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Original Article

A Comparative Study on the Efficacy and Safety Profile of Bupivacaine versus Ropivacaine for Intrathecal Anesthesia in Lower Abdominal and Lower Limb Surgeries – A Prospective Randomized Controlled Study

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Abstract

Background: Ambulatory anesthesia's primary goal is fast healing, leading to the early hospital discharge with minimal post-operative side effects. The present study compared the intrathecal administration of 3 mL of 0.75% isobaric ropivacaine with 3 mL of 0.5% hyperbaric bupivacaine on these parameters on the onset duration, hemodynamic stability, and side effects of anesthesia.

Materials and Methods: This study enrolled 60 patients. They were between 18 and 75 years old and over 160 cm tall. Under spinal anesthesia, they underwent elective lower abdominal and lower limb surgeries. This prospective, randomized, and controlled study compared the onset, duration, hemodynamic stability, and side effects of the subarachnoid block between 0.5% bupivacaine hyperbaric and 0.755% ropivacaine isobaric.

Results: In Group B (2.17 ± 0.26 min), the onset of sensory blockade was rapid, whereas, in Group R (6.76 ± 0.19 min), it was delayed. Regression of sensory blockade lasted significantly longer in Group B (102 ± 10.88 min) than in Group R (58 ± 11.73 min), which was clinically significant ($P < 0.0001$). In Group B, the duration of the blockade was 3.68 ± 0.09 h, whereas, in Group R, it was 2.26 ± 0.14 h, indicating a significant difference between the groups.

Conclusion: This study discovered that intravenous injection of 3 mL of 0.75% isobaric ropivacaine resulted in a delayed onset, sensory block (analgesia), and motor blockade for a short period compared to 3 mL of 0.5% hyperbaric bupivacaine.

Key words: Bupivacaine, Intrathecal, Ropivacaine

INTRODUCTION

In the current situation, surgery is moving quickly from being done on inpatients to outpatients. Therefore, traditional anesthetic techniques must be changed to fit the outpatient setting. Ambulatory anesthesia's primary goal is to expedite the healing process, resulting in a shorter hospital stay and fewer side effects. Furthermore, minimal side effects and rapid recovery after anesthesia are possible due to the availability of fast-acting anesthetics, analgesics, muscle relaxant drugs, and modern, sophisticated monitoring equipment.[1] In arthroscopic knee surgery, spinal anesthesia is gradually gaining ground on general anesthesia due to its lower post-operative morbidity and hospital stay.[2] Globally, the demand for rapid ambulation, rapid and complete recovery, and minimal side effects have increased after surgery.

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In contrast, regional anesthesia has gained global acceptance among anesthesiologists due to its numerous advantages.[3,4] For spinal anesthesia, bupivacaine has become the most common drug used. However, it has undesirable side effects, including bradycardia, hypotension, prolonged motor paralysis, neurotoxicity, and cardiotoxicity.[5-8] This led to the identification of pure S-enantiomer ropivacaine with a prolonged action mechanism.[9] Ropivacaine and bupivacaine are nearly identical in quality, onset, and sensory blockade duration. Still, ropivacaine produces a shorter duration of motor blockade and is safer.[3] This medication is beneficial for brief surgical and early recovery. This study compared the effectiveness and safety of ropivacaine and bupivacaine in the lower abdominal and lower limb surgeries. Using various adjuvant drugs and local anesthetic agents in conjunction with spinal anesthesia is a safe, reliable, and affordable technique that offers surgical anesthesia and prolonged relief from post-operative morbidity.

It provides a fast onset and sensory and motor blockade of pain and responses from the somatic, autonomic, and endocrine systems.[10] Epidural bupivacaine and etidocaine are frequently used in Cesarean section anesthesia in pregnant women, causing fatal cardiac toxicity. As a result, there is a need for pure selective, safe s enantiomer local anesthetics such as ropivacaine and levobupivacaine. Ropivacaine helps in safe ambulatory surgery due to its low incidence of transient neurological symptoms. It also can be an ideal alternative to lidocaine for this purpose.[11]

Bupivacaine is a long acting local anaesthetic agent of the amide type. However, hyperbaric bupivacaine achieves more effective sensory intrathecal anesthesia than glucose-free or plain bupivacaine, particularly when anesthesia is administered in the lateral position of patients.[11-14] However, the behavior of plain bupivacaine is often unpredictable, spreading to dermatomal levels of the cervical region. Large doses of intrathecal bupivacaine (IB) are frequently associated with extreme hypotension and delayed motor block recovery.[12] In contrast to bupivacaine and amide local anesthetic, ropivacaine is a long-acting agent with less penetration into massive myelinated motor fibers and low lipophilic than bupivacaine, resulting in a lower level of motor blockade. Due to its greater ability to differentiate between motor and sensory blocks, ropivacaine may be useful when the motor blockade is unpredictable. Central nervous system and cardiovascular toxicity are both less likely to occur due to the reduced lipophilicity feature.[13]

MATERIALS AND METHODS

The study was carried out at Government Villupuram Medical College and Hospital, Mundiyampakkam, after receiving approval from the Hospital Ethics Committee and signed informed consent from patients. This study enrolled 60 patients. They were between 18 and 75 years old and over 160 cm tall. Under spinal anesthesia, they underwent elective lower abdominal and lower limb surgeries. This prospective, randomized, and controlled study compared the onset, duration, hemodynamic stability, and side effects of the subarachnoid block between 0.5% bupivacaine hyperbaric and 0.755% ropivacaine isobaric. Patients who refused to participate, wanted to be rescheduled for emergency surgery, had a spinal anesthesia contradiction, had an allergy to amide local anesthetics, had a history of drug or alcohol abuse or were obese were excluded from the study.

Patients were randomly assigned to two groups. Group B was given 3 mL of % hyperbaric bupivacaine, while Group R was given 0.75% isobaric ropivacaine.

Patients were well instructed on the procedure of sensory or motor assessments before the start of the anesthetic procedure. Fifteen minutes before the surgical process, an intravenous line was demarcated after Ringer Lactate (500 mL) was given. The baseline blood pressure, heart rate, and oxygen saturation data were captured through non-invasive monitoring. Then, a 25 Quincke Babcock spinal needle was used to inject anesthetic into L3–L4 in the lateral position using a midline approach. The cerebral fluid was discovered to be clear and readily flowing, and analgesia was given at a rate of 0.2 mL/s. Blood pressure, heart rate, and oxygen saturation were checked on the patient following intrathecal anesthesia every 5 min for the remainder of the procedure, then every 10 min after that, and finally, every hour after that. We were alert and took care of adverse effects such as bradycardia, nausea, and vomiting.

After the T6 or higher dermatome was blocked, the surgery could begin. First, a sensory blockade was tested using a hypodermic needle every 10 min until full recovery was achieved, then every 5 min until loss of sensation was detected. Next, we evaluated motor blockades using a modified Bromage scale.

In this study, the Bromage score of 3 and the intrathecal administration time interval are used to determine the onset time of motor blockade [Table 1].

When referring to the duration of a sensory or motor blockade, this term refers to the period beginning with the intrathecal administration of the drug and ending with the point at which the sensory blockade has been completely resolved or the point at which the Bromage score has returned to zero, whichever comes first.

The sensory blockade's maximum level of action, the onset, sensory and motor blockade duration, and the interval from the intrathecal route of administration to the point of a two-segment regression function were all recorded. The quality of intraoperative analgesia was graded as

1. Excellent (no discomfort or pain)
2. Good (pain or discomfort and no need for analgesia) borrowed
3. Fair (pain that required additional analgesics)
4. Poor (moderate or severe pain requiring 100 mcg fentanyl or general anesthesia). Patients were assessed for adverse effects such as headache, backache, and temporary neurological symptoms on surgical days 1 and 6.

Statistical Analysis

The analysis was performed using the statistical software SPSS. Continuous variables are given as median (IQR) or mean (standard deviation). Proportional variables are categorical variables. Continuous variables are compared for significance with the help of a *t*-test. The Chi-square test was used for categorical data. <0.05 *P*-value is considered significant.

RESULTS

We found no statistically significant difference between Group R and Group B in terms of gender, age, ASA grading, sensory level blockage hemodynamic parameters, such as heart rate, diastolic blood pressure, systolic blood pressure, respiratory rate, and mean arterial pressure. However, there are statistically significant differences between the two groups' onset, duration, and sensory and motor blockade regression. The onset of sensory blockade was fast in Group B (2.17 ± 0.26 min), whereas in Group R (6.76 ± 0.19 min), it was delayed. This difference in the onset of sensory blockade between Groups B and R was significant ($P < 0.0001$). About 93.3% of patients in Group R had a maximum sensory level of T6, compared to 83.3% in Group B. T4 levels were achieved in 16.6% of Group B patients and 6.7% of Group R patients [Table 2]. Regression of sensory blockade duration was greater in Group B (102 ± 10.88 min) while in it was half in Group R (58 ± 11.73 min); this difference was clinically significant ($P < 0.0001$). The onset of motor blockade onset is earlier in Group B, which was 2.42 ± 0.13 min, compared to Group R, which was 8.82 ± 0.11 min, with a clinically significant difference ($P < 0.0001$). The duration of analgesia refers to the length of the blockade, which was longer in Group B (3.68 ± 0.09 h) than in Group R (2.26 ± 0.14 h), indicating a significant ($P < 0.0001$) difference between the groups. The length of the blockade was longer in Group B than in Group R [Table 3].

Table 1: Modified Bromage scale for motor blockade assessment

Grade	Criteria	Degree of motor blockade
1	Movement of the feet and legs	0% (Nil)
2	Only able to bend knees with little restriction on foot movement	33% (partial)
3	Having unrestricted movement in the feet yet unable to bend the knees	66% (almost complete)
4	Unable to move legs or feet	100% (complete)

DISCUSSION

A subarachnoid block is a well-regarded effective anesthetic method with a high success rate and a decent safety profile. As a result, research is still ongoing to find an appropriate medicine that is inexpensive and effective and has minimum side effects while also speeding up the recovery of patients. New local anesthetics are being developed in this approach, with the primary goal of improving the condition of patients. In addition, the medicine should act quickly and without side effects, allowing patients to be discharged sooner. Due to this, we decided to compare ropivacaine's effectiveness to bupivacaine, the most often prescribed and well-established anesthetic.

Mantouvalou *et al.*[10] discovered a greater cephalad spread of sensory blocks with bupivacaine compared to 15 mg of intrathecal isobaric ropivacaine and 10 mg of bupivacaine during the resection of the prostate, which is consistent with our study group's findings. A double-blind and randomized controlled trial by Chari *et al.* found that levobupivacaine's motor block onset was nearly the same in both groups. In contrast, the bupivacaine group's onset was significantly faster and more effective than the ropivacaine group ($P < 0.05$).[14]

Similarly, other comparative studies found that ropivacaine produces delayed onset compared to bupivacaine.[10,15] In

Table 2: Level of sensory blockade among participants

Group	T4	T6	Total	Chi-square	*P*-value
Group B	5	25	30	1.45	0.22
Group R	2	28	30		
Total	22	38	60		

Table 3: Blockade among participants

Blockade	Group B	Group R	*P*-value
Time of onset of sensory blockade	2.17±0.26	6.76±0.19	0.0001
Regression of sensory blockade to l1	102±10.88	58±11.73	0.0001
Time of onset of motor blockade	2.42±0.13	8.84±0.11	0.0001
Duration of motor blockade	3.68±0.09	2.26±0.14	0.0001

the present study, Group B experienced sensory blocking in 2.17 min, whereas Group R experienced it in 6.76 min. According to hemodynamic measurements, there was no significant difference across groups. In Group R, 93.3% of patients had a maximum sensory level of T6, compared to 83.3% in Group B. T4 levels were achieved in 16.6% of Group B patients and 6.7% of Group R patients. The level of sensory blockade was enough in both groups, which was consistent with a finding of the Bhat and Upadya study.[16]

The time for regression of sensory blockade is more in Group B (102 ± 10.88 min) compared to Group R (58 ± 11.73 min). Similarly, when Arish Sadaf and his colleagues studied 70 patients separated into two groups for their comparative and observational study, Group R received ropivacaine (0.75%) + Fentanyl 25 μg (0.5 mL). Group B received bupivacaine (0.5%) + Fentanyl 25 μg (0.5 mL). There was a statistically significant regression in sensory blockage in the group given ropivacaine, which had $P < 0.001$ value, while the group receiving bupivacaine had no such regression.[17]

Intrathecal ropivacaine (IR) and IB were examined in a study by Sanchez and colleagues in 2009. Although they observed a significant difference in the length of a blockade in the groups $P < 0.001$, the IB Group (266.5 ± 29.5) had a longer period of a blockade than the IR Groups (226.4 ± 22.3 min).[18] We discovered that Group B's blockade lasted an average of 3.68 ± 0.09 h. In contrast, Group R's lasted for an average of 2.26 ± 0.14 h, indicating a significant difference between Group R and Group B.

CONCLUSION

Compared to 0.5% hyperbaric bupivacaine, 0.75% isobaric ropivacaine administered in an equal volume of 3 mL resulted in a delayed onset, sensory block (analgesia), and motor blockade for a brief period. Hemodynamic measurements did not show any difference between the groups. Therefore, ropivacaine is a safer option than bupivacaine for the surgeries of perineal, lower abdominal, and lower limbs due to its lower incidence of adverse effects such as neurotoxicity and cardiovascular, as well as provide motor blockade for a short duration.

Limitations

The sample size should be increased to improve generalization. This study had only 60 participants divided into two groups. In addition, this study did not consider the basicity of local anesthetic, which is an important factor responsible for the peak height of sensory anesthesia.

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