A Comparative Study of Intrathecal 0.5% Hyperbaric Bupivacaine & Intrathecal 0.75% Isobaric Ropivacaine in Lower Abdominal Surgeries

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ABSTRACT

BACKGROUND

Ropivacaine, a long acting amide local anaesthetic, has reduced potential for neurotoxicity and cardiotoxicity and is considered to block sensory nerves to a greater degree than motor nerves. In today's world, faster recovery along with minimal side effects and early ambulation after surgeries under spinal anaesthesia are very important. So, this prospective randomized study was aimed at evaluating and comparing the efficacy and safety of intrathecally injected isobaric ropivacaine and intrathecally injected hyperbaric bupivacaine in patients posted for lower abdominal surgeries under spinal anaesthesia.

METHODS

90 patients belonging to ASA physical status I & II scheduled for lower abdomen surgeries were randomly selected for the study and were divided into two groups of 45 each. Group B received 3 ml of 0.5% hyperbaric (15 mg) bupivacaine intrathecally. Group R received 3 ml of 0.75% isobaric (22.5 mg) ropivacaine intrathecally. Onset and extent of sensory block, onset and duration of motor block, maximum height of sensory block, duration of analgesia, hemodynamic parameters and adverse effects if any were studied. SPSS 20.0 and GraphPad Prism 6.0 were used for the analysis of the data.

RESULTS

The mean time for onset of sensory block was significantly faster in group B as compared to group R (8.28±2.2 min v/s 7.98±2.2 min). There was no significant difference between the groups regarding the time for two segment regression. Mean time of onset of motor block was significantly faster in group B. The mean duration of motor blockade was 146.89±14.11 min in group R and 208.91±14.62 min in group B. The mean duration of analgesia was comparable in both the groups. Hemodynamic parameters and side effects were comparable in both the groups.

CONCLUSIONS

0.75% isobaric ropivacaine provided similar duration of analgesia with a shorter duration of motor block as compared to hyperbaric 0.5% bupivacaine and it also provided adequate level of sensory block for the surgery with minimal intraoperative and postoperative side effects and stable haemodynamics throughout the surgery.

KEY WORDS

Ropivacaine, Bupivacaine, Intrathecal, Spinal Anaesthesia, Lower Abdominal Surgeries

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BACKGROUND

Spinal anaesthesia or sub-arachnoid block (SAB), is a form of regional anaesthesia involving injection of a local anaesthetic into the cerebrospinal fluid (CSF) through a needle. It is a common, safe, economical, easy to perform and effective technique which provides rapid and reliable anaesthesia with less systemic and metabolic disturbances and with muscle relaxation for patients undergoing lower abdominal surgeries, caesarean sections, orthopaedic lower limb surgeries and urological surgeries.[1,2,3] A few of the important advantages of spinal anaesthesia over general anaesthesia are easier to perform, awake patient, no airway manipulation, decreased risk of pulmonary aspiration of gastric contents, rapid onset of action, good motor and sensory blockade, cost effectiveness with minimal drug pricing, avoidance of polypharmacy, early ambulation to allow early discharge making this the preferred technique of choice for various surgical procedures.[4]

Presently the most widely used drug for spinal anaesthesia is inj. hyperbaric bupivacaine 0.5%. As it is a racemic (50:50) mixture of S and R enantiomers, it is more cardiotoxic because of R enantiomer.[5] Major limitation with the use of bupivacaine is its neurotoxicity, cardio toxicity and prolongation of motor block.[6] In today's world which is very high evolving and fast paced, faster recovery along with minimal side effects and early ambulation are now the demands of this hour especially for the day care surgeries.[7] For this reason, there has been a search for alternative drugs with desirable blocking properties of bupivacaine but with a greater margin of safety and early recovery from motor block.[2]

Ropivacaine is a relatively newer long acting amide local anesthetic, which has a wide margin of safety like less cardiotoxicity and early recovery from motor block compared to bupivacaine.[1,8] Ropivacaine is an enantiomerically pure S-enantiomer local anaesthetic agent.[5,8] Ropivacaine produces motor blockade of shorter duration which relives the psychological distress of being immobile for a longer period of time after surgery compared to intrathecal bupivacaine during lower abdomen surgeries.[9,10] Because of sensorimotor dissociation, ropivacaine should be a favourable local anaesthetic for day-care surgeries and could be associated with earlier postoperative mobilization.[11]

Based on the above hypothesis, this study was aimed at evaluating and comparing the efficacy and safety of intrathecally injected isobaric ropivacaine and intrathecally injected hyperbaric bupivacaine in the patients posted for lower abdominal surgeries under spinal anaesthesia with the primary objective of evaluating and comparing the duration of motor block among two intrathecally administered drugs for spinal anaesthesia and the secondary objectives of evaluating and comparing the time of onset and extent of sensory block, time of onset of motor block, duration of analgesia, any associated side effects (hypotension, bradycardia and arrhythmias) in the two study groups.

METHODS

After obtaining institutional ethics committee permission and written informed consent, this prospective, randomized study was carried out in the Department of Anaesthesiology at Acharya Vinoba Bhave Rural Hospital (AVBRH) attached to Jawaharlal Nehru medical college (JNMC), DMIMS, Sawangi (Meghe), Wardha over a period of 2 years and 6 months. Assuming the average duration of motor block of 128.3 minutes and SD of 38.3 (with reference to the study done by Bansal et al[12]) keeping power at 80% and confidence interval at 95%, a sample size of 43 samples in each group would be required to detect a minimum difference of 20% in the mean duration of motor block. So, considering the probable dropouts, the total sample size was kept at 90 i.e. 45 samples in each group. This study was conducted on 90 patients, of either gender, scheduled for elective lower abdominal (appendicectomy, hernia, hydrocoele), gynaecological (abdominal and vaginal hysterectomy) and urological (TURP, URSL) surgeries under subarachnoid block.

Patients included in the study were between 18-60 years age group with height between 150 – 180 cms belonging to ASA (American society of anaesthesiologist) Physical status of I & II[2]. Exclusion criteria included patient refusal**,** ASA physical status III and above**,** pregnant patient**,** diabetics and patients on beta blockers**,** patients with medical complications like anaemia, heart disease, severe hypovolemia, shock, septicaemia**,** local infection at the site of proposed puncture for spinal anaesthesia**,** on chronic anticoagulation or antiplatelet drugs**,** patients having allergy to the study drugs**,** patients with spinal deformity/ previous spine surgery**,** any other contraindications to spinal anaesthesia.

All patients were randomly divided into 2 groups of 45 each using computer generated randomization. Allocation of groups was done using sealed envelopes. The anaesthesiologist who administered the medication was blinded from its constituents. The observers and the patients were blinded to the group the patients belonged to. In Group B (bupivacaine group) patients were given 0.5% hyperbaric bupivacaine 3 ml intrathecally. In Group R (ropivacaine group) patients were given 0.75% isobaric ropivacaine 3 ml intrathecally.

Pre-anaesthetic check-up was carried out on previous evening of the surgery. Pre-operatively procedure was explained in detail and written consent was taken. Patients were explained regarding VAS (visual analogue scale) which has to be assessed for pain in postoperative period (denoting 0 = no pain and 10 = worst imaginable pain). All the patients were kept fasting for 8 hours prior to the scheduled operation & premedicated with tab. alprazolam 0.25 mg, tab. pantoprazole 40 mg and tab. ondansetron 4 mg a night before the surgery. On the day of surgery, patient was shifted on the OT table. The monitors that were connected to the patient included ECG, non-invasive B.P., pulse oximeter (for oxygen saturation and HR).

Baseline heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and respiratory rate (RR) were recorded. Intravenous access was obtained with an 18 G/20 G cannula. Fluid therapy was maintained with lactated ringer's solution (10 mL/kg/hr) throughout the surgery. With the patient in the lateral position, under strict aseptic conditions, lumbar puncture was performed at the level of L_3 –L_4 intervertebral space using a 25-gauge Quincke Babcock spinal needle.[6] Once free flow of clear cerebrospinal fluid was obtained, study drug for the patient (either bupivacaine or ropivacaine) according to the group they belong was injected over 20 – 30 seconds and patient was placed in supine position immediately and gently without raising the extremities. After giving spinal anaesthesia, record of vital parameters such as HR, MAP, RR was done at every 5 minutes for 15 minutes, then every 15 minute interval till 60 minutes and then every 60 minute interval till 180 minutes.

In the postoperative period also thorough hemodynamic monitoring was maintained and patients were monitored for regression from motor block and requirement of first rescue analgesic (injection diclofenac sodium 75 mg IM) when VAS >= 4.[13] Sensory block was assessed by using pinprick method in midclavicular line after administration of the study drug every 30 seconds.[13] Parameters noted were onset of sensory block (time from deposition of study drug into the subarachnoid space till the patient does not feel the pin prick at T10 level),[13] time for achieving peak sensory block (Time from deposition of the study drug to the maximum sensory block attained). The degree of motor blockade was assessed by loss of antigravity movements of the legs by the Bromage scale[14] every 30 seconds. Parameters like onset of motor blockade (time taken in minutes from deposition of the study drug into the subarachnoid space to the Bromage grade 3 motor block),[13] duration of motor block (time in minutes from deposition of the study drug to the regression of motor block to Bromage grade 0) were noted.[13]

Bromage Scale[14]

Grade Motor Block

0 - The patient is able to move the hip, knee and ankle

1 - Patient is unable to move hip but able to move knee and ankle

2 - Patient is unable to move hip and knee but able to move ankle.

3 - Patients is unable to move hip, knee and ankle (unable to move the leg)

Assessment of analgesia was done by VAS score. Duration of analgesia is defined as the time from the deposition of the study drug till the injection of first rescue analgesic when VAS score was > = 4.[13] Side effects if any like hypotension, bradycardia and cardiac arrhythmias were noted. Hypotension was described as 20% decrease in blood pressure from baseline values, and was treated with fluid therapy or single intravenous bolus dose of mephentermine 6 mg.[15] Bradycardia was described as pulse rate less than 60 bpm and treated with iv atropine 0.6 mg.[15] Respiratory distress was described as RR<10/min, SpO2 <90% and was treated with oxygen supplemented with mask at 4 – 6 L/min.[16]

Statistical Analysis

All values were expressed as mean ± standard deviation. Quantitative data was analyzed by student's t-test and qualitative data was analyzed by Chi-square test. $p<0.05$ was considered statistically significant. The Statistical software namely SPSS (statistical package for social sciences) 20.0 and GraphPad Prism 6.0 version were used for the analysis of the data.

RESULTS

Table 1 shows comparison of demographic data between the two groups. As far as demographic profile, such as age, gender, ASA physical status, weight and height is concerned there was no statistical significant difference between the two groups and the data was comparable between the groups. Mean duration of surgery was comparable between two groups and statistically non-significant.

Parameters	Group B (n = 45)	Group R (n = 45)	p - Value
Age (Years)	42.04±8.51	39.91±8.77	0.24*
Gender (M/F)	20/25	23/22	0.53*
ASA PS (I/II)	20/25	18/27	0.67*
Height (cms)	163.6 0±8.46	164.02±5.78	0.78*
Weight (kgs)	59.15±5.89	57.60±4.80	0.17*
Duration of Surgery	89.44±12.58	86.68±12.69	0.30*

Table 1. Demographic Data and Duration of Surgery

*NS – Non-significant

As shown in table 2, the mean time of onset of sensory block in group B was 4.07±0.93 minutes and in group R was 6.28±0.91 minutes. Onset of sensory block was significantly faster in group B as compared to group R ($p < 0.05$).The mean time for the achievement of peak sensory block in group B was 7.8±1.03 minutes and in group R was 9.37±1.03 minutes, with a p value < 0.05, the difference between the groups was statistically significant. The mean time required for the onset of motor blockade in patients belonging to group B was 6.70±0.99 minutes while that for patients in group R was 7.90±0.79 minutes. The result was clinically and statistically significant ($p < 0.05$) indicating that onset of motor blockade was significantly faster in group B as compared to group R. The mean duration of motor blockade was 146.88±14.11 mins in group R and 208.91±14.62 mins in group B. We observed a significantly shorter duration of motor block with group R compared to group B. The difference in the meantime of duration of motor block in group R and group B was clinically and statistically highly significant ($p < 0.01$). The hemodynamic parameters including heart rate (HR), mean arterial pressure (MAP), RR were comparable between both the groups and no significant hemodynamic alteration was seen in the two groups (Figure 1, Figure 2, Figure 3) ($p>0.05$). The mean duration of analgesia was 220.58±11.16 minutes in group B and it was 217.18±8.03 minutes in group R. The difference between the groups was statistically non-significant ($p>0.05$).

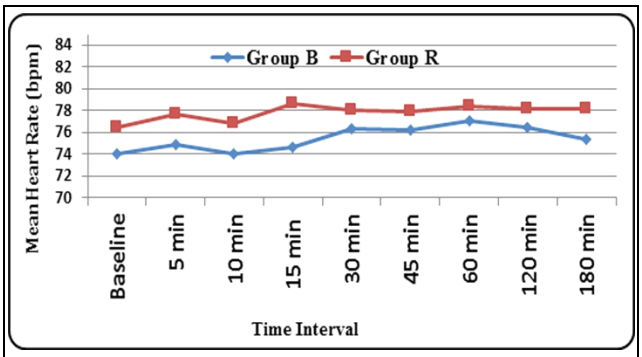

Figure 1. Comparison of Mean Heart Rate (bpm) in Two Groups

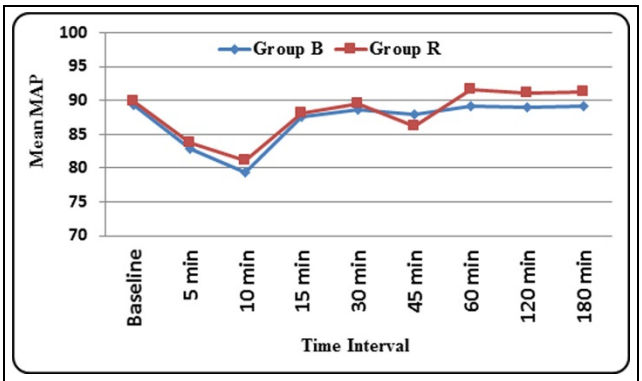

Figure 2. Comparison of Mean MAP (mmHg) in the Two Groups of Patients

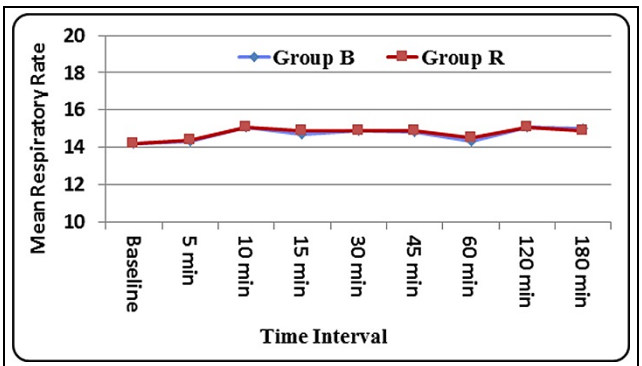

Figure 3. Comparison of Mean Respiratory Rate in the Two Groups of Patients

Parameters (min)	Group B (n = 45)	Group R (n = 45)	p - Value
	Mean ± SD	Mean ± SD	
Onset of sensory block	4.07±0.93	6.28±0.91	< 0.0001 (S)
Onset of peak sensory block	7.80±1.03	9.37±1.03	<0.001 (S)
Onset of motor block	6.70±0.99	7.90±0.79	< 0.001 (S)
Duration of motor block	208.91±14.62	146.89±14.11	< 0.001 (S)
Duration of Analgesia	220.58±11.16	217.18±8.03	0.10 (NS)

Table 2. Comparison of Parameters between the Two Groups

S – Significant; NS – Non-significant

Three (6.67%) patients in group R had episodes of hypotension after intrathecal administration of the drug, whereas, the episode of hypotension in group B was seen in 4 (8.88%) patients after drug administration. Bradycardia was seen in 2 (4.44%) patients of the group B and 1 (2.22%) patient of the group R. None of the cases reported any episode of cardiac arrhythmia, allergy and respiratory depression in our study. The difference between the groups regarding the side effects was non-significant as can be seen in figure 1, 2, 3 ($p > 0.05$).

DISCUSSION

Subarachnoid block is a commonly employed anaesthetic technique for performing surgeries of the lower abdomen as it is a simple, safe, inexpensive and easy-to-administer technique which also offers a rapid onset of action and high level of post–anaesthesia satisfaction for patients.[2,17] Hyperbaric bupivacaine remains one of the most popular local anaesthetic agents for spinal anaesthesia because of its high potency and minimal neurological symptoms but caution is required because of its prolonged motor block and toxicity profile particularly to the cardiovascular system due to its R - enantiomer.[4,6] In this fast moving world, there is a need for such a local anaesthetic which can provide adequate duration of sensory block as that of bupivacaine with lesser duration of motor block.

Ropivacaine, a pure S – enantiomer of propyl derivative of pipecoloxylidide, has low lipid solubility as compared to bupivacaine.[18] Since anaesthesia due to local anaesthetics is directly related to the myelination and size of the nerve fibers, more lipophilic local anaesthetic (such as bupivacaine) will penetrate large myelinated motor fibers (Aβ fibers) more effectively then the less lipophilic local anaesthetics such as ropivacaine. So less lipophilic local anaesthetics (ropivacaine) would block fibers controlling motor function to a lesser degree in comparison to more lipophilic local anaesthetics (bupivacaine).[18] Because of this sensory motor dissociation, ropivacaine could be a favourable local anaesthetic for the patients requiring early postoperative mobilization such as in day-care surgeries. Low lipid solubility of ropivacaine also renders a major advantage of being less cardiotoxic and decreased potential for CNS toxicity over bupivacaine.[1,6,11,18]

Commercially available hyperbaric bupivacaine for spinal anaesthesia is at a concentration of 0.5%. This concentration was found to be adequate for providing effective sensory as well as motor block of spinal anaesthesia.[19] Similarly 3 ml volume of intrathecally injected hyperbaric bupivacaine was found to be effective enough for surgeries to be carried out over lower abdomen.[16] Ropivacaine which is commercially available only as an isobaric solution have a equipotent ratio of 3:2 or 2:1 with that of bupivacaine.[20,21,22] So, in order to keep the volume of 3 ml intrathecal dose in both the group, we used concentration of ropivacaine as 0.75% in our study,[1,23] which was found to be effective in spinal anaesthesia in patients posted for lower abdominal surgeries.[1,6] Preparation of hyperbaric solution of ropivacaine needs indigenous mixing of dextrose which could lead to an unsterile solution and may present a risk of infection, so we have used isobaric solution of ropivacaine in our study.[8]

As shown in table 2, Onset of sensory block was significantly faster in group B as compared to group R. Nema et al[15] also observed that onset of sensory block was faster in bupivacaine group then in ropivacaine group. No statistically significant difference was noted between the two groups in terms of highest level of sensory block achieved. From table 2, we can infer that the time to achieve peak sensory level was significantly prolonged in group R than group B and similar results were also observed in a study by Chari et al[24] and Bansal et al.[12] Onset of motor blockade was significantly faster in group B as compared to group R. Similar result was also seen in the study by Nema at el[15] where the time of onset

of motor block was significantly delayed in ropivacaine group (12.51±0.99 minutes) as compared to bupivacaine group (6.14±0.70 mins). We observed a significantly shorter duration of motor block with group R as compared to group B ($p<0.01$) (Table 2). The results of the studies done by Bhat et al[6], Kallio et al,[11] Surekha et al[2] and Malinovsky et al[22] were in accordance with our study where duration of motor block was significantly shorter with ropivacaine as compared to bupivacaine. The mean duration of analgesia was similar in both the groups and was statistically non-significant (p Value > 0.05). Serap et al[23] and Chari et al[24] also showed similar results in their studies where the mean duration of analgesia was similar and comparable in both the groups. Although incidence of side effects was lesser in group R as compared to group B but the difference was statistically non-significant and comparable($p > 0.05$). Nema at el[15] and Nanavati et al[16] reported similar findings in their study where the incidences of side effects (such as hypotension and bradycardia) were similar between the groups.

CONCLUSIONS

0.75% isobaric ropivacaine can be used as a possible alternative to routinely used 0.5% hyperbaric bupivacaine for spinal anaesthesia in lower abdominal surgeries as it provides similar duration of analgesia with a shorter duration of motor block, it also provides adequate level of sensory block for the surgery with minimal intraoperative and postoperative side effects and stable haemodynamics throughout the surgery.

Limitations

1. As all patients were either ASA physical status I or II, results cannot be generalized to ASA physical status III and above patients.
2. Surgeon's satisfaction regarding degree of motor block and muscle relaxation during the surgery was not considered in our study.

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