (0.75%), they found that the mean duration of complete motor blockade was significantly more in bupivacaine group (P<0.001).

In our study a statistically significant difference was found in the mean duration of analgesia among the three groups (P<0.001) shows that Group HB has the longest duration of analgesia, suggesting potentially better pain control. In contrast, Groups IR and HR have slightly shorter durations.

Our study is in accordance with a study done by Subba et al.,[14] comparing the efficacy and safety of 0.5% HR with 0.5% HB, who found Duration of analgesia was longer in bupivacaine group than in ropivacaine group.

Limitations of the study

The investigator was unable to objectively quantify and evaluate post-operative pain which being a subjective experience.

CONCLUSION

From our study, we concluded that

1. HR produced a rapid and more reliable onset of sensory and motor block with shorter duration when compared to IR and HB.
2. HB produced a longer duration of motor and sensory block when compared to IR and HR.
3. HB produced a longer duration of analgesia.
4. Hypotension was the most common side effect observed but side effects were comparable in all the three groups.

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AS- Concept, literature survey, intellectual contents, prepared first draft of manuscript, implementation of study protocol, data collection, data analysis, manuscript preparation and submission of articles; **AM-** Concept, design, clinical protocol, manuscript preparation, editing, manuscript revision and supervision; **UPY-** Data collection, coordination and preparation of manuscript; **PG-** Proof-reading and revision of manuscript.

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