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A study to compare 0.5% hyperbaric bupivacaine with 0.5% isobaric ropivacaine intrathecally for elective lower limb surgery.

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Abstract

Background: Spinal anaesthesia is the most appropriate method that is more advantageous than general anaesthesia. The study was planned to comparatively assess the effects of hyperbaric 0.5% Bupivacaine with isobaric 0.5% Ropivacaine in Elective Lower Limb Surgery.

Methodology: One hundred patients belonging to American Society of Anesthesiologists (ASA) class I and II were selected for elective lower segment operation. Participants were assorted into two groups without following any fixed criteria and treated as; Group B and R, injected with bupivacaine in 0.5% hyperbaric condition and 0.5% isobaric ropivacaine, respectively.

Results: The time of onset of blockage of sensation was prominently lesser in Group B contrary to Group R. The time slot of attainment of maximum sensory block up to T6 level was statistically significant and was smaller in Group B. The duration for the two-segment regression's sensorial blockage was more duration in Group B. The average extent of blockage of sensation was lesser in the R group. The time to achieve maximum motor blockage when testing via Bromage scale 2 was lower in the B group. In group B, the mean duration of the motor blockade was calibrated from the Bromage scale.

Conclusion: The use of ropivacaine given for lower segment surgeries provided an efficient level of block required during the surgery with a speedy outset of motor and sensory blockade and less time needed to achieve motor blockade.

Keywords

Hyperbaric Bupivacaine, Lower Limb Surgery, Spinal Anesthesia, Isobaric Ropivacaine, Anesthetic.

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Introduction

Spinal anesthesia, also called spinal analgesia or sub-arachnoid block (SAB), is a form of regional anesthesia involving a local anesthetic injection into the cerebrospinal fluid through a fine needle[1]. Bupivacaine is extensively used and produces an efficient sensory and motor blockade[2]. When using bupivacaine, fewer patients complain of mild localized self-limiting tenderness at the lumbar puncture site for the next day. Bupivacaine has a more significant early sensory onset than ropivacaine, i.e., between 12-26 minutes, and has a motor onset, i.e., 19-35 minutes.

However, the cons include cardiac and central nervous system toxicity due to the accidental intravascular injection or pronounced overdose[3]. Bupivacaine is more lipophilic than ropivacaine therefore associated with increased potential for Central nervous system (CNS) and cardiotoxicity. The patients who receive bupivacaine develop hypotension. Bupivacaine has a significantly greater degree and duration of motor block, i.e., late mobilization of the patient postoperatively and simultaneously passing urine late. More patients develop bradycardia and need the sympathomimetic drug[4].

The newly introduced drug, i.e., ropivacaine, has a more specific effect on the motor nerve fibers[5-7]. Furthermore, this drug has lesser cardiac toxicity[8]. On the other hand, bupivacaine possesses a faster onset and regression of sensory and motor blocks. The patients' acceptability is also increased when this drug is administered. Also, there is research that positively supports the finding of delayed sensory onset and the motor onset when given intrathecally in the case of elective lower limb surgery[9]. Some studies also suggest the evidence of no benefit when the duration of action of the drugs is of the lesser period[5,10]. But in other studies where intrathecal administration of ropivacaine is conducted, the shorter duration of action has been considered a positive outcome[1,9]. Also, the lipophilic nature of 0.5% ropivacaine is reduced contrary to bupivacaine. The possible positive results of employing isobaric ropivacaine compared with hyperbaric bupivacaine remain undetermined in the case of Elective Lower Limb Surgery.

No study conducted on the Pakistani population indicates for Elective Lower Limb Surgery to compare the effectiveness and patient safety. It is hypothesized in this study that the lipophilic effect of 0.5% ropivacaine is less compared to bupivacaine which is subsequently less cardiotoxic and CNS toxic. Thus, the study is planned to comparatively assess the effects of hyperbaric 0.5% Bupivacaine with isobaric 0.5% Ropivacaine in Elective Lower Limb Surgery.

Methodology

Before the study initiation, ethical and scientific review committee of Karachi Medical & Dental College, approved the study plan (Ref: 0031/14). This research was carried out following all the ethical measurements of the Helenski Declaration and the Pakistan Medical and Research Council. Before enrolment in the study, a written consent was procured from the patients. The aim of the study, treatment given, procedure involved in the pooling of data, pros and cons of the study were mentioned. The response of the participants was maintained anonymously and privately throughout the entire study period. Only the principal investigator was provided access to the data.

The study was carried out from July 7, 2020, to January 8, 2021 at the Orthopedic department, Operation Theatre of Abbasi Shaheed Hospital. One hundred patients belonging to ASA classes I and II were selected for elective lower segment operation. Participants were assorted into two groups without following any fixed criteria and treated as; Group B and R were injected with bupivacaine in 0.5% hyperbaric condition and 0.5% isobaric ropivacaine respectively. Pregnant women or Subjects greater than 60 years or Hematological disorders predisposing to coagulopathies or patients on anticoagulant therapy, bleeding, or coagulation test abnormalities or Pre-existing disease of CNS or History of severe disturbances in heartbeats and history of shock, hypotension, hypertension, and heart block or Arthritis or spinal deformity or contraindications for intrathecal block:

Drug allergy, increased ICP, bleeding disorder, infection at the site or Patients with lipid disorders were excluded from the study.

For blinding purposes, the syringes were arranged by an anesthesiologist having experience of 25 years, and he was not the investigator in this study. Thus, 50 study participants were randomly classified in Group B while the remaining 50 study participants as Group R for elective lower abdominal and limb surgery as spinal anesthesia. A complete examination and physical history were taken from all the subjects of both groups. For the 18 h period, the patients fasted before the day when the operation was scheduled. Patients were checked for respiratory rate, pulse rate, oxygen saturation, ECG changes, and blood pressure in the pre-OPs room. Clinical patients injected 0.4 % HES in the concentration of 6 ml/kg body weight, and this was infused 15 min before the subarachnoid block.

An anesthesiologist who has experience of 25 years of performing this operation under aseptic conditions. A suitable small-bore spinal needle was used to give anesthesia (26 G Quinke). Intrathecally patient was operated on in a sitting or lateral position in a mid-line. Bupivacaine (3 mL of 0.5%) was given to Group B, and the patients grouped in the R group were injected with the same volume and concentration of R. The vitals such as BP, oxygen saturation (SpO_2), and arterial pulse were recorded for 300 sec. It was measured for 30 min. After half an hour, these measurements were carried out for 10 min.

The sensory block was assessed until it attained T5 to T6 level using the pinprick test, and after that surgical incision was carried out. Loss in antigravity movements of the legs was used to measure the intensity of motor blockade concerning the divisions of the Bromage scale. The patient's anthropometric measurements (i.e., age, weight, height, BMI, etc.) were recorded. Hemodynamic parameters, oximeter and ECG leads, and SpO_2 of all patients were recorded. On the structured proforma, T0 (time at which the drug was administered), outset, and time required for motor and sensory block were also noted down. The administration of fluids balanced intraoperative losses. On surgical indication, catheterization of the bladder was done. Patients were motivated to move exclusively when the sensory block had reverted before S2.

The sample size was computed by Openepi sample size software. The duration of sensory blockade was the primary outcome. The two dermatomes sensory segment regression in Group R was 117.20 ± 12.5 min compared to Group B, 108.5 ± 10.61 min[10]. The reference study was inserted in the Openepi sample size calculator. 50 patients in each group were needed to achieve 90 % power to assess the differences within the tested groups with 5 % type I error on the test.

SPSS version 20.0 was used to analyze the data obtained in this study. A definite point estimate was presented in proportion and percentage. Numeric point estimates, i.e., age, weight, height, BMI, sensory and motor block time, etc., were presented as mean ± SD. Patients' characteristics such as mean age, weight, height, BMI, and operation duration between the two arms of the trial were compared using an independent t-test. The comparison of class I and II ASA categories was achieved using the Chi-square test of the B and R groups. A p-value of ≤0.05 was set as a significant value.

Results

In this study, the total of 100 patients for elective lower segment operation was classified into Group B and R on a random basis. An insignificant difference was found between the tested groups in variables demographically and the time required for surgery (Table 1).

Table 1: Characteristics with respect to study groups.

Variables		Group B (n=50)	Group R (n=50)	p-value
		Mean ± SD		
Age (years)		45.20±12.28	40.62±14.63	0.093
Height (cm)		78.44±12.07	75.82±8.66	0.210
Weight (kg)		165.62±11.88	165.06±9.50	0.790
BMI (kg/m^2)		29.06±6.32	28.18±5.03	0.450
Duration of surgery (min)		38.44±4.36	40.08±4.92	0.080
Gender; n(%)	Male	25(50)	31(63)	0.227
	Female	25(50.09)	19(38.09)	

Group B-Bupivacaine group; Group R-Ropivacaine group.

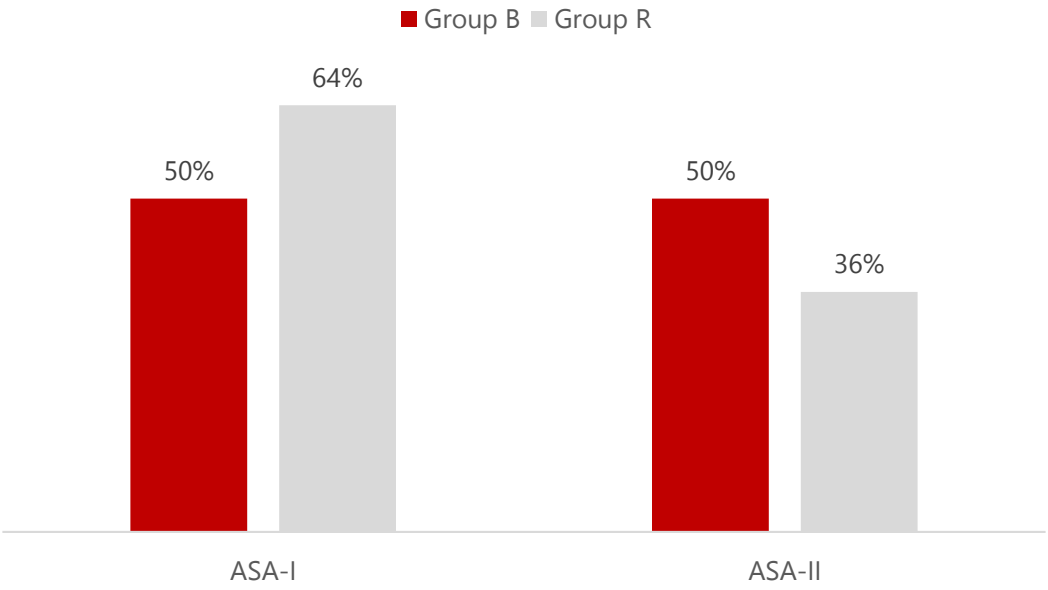

Figure 1: ASA status in Group B and R (n= 100).

Regarding ASA status, a non-significant difference was observed between the two groups (p=0.157). The statistically significantly faster time of onset of sensory block in Group B when Group R was compared considering p=0.0005. Duration of attainment of maximum sensory block up to T6 level was smaller in Group B than in the R group (3.94 ± 0.84 minutes vs. 4.80 ± 0.70 minutes). Two sensory segment reversion time was elevated in Group B, i.e., 112.52 ± 6.48 minutes compared to the R group (85.18 ± 5.47 minutes) at p=0.0005. Similarly, the mean duration of sensory block was 186.02 ± 18.44 minutes in the B group and 153.38 ± 12.91 minutes in Group R. The mean time of sensory blockade was lesser in Group R when p<0.05, as depicted in table 2.

Table 2: Time of sensory block between groups.

Variables	Group B (n=50)	Group R (n=50)	p-value
Period of start of sensory Block (i.e., T-6)	3.1±0.83	3.84±0.62	0.0005*
Period of T6 maximum level (i.e., above T-6)	3.94±0.84	4.80±0.70	0.0005*
Period of two segment regressions (i.e., T-8)	112.52±6.48	85.88±5.47	0.0005*
Period of regression to S2	186.02±18.44	153.38±12.91	0.0005*

Group B-Bupivacaine group; Group R-Ropivacaine group.
*p<0.05 is considered statistically significant.

No major variations were observed in the case of the motor block mean onset. Duration to attain maximum motor block in terms of Bromage score 2 was lesser in Group B, i.e., 5.82 ± 0.95 and 6.68 ± 1.06 minutes at p<0.05 respectively. The average difference in duration of motor block was lesser in Group R, which was observed as 216.92 ± 18.46 vs. 260.24 ± 19.07 minutes at p<0.05, as presented in table 3.

Table 3: Time of motor block between groups.

Variables	Group B (n=50)	Group R (n=50)	p-value
The onset of Motor Block (i.e., Bromage 2)	4.96±0.78	5.28±1.26	0.130
Time to maximum Motor Block. (i.e., Bromage 3)	5.82±0.95	6.68±1.06	0.0005*
Duration of Motor Block (i.e., Bromage 0)	260.24±19.07	216.92±18.46	0.0005*

Group B-Bupivacaine group; Group R-Ropivacaine group.
*p<0.05 is considered statistically significant.

Discussion

Spinal anesthesia is preferable to general anesthesia due to many reasons. The advantages are likely linked with the patient's acceptance of the drugs tested. Spinal lignocaine has a lesser duration of anesthetic blockage, but it also possesses certain neurological impairment, which has caused its retrieval from the practical applications[11-15]. However, spinal bupivacaine causes profound longer-duration motor blockade, and early discharge of the patients after ambulatory surgery is delayed[16].

Ropivacaine is a local amide anesthetic that has been currently marketed. It is used successfully to provide epidural analgesia for women in labor, postoperative analgesia, and cesarean delivery[17,18]. It is also used for intrathecal sensory block accompanying early motor recovery[19,20]. It is also featured with lesser toxic effects on the cardiac and the nervous system, causing this drug to be favored most[21]. Some other drugs, such as Opioids, have the same mechanism of action. Still, they tend to negatively impact the sensory blockade, simultaneously not affect the sympathetic block[22,23].

This study elaborated on a lesser time of onset of sensory blockade in bupivacaine-treated patients (p=0.0005). Similarly, the mean duration of sensory block was 186.02 ± 18.44 minutes in the same tested group and 153.38 ± 12.91 minutes in the patients who received Ropivacaine (p=0.0005). Some other researchers also concluded the same findings[9] comparing the anesthetic effect of hyperbaric B with isobaric R given intrathecally for Elective Lower Limb Surgery. They reported that the onset of sensory blockade in the patients who had received ropivacaine was significantly prolonged compared to the other group having a p-value of 0.001.

In a study, Malinovsky et al. compared intrathecal isobaric R when administered in 15 milligram doses with 10 g of B in transurethral resection of the prostate surgeries[24]. They concluded that sensory block that spread towards the head was more in the patients treated with bupivacaine when compared with ropivacaine.

In our study, the time to attain maximum motor blockade, given by Bromage Scale (2), is quicker in the B group than R, i.e., 5.82 ± 0.95 vs. 6.68 ± 1.06 minutes; p=0.005 respectively. Kallio et al. and McNamee et al. made similar observations[25,26].

The time needed to attain individual Bromage scores subsequently was found to be alike in both the studied groups. Similar observations were made by Gudul et al[27]. In this research, at Bromage

score=0 mean duration of motor blockade was lesser in patients belonging to the R group when compared with the B group, i.e., 216.92 ± 18.46 vs. 260.24 ± 19.07 minutes at p=0.0005. Another study[9], which compared the anesthetic effect of both the drugs given intrathecally for elective lower limb surgery, reported that in the R group, the sensory, motor onset, peak sensory time, and peak motor time were significantly prolonged on the contrary to B group at p<0.001.

In Group R, when p was 0.001, the two dermatomes' sensory segment regression and duration of motor block were prolonged as compared to Group B. In contrast to the duration of postoperative heart rate and blood pressure, no significant differences were elaborated. Furthermore, no side effects on the respiratory tract were observed when the study drugs were administered[1].

This trial elaborated that the studied groups, i.e., B and R acting as an adjuvant, showed maximum anesthetic situations for lower limb surgeries. R is nearly similar to B based on the outset, duration, and quality of sensory blockade, but it yields a lower duration of motor blockade and has a greater patient safety[22].

The efficacy of the drugs is altered when a prolonged duration surgery is in progress. The limitations of this study include the risk of hypotension due to excessive administration of the drugs. These drugs may have an adverse effect on a specific group of patients despite effective amounts of sedative drugs given to them.

Conclusion

It is concluded that the use of ropivacaine presented an ample amount of blockade for lower segment operations given intrathecally. It has a rapid outset of motor and sensory blocks, and less time is required for the motor blockade.

Conflicts of Interest

The authors have declared that no competing interests exist.

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