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To compare the efficacy of intrathecal 0.75% heavy ropivacaine and 0.5% heavy bupivacaine for lower abdominal and lower limb surgery

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ABSTRACT

Background: Spinal anesthesia is the most popular regional anesthesia technique for lower limb and lower abdominal surgery. Bupivacaine 0.5% heavy is commonly used for intrathecal use. New long-acting local anesthetic agents such as ropivacaine have claimed benefits of reduced cardiac toxicity on overdose and more specific effects on sensory rather than motor nerve fibers. The use of intrathecal hyperbaric ropivacaine is not much studied. With this background, we studied intrathecal ropivacaine hyperbaric 0.75% against intrathecal bupivacaine hyperbaric 0.5% for lower abdominal and lower limb surgery. **Aims and Objectives:** To note the effectiveness of intrathecal ropivacaine and bupivacaine on characteristics of subarachnoid block such as sensory block, motor block, hemodynamic parameters, and complications if any. **Materials and Methods:** We randomized patients undergoing lower abdominal surgeries and lower limb orthopedic surgeries under spinal anesthesia into two groups so as to receive intrathecal either ropivacaine 0.75% hyperbaric (3 mL) or bupivacaine 0.5% hyperbaric (3mL) and noted study parameters. **Results:** Time of sensory block onset (P = 0.0005), peak sensory level (P = 0.0029), and onset of L1 bromage-3 motor block (P = 1.27E−08) was significantly delayed in the ropivacaine group as compared to bupivacaine group. However, maximum sensory level achieved (T6), time required for two-segment sensory regressions (P = 0.1162), and time of onset of pain (P = 0.1162) were comparable in both groups. **Conclusion:** Intrathecal ropivacaine 0.75% hyperbaric produced slow onset sensory and motor block than 0.5% hyperbaric bupivacaine with comparable cephalic spread and duration of sensory block.

Key words: Bupivacaine; Hyperbaric; Intrathecal; Motor; Ropivacaine; Sensory

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INTRODUCTION

Spinal anesthesia is the most popular regional anesthesia technique for lower limb and lower abdominal surgery.[1] Bupivacaine 0.5% heavy is commonly used for intrathecal use. New long-acting local anesthetic agents (ropivacaine and levobupivacaine) have recently been introduced for clinical use.[2] The claimed benefits of these are reduced cardiac toxicity on overdose and more specific effects on sensory rather than motor nerve fibers.[3] There are various studies of isobaric ropivacaine in peripheral nerve blocks. However, the use of intrathecal hyperbaric ropivacaine is not much studied. Recently, ropivacaine 0.75% have made hyperbaric by the addition of deextrose to it for intrathecal use. With this background, we have decided to study the efficacy of intrathecal ropivacaine heavy 0.75% against intrathecal bupivacaine 0.5% heavy for lower abdominal and lower limb surgery under spinal anesthesia.

Aims and objectives

1. To study the effectiveness of intrathecal ropivacaine heavy 0.75% and intrathecal Bupivacaine 0.5% heavy

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on characteristics of subarachnoid block such as the onset of sensory block and motor block, peak sensory level with its duration and 2 segments sensory regression time.
2. To study the duration of postoperative analgesia as time for the first onset of pain.
3. To study effects on hemodynamic parameters and vitals parameters.
4. To study complications if any.

MATERIALS AND METHODS

This was a prospective randomized double-blind clinical study conducted the study at our Government Tertiary Care Institute with the appropriate approval of the ethical committee (IEC Letter no. GMCJ/IEC Approval/053/2022 dated February 09, 2022) and necessary trial registration (CTRI No.-CTRI/2022/03/040955).

With complete pre-anesthetic evaluation and necessary investigations, patients selected for study with appropriate consent who were fulfilling the criteria as follows:

Inclusion criteria

All patients undergoing elective lower limb orthopedic and lower abdominal surgery under spinal anesthesia having an age group of 20–50 years, weight of 50 –70 kg, and height of 150–170 cm of either sex with ASA physical status 1 and 2 acceptance.

Exclusion criteria

Patients having contraindications to spinal anesthesia, known drug allergy, and those not willing to study were excluded from the study.

These patients were randomized into two groups of 25 each by picking up random number chits as follows-

Group 1 - Received injection of bupivacaine 0.5% heavy intrathecal 3 mL

Group 2 - Received injection ropivacaine 0.75% heavy intrathecal 3 mL

After taking the patient to the operation table multipara monitor was applied and an intravenous line was secured with 20G angiocath with preloading of 10 mL/kg of RL. Baseline parameters noted on multipara monitors comprising blood pressure (BP), pulse rate (PR), and SPO_2. It was taken as the baseline value. By picking up random chit numbered from 1 to 50, patients were allocated to either Group 1 or Group 2 so as to receive intrathecal bupivacaine or ropivacaine, respectively. According to it study drug to be administered was prepared by a trained anesthesia resident not involved in data collection or further study to ensure blinding. Under all aseptic precautions spinal anesthesia was given by a trained anesthetist with 25G spinal needle in a sitting position in L3–4 interspace with injecting either of the drugs depending on group allocation. The patient as well as anesthesiologist who performed spinal anesthesia and collected data were blind about group allocation. The patient was given immediately a supine position. The time of spinal anesthesia was noted and taken as 0 min. The duration of onset of sensory block up to L1 by pinprick and motor block up to L1 by Bromage scale of 3 of inability to flex thigh, knee, and ankle was assessed. The peak sensory level achieved was also noted and the time required for it was noted. This assessment was done every 30s. Furthermore, hemodynamic parameters such as BP, PR, and SpO_2 were noted every 5-min interval up to 30-min time period, and variation of±30% from baseline value were marked and accordingly intervention with injection mephentermine 6mg top up for hypotension and injection atropine 0.6mg for bradycardia was planned and implemented. Oxygen supplementation with Hudson mask was planned if SpO_2 goes below 90%. The time required for two-segment sensory regression was noted.

Postoperatively, the duration of analgesia was noted with the first occurrence of sensation of pain as complained by the patient.

Side effects if such as itching and urinary retention were also noted.

RESULTS

Data were collected and expressed as mean with standard deviation.

Statistical analysis

Statistical analysis was done using IBM SPSS version 20.0 software (App On Fly, Inc. Online IBM SPSS software started in 2005). t-test applied and a significant (2-tailed) value was calculated.

In our study, a total of 50 patients undergone lower limb orthopedic and lower abdominal surgery were randomized into two groups of 25 each and studied. In both groups, demographic parameters such as age, sex, weight, and height were comparable (Table 1). The duration of surgery was comparable in both groups.

Sensory block characteristics

Sensory block onset was significantly delayed in Group 2 as compared to Group 1. In addition, time required for peak sensory level was significantly delayed in group 2

as compared to group 1. However, the time required for two-segment sensory regression was comparable in both groups. Furthermore, the maximum sensory level achieved (T6) in both groups was comparable in both groups (Table 2).

Motor block characteristics

Motor block onset up to L1 by Bromage scale of 3 that is inability to flex thigh, knee, and ankle was delayed in Group 2 as compared to Group 1 with highly significant difference (Table 3).

Hemodynamic parameters

Intraoperative hemodynamic parameters were comparable in both groups. In group 1 (Bupivacaine), 2 patients (8%) developed a single episode of hypotension in the first 10 min which responded to injection mephentermine. In group 2 (ropivacaine), 1 (4%) patient developed hypotension in first 15 min which responded to injection mephentermine. In both groups, 1 (4%) patient developed a single episode of bradycardia which responded to injection atropine 0.6 mg. This bradycardia in bupivacaine group occurred in first 10 min whereas in ropivacaine group, it occurred during surgery when patient had stretch sensation.

Duration of analgesia

The duration of the first onset of pain was comparable in both groups (Table 4). The pain started earlier in lower abdominal surgeries than lower limb surgeries in both groups.

Associated findings

It was found that in ropivacaine group 3 patients (12%) complained of a sensation of stretching during the operative procedure in abdominal surgery which subsided by additional supplementation of sedation with benzodiazepine and opioids. Out of these 3 cases, in two cases (8%) surgeon also complained of slight tightness of muscle during surgery.

None of the patients in both group developed respiratory depression requiring oxygen supplementation.

Table 1: Demographic parameters

Parameter	Group 1 (Bupivacaine 0.5% Heavy) Mean±SD	Group 2 (Ropivacaine 0.75% Heavy) Mean±SD	P two tailed value (Test of significance value)
Age in years	39.12±10.0013	40±10.0083	0.6787
Weight in kg	64.6±6.6583	65.56±6.2187	0.5256
Height in cm	161.72±5.264	162.76±5.6219	0.4149
Sex (M/F)	20/5	20/5	
Abdominal, perennial surgeries/lower limb surgeries	15/15	16/14	

SD: Standard deviation

Table 2: Sensory block characteristics

Sensory block parameter	Group 1 (Bupivacaine 0.5% Heavy) Mean±SD	Group 2 (Ropivacaine 0.75% Heavy) Mean±SD	P two-tailed value (Test of significance value)
Time of onset up to L1 by pinprick in minute	2.08±0.7023	2.96±0.9673	0.0005
Time required for maximum sensory level in a minute	6.14±1.4681	7.76±2.1462	0.0029
Time to two segment sensory regression in min	64.24±3.1128	62.36±6.6638	0.1162

SD: Standard deviation

Table 3: Motor block characteristics

Motor block parameter	Group 1 (Bupivacaine 0.5% Heavy) Mean±SD	Group 2 (Ropivacaine 0.75% Heavy) Mean±SD	P two tailed value (Test of significance value)
Time of onset up to L1 by Bromage scale of 3inability to flex thigh, knee, and ankle in minute	2.98±0.637	5.6±1.3539	1.27E-08

SD: Standard deviation

Table 4: Duration of analgesia

Analgesic parameter	Group 1 (Bupivacaine 0.5% Heavy) Mean±SD	Group 2(Ropivacaine 0.75% Heavy) Mean±SD	P two-tailed value (Test of significance value)
Time of first onset of pain in minute as complained by patient	108.08±8.6646	110.6±8.4705	0.2972

SD: Standard deviation

One (4%) patient in both Groups developed transient shivering during intraoperative period and responded to ondansetron and warm blankets. Two patients in bupivacaine group required catheterization for urinary retention in the post-operative period whereas none in ropivacaine group required catheterization.

DISCUSSION

Lower limb orthopedic and lower abdominal surgeries are very common worldwide. Spinal anesthesia is the most popular regional anesthesia technique for these surgeries.[1-3] Advantages of spinal anesthesia are predicted onset and duration, low cost, no airway handling, less bleeding, good intraoperative pain relief, better hemodynamic parameters etc.[3] Various local anesthetic agents are used by intrathecal route for spinal anesthesia such as lignocaine, bupivacaine, chlorprocaine, levo-bupivacaine, and ropivacaine.[4,5] Bupivacaine 0.5% heavy which is a racemic mixture is commonly used for spinal anesthesia for different lower limb and lower abdominal surgeries. Newer amide local anesthetic agents such as ropivacaine, Levobupivacaine have come into practice. Ropivacaine is a pure S (−) enantiomer of propivacaine. It has reduced potential for cardiotoxicity and neurotoxicity on accidental intravascular injection or with a toxic dose limit and is thus claimed to be safer than the racemic preparation, Bupivacaine.[6-9] Ropivacaine is less lipid soluble than bupivacaine. Therefore, it has lower penetration into myelinated motor fibers and thus produces lesser motor blockade than a sensory block.[6-8] Initially, ropivacaine was available in isobaric preparation such as 0.2%, 0.5%, and 0.75% only. It was used for peripheral nerve blocks, epidural analgesia, caudal block, local infiltration, intra-articular administration, or spinal anesthesia. It is less potent than Bupivacaine when used in low doses such as for epidural analgesia or spinal anesthesia. However, in high doses, for example, when used for peripheral nerve block, the potency and efficacy of these agents appear to be similar.[6-11]Initially it was studied in spinal anesthesia in isobaric form 10 Later on hyperbaric preparations came into the practice for intrathecal use with the addition of dextrose.[9,11] Ropivacaine has been extensively studied over the last many years for its intrathecal use. When identical doses of isobaric Ropivacaine and Bupivacaine were compared, ropivacaine was found to have almost similar efficacy but a shorter duration of sensory and motor block.[9,11] On using bupivacaine and ropivacaine in 1:1.5 dose ratio, the block characteristics were almost comparable with the two local anesthetics.[9,11] Hyperbaric solutions of ropivacaine have been compared to the isobaric solution of the drug for various procedures and generally resulted in a faster onset and recovery from the blocks.[9] Macnamee and McClelland[12] studied and compared equivoque (3.5 mL) plain ropivacaine 5 mg/mL with bupivacaine 5 mL/mL in spinal anesthesia for major orthopedic surgery and found that Onset of motor and sensory block was rapid with no significant differences between the two groups. However, the median duration of the motor block was significantly shorter in ropivacaine group. Surekha et al.,[13] studied equivoque (2.2 mL) isobaric Ropivacaine 0.75% against isobaric bupivacaine 0.5% in spinal anesthesia for lower abdominal and lower limb surgeries and found that ropivacaine provided comparable quality of sensory block, but the slower onset and significantly shorter duration of motor block and better hemodynamic stability compared to Bupivacaine. Adhikari et al.,[14] studied intrathecal equivoque (3 mL) 0.75% isobaric ropivacaine against 0.5% isobaric bupivacaine for lower abdominal surgeries and found comparable sensory block characteristics in both groups with significantly early motor recovery and lower incidence of hypotension and bradycardia in ropivacaine group. Olapour et al.,[15] studied 15 mg 1% ropivacaine against 10 mg 0.5% Bupivacaine in caesarian delivery under spinal anesthesia and found that onset time of sensory and motor blockade of Ropivacaine was significantly longer than that of Bupivacaine with short duration of sensory and motor block. They found no difference in systolic and diastolic pressure in both groups with significantly higher heart rates in bupivacaine group. Chari et al.,[16] studied 22.5 mg isobaric 0.75% ropivacaine against 15 mg of hyperbaric 0.5% bupivacaine intrathecal in the lower limb and lower abdominal surgeries and found that sensory and motor onset was significantly slower with significantly shorter motor duration in ropivacaine group than Bupivacaine group. However, the analgesic duration and Hemodynamic parameters were comparable in both the groups. Purohit et al.,[17] studied 3 mL hyperbaric ropivacaine against 3 mL hyperbaric bupivacaine intrathecal in lower limb and lower abdominal surgeries and found significantly slow onset of sensory and motor characteristics with early motor recovery in ropivacaine group than bupivacaine group. In addition, they found that Hemodynamic parameters were stable in ropivacaine group as compared to bupivacaine group, as more patients in the Bupivacaine group required treatment for hypotension. Kulkarni et al.,[18] studied 15 mg 0.5% hyperbaric ropivacaine against 0.5% hyperbaric Bupivacaine intrathecally for infraumbilical surgeries and found significantly slow sensory onset with shorter mean sensory duration and mean motor duration of block in ropivacaine group than Bupivacaine group. They also found that the incidence of hypotension was clinically higher in bupivacaine group as compared to ropivacaine group with comparable incidence of bradycardia. In additon, patients in ropivacaine group passed urine significantly

earlier than bupivacaine group. Kharat et al.,[19] studied 4 mL of 0.5% hyperbaric Bupivacaine against 0.5% hyperbaric ropivacaine by intrathecal route for lower abdominal, perennial, and lower limb surgeries and found significantly early onset and peak sensory level duration in bupivacaine group than ropivacaine group with comparable level of cephalic spread of drug in both groups. They also found that ropivacaine gave a lesser degree of motor block which regressed faster than bupivacaine. There was no significant difference in hemodynamic parameters except that diastolic and mean pressures remained on a lower side in bupivacaine group. With all these references we compared higher concentration dose of hyperbaric Ropivacaine than hyperbaric Bupivacaine by the intrathecal route. We used 0.75% Ropivacaine 3 mL against 0.5% Bupivacaine 3 mL by intrathecal route for lower abdominal and lower limb surgeries under spinal anesthesia. We found that the onset of sensory block by L1 pinprick and time for peak sensory level was significantly earlier (P=0.0005 and P=0.0029 respectively) in bupivacaine group than ropivacaine group. However, the level of cephalic spread and duration of sensory block as per two segments of sensory regression time was comparable in both groups. In addition, we found that the time of onset of motor block up to L1 by Bromage scale of 3 of inability to flex thigh, knee, and ankle was delayed in the ropivacaine group than bupivacaine group with highly significant difference. (P=1.27E–08). The duration of analgesia as estimated by the first onset of pain in both groups was comparable. Hemodynamic parameters were more favorable and stable in ropivacaine group. Motor block characteristics in ropivacaine group required additional sedation for better tolerance. There was no urinary retention in ropivacaine group. Our results were comparable to previous studies and the use of a higher dose of hyperbaric ropivacaine has no difference in motor block characteristics as compared to previous studies.

Limitations of the study

Our sample size was small, so for a better assessment more large sample trials may be beneficial.

CONCLUSION

Primarily, we conclude that intrathecal 0.75% hyperbaric ropivacaine produces a more preferable sensory block than motor block with slow onset and comparable duration with better hemodynamic profile.

In addition, we observed that increasing concentration of intrathecal hyperbaric ropivacaine to 0.75% did not add to the motor block pattern in previous studies. Tolerability of motor block characteristics may be enhanced by additional intravenous supplementary sedation.

Suggestion

We may suggest further study using additives to intrathecal hyperbaric ropivacaine to enhance motor block characteristics if required.

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