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COMPARISON OF HYPOBARIC ROPIVACAINE 0.33% VS 0.5% FOR UNILATERAL SPINAL ANAESTHESIA FOR LOWER LIMB SURGERY, A RANDOMIZED CONTROLLED TRIAL

Anaesthesiology

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ABSTRACT

Background And Aims: Unilateral spinal anesthesia is an emerging and safe option for patients undergoing lower limb surgery. With the use of hypobaric drugs a unilateral spinal anaesthesia can be given which produces a dose dependent sensory and motor block on the affected side while overcoming the side effects associated with bilateral spinal anaesthesia.The stable hemodynamic profile allows its use in high risk patients and the rapid recovery from the block allows early ambulation and reduced hospital stay. The objective of this study is to compare the anaesthetic efficacy of intrathecal hypobaric ropivacaine 0.33% vs 0.5% for unilateral spinal anaesthesia in lower limb surgeries with respect to: 1. Onset and duration of sensory block, 2. Onset, quality and duration of motor block, 3. Hemodynamic changes. **Methods:** A double blind RCT is conducted between two groups of patients receiving drug A 0.5% ropivacaine hypobaric (obtained by mixing 2ml of 0.75% ropivacaine isobaric with 1 ml of sterile water) and drug B 0.5% ropivacaine hypobaric (obtained by mixing 0.33% of ropivacaine isobaric with 1 ml of sterile water). [2] The two groups are then compared for the Onset and duration of sensory block, onset, quality and duration of motor block, and hemodynamic changes. **Results**: Only 2 ml of each drug is given to each group. Drug A shows early onset as well as duration of motor and sensory block as compared with drug B. ($p< 0.05$). **Conclusion:** Intrathecal administration of hypobaric solutions of ropivacaine can produce a purely unilateral dose dependent sensory and motor block on the affected side with minimal hemodynamic disturbances.

KEYWORDS

Unilateral spinal anaesthesia; Ropivacaine ; Hyperbaric ; Hypobaric ; isobaric

INTRODUCTION

Background Of The Study

When it comes to lower extremity surgery, spinal anesthesia is a quick, low cost, safe method that has controllable effects on breathing and circulation and offers superior postoperative analgesia than general anesthesia.[1] Although the procedure has several benefits, many institutions avoid using it for outpatient surgery because urine retention and extended immobility following a traditional bilateral block with bupivacaine might prolong hospital stay.[2] Although they shorten the time required for discharge, shorter-acting local anesthetics like lignocaine are not recommended because of the high rate of neurological side effects.[3]

The low solubility of ropivacaine leads to greater sensory-motor differentiation by blocking sensory nerve fibre more readily than motor fibre. Early recovery of motor function is associated with decreased incidence of venous thromboembolism, early mobilization, and shorter hospitalization. [4,5]

Baricity represents the ratio of the density of local anaesthetic concerning CSF. Cerebrospinal fluid has a density of 1.00059 g/L. As the density changes with temperature, the baricity of a local anesthetic solution is defined conventionally at 37 degree calcius. Solutions with a baricity of less than 0.9990 are considered hypobaric, whereas those with a baricity of more than 1.0015 are considered hyperbaric.[6]. At 37-degree calcius, isobaric ropivacaine 0.5 % and 0.75 % are hypobaric as concluded by McLeod G.A. et all in their study of the density of spinal anaesthetic solutions of bupivacaine, levobupivacaine, and ropivacaine with and without dextrose. (table 1) [7] The addition of sterile distilled water or heating the isobaric solutions can form hypobaric solutions.

TABLE 1 Densities of various local anesthetics at 23 and 37 degeree calcius

Solution	Density at 23°C mg ml^{-1}	Density at 37°C mg ml^{-1}
Bupivacaine 2.5 mg ml^{-1}	1.00345 (0.00003)	0.99921 (0.00009)
Bupivacaine 5 mg ml^{-1}	1.00376 (0.00002)	0.99944 (0.00012)
Bupivacaine 7.5 mg ml^{-1}	1.00369 (0.00002)	0.99938 (0.00017)
Levobupivacaine 2.5 mg ml^{-1}	1.00418 (0.00001)	0.99985 (0.00002)
Levobupivacaine 5 mg ml^{-1}	1.00419 (0.00002)	1.00024 (0.00009)
Levobupivacaine 7.5 mg ml^{-1}	1.00482 (0.00002)	1.00056 (0.00010)
Ropivacaine 2 mg ml^{-1}	1.00372 (0.00002)	0.99960 (0.00006)
Ropivacaine 5 mg ml^{-1}	1.00380 (0.00002)	0.99953 (0.00013)
Ropivacaine 7.5 mg ml^{-1}	1.00380 (0.00003)	0.99953 (0.00014)
Ropivacaine 10 mg ml^{-1}	1.00381 (0.00002)	0.99950 (0.00010)

Need For The Study

Extensive clinical data have shown that ropivacaine is effective and safe for regional anaesthetic techniques such as epidural and brachial plexus block. However, the experience of intrathecal anaesthesia with ropivacaine is not as well documented. To our knowledge, there isn't much research on the use of hypobaric ropivacaine for spinal anesthesia during obstetric, abdominal, and orthopaedic procedures, even though the drug was released a few years ago. Furthermore, there isn't much research on Asian people. The majority of the current research on the use of these medications focuses on peripheral nerve blocks and epidural and labor analgesia.

The aim of the study is to compare the efficacy, duration of analgesia, hemodynamic stability, and side effects of making two hypobaric concentrations of ropivacaine 0.5% and 0.33% to determine which is more suitable for patients undergoing lower limb surgery. The significance of this problem statement lies in its potential to enhance patient comfort, reduce anaesthesia-related risks, and improve postoperative recovery, which is crucial for the patient's overall surgical experience and outcome. The findings could guide anesthesiologists in selecting the most appropriate concentration of ropivacaine for unilateral spinal anaesthesia in lower limb surgeries. The objective of this study is to compare the anaesthetic efficacy of intrathecal hypobaric ropivacaine at two different concentrations in lower limb surgeries concerning: 1. Onset and duration of sensory block, 2. Onset, quality and duration of motor block, 3. Hemodynamic changes.

METHODS

This double blind randomised controlled trial was conducted in GSVM medical college Kanpur and associated LLRH Kanpur over 2 months from June 2024 to August 2024.Approval was obtained from the institutional ethical committee (ethics committee, GSVM Medical College, Kanpur Ref no: EC/259/June/2024, Dated 1-06-2024).we included 60 patients who fulfill inclusion criteria. Inclusion crieteria were patients with age >18, ASA physical status I-II and undergoing unilateral lower limb surgery while patients who refused to give consent, had neurovascular injury allergy to local anesthetics, ASA grade ≥ 3 or bilateral surgeries were excluded from the study.

Patients presenting to orthopedic OT for unilateral lower limb surgery were randomly divided into two groups. All the patients received spinal anaesthesia in lateral decubitus position with the operative side

up. Local anesthesia used: 2 ml of 0.5% ropivacane isobaric and 0.75 % ropivacaine isobaric diluted with 1 ml distilled water to make 0.33% ropivacaine hypobaric and 0.5 % ropivacaine hypobaric respectively. Group A received (2 ml of 0.75% ropivacaine (isobaric) drug + 1 ml distilled water) = 2 ml injected into the intrathecal space. Group B received (2 ml of 0.5% ropivacaine (isobaric) drug + 1 ml distilled water) = 2 ml injected into the intrathecal space. All the patients were kept in lateral decubitus position with the operative side up for 20 minutes following administration of the drug. Systolic pressure, diastolic pressure, mean arterial pressure, heart rate, and oxygen saturation (SpO2) were recorded at 0 minutes, every 5 minutes during the first 20 minutes, every 15 minutes until the 90th minute and every 30th minute until the 180th minute. Clinically relevant hypotension (decrease in systolic arterial blood pressure ≥ 30% from baseline) was treated with intravenous infusion of ringer lactate solution (200 mL over minutes); if this is found ineffective, 1 mL of mephenteramine (6mg/ml solution) was given intravenously. Bradycardia (heart rate < 50 beats/min) was managed with 0.5 mg of intravenous atropine. The sensory block level at the T12 dermatome was determined on both the operated and the non operated side using a pin-prick test in the mid-clavicular line with a 20G hypodermic needle. The maximum sensorial block level reached was determined and recorded for both sides based on the pin-prick test. The level of the sensorial block on both sides was recorded at zero, 5, 10, 15, 30, 60, 90, 120 and 180 minutes following the administration of SA. The motor block level on both sides was recorded at 0, 5, 10, 15-, 120, 150 , and 180 minutes post-SA, according to the modified Bromage scale. The time from achieving maximum sensory block to a two-segment regression on both sides was also recorded. Successful unilateral spinal anesthesia is defined as a total motor block (level 3 on the modified Bromage scale) and loss of pain sensation at the T12 dermatome level on the operated side, with the non-operated side retaining somatic sensation and having a motor block level < 2 on the modified Bromage scale.

Score	Degree of motor block	
1	Complete block; unable to move feet or knees	
2	Able to move feet only	
3	Just able to flex knees; free movement of feet	
4	No block; full movement of knees and feet	

Ethical Consideration

Informed and written consent (in the language best understood by the patients or attendant) was obtained from each subject before data collection. Only volunteers were included, and their data were kept confidential. The study did not impose any burden on the subjects or the institute, thus justifying its ethical basis. The study was approved by the Institutional Ethical Committee.

Observation And Results

The patients present in both groups were similar with respect to age distribution, sex, ASA grade, and clinical scenario. A similar type of surgery was performed in both groups. Heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure variations in both groups were comparable as can be inferred from Table 2 and Table 3. Adequate volumes of fluid and blood were administered during the surgery, and no significant cardiovascular changes were observed perioperatively in either group. The onset of sensory and motor blockade in Group B was slower compared to Group A, which was statistically highly significant with a P value of <0.05. The mean time for onset of motor block in group A was 12.07±1.2 minutes while in group B it was 18.93±0.94 minutes which was highly significant with a P value of <0.001. (Table 4) The duration of motor block i.e. modified Bromage scale 3 on the operative side was more in patients receiving drug A (97.17±7.8 minutes) as compared with those receiving drug B (71.47±6.3minutes) with a P value of <0.001. (table 4) The mean time for onset of sensory block was longer in group B (15.9±1.15 min) as compared with group A (8.07±1.0 min) with a P value of <0.001. (Table 5) The duration of sensory block i.e. loss of pinprick sensation at T12 on the operative side was more in patients receiving drug A (100.83±7.6 minutes) as compared with those receiving drug B (79.30±21.9 minutes) with a P value of <0.001. (table 5)

Table 2: Distribution of the studied patients based on heart rate in both groups at different intervals

HR (beats/minute)	Group A (n=30)	Group B ((n=30)	p-value
Pre-operative	86.6±13.5	85.0±15.8	0.688
1 minute	88.5±13.0	85.8±15.9	0.486
3 Minute	85.2±12	83.0±13	0.531
15 Minute	83.1±11	80.3±14	0.422
30 Minute	80.9±10	78.6±13.6	0.466
60 Minute	79.03±10.3	77.5±13.3	0.629
90 Minute	77.5±10	76.8±12	0.814
120 Minute	76.7±10.6	75.1±11.6	0.596

Table 3: Distribution of the studied patients based on mean arterial pressure in both groups at different intervals

MAP (mmHg)	Group A (n=30)	Group B (n=30)	p-value
Pre-operative	91.6±8.7	93.3±10.6	0.493
1 minute	86.8±8.0	89.2±10.3	0.318
3 Minute	87.8±9.5	89.7±9.4	0.439
15 Minute	88.3±8.7	89.1±9.6	0.726
30 Minute	88.8±9.0	91.0±9.5	0.377
60 Minute	89.6±8.2	91.6±9.4	0.398
90 Minute	90.2±8.8	91.4±8.8	0.625
120 Minute	90.0±8.2	92.2±8.9	0.324

Table 4: Distribution of the studied patients based on Motor block in both groups

Motor Block	Group A(n=30)	Group B ((n=30)	p-value
Duration of motor block up to Bromage scale 3 (minutes)	97.17±7.8	71.47±6.3	<0.001
Onset of motor block up to modified Bromage scale 3 (minutes)	12.07±1.2	18.93±0.94	<0.001
Time of regression of motor block from Bromage 3 to 2 (minutes)	97.50±8.0	71.47±6.9	<0.001

Table 5 Distribution of the studied patients based on sensory block in both groups

Sensory Block (minutes)	Group A (n=30)	Group B (n=30)	p-value
Duration of sensory block (loss of pinprick sensation at T12)	100.83±7.6	79.30±21.9	<0.001
Onset of sensory block at T12	8.07±1.0	15.9±1.15	<0.001
Time of two-segment regression of sensory block	105.5±21.7	83.1±5.9	<0.001

DISCUSSION

The purpose of our study was to compare the differences in the onset, duration of action and complications of intrathecal hypobaric ropivacaine obtained by diluting 2 ml of 0.75% isobaric ropivacaine with 1 ml sterile water (Group A) and intrathecal hypobaric ropivacaine obtained by diluting 2ml of 0.5% isobaric ropivacaine with 1m sterile water (Group B) in elective lower limb surgeries. A solution is said to be hypobaric if its density is lower than three standard deviations below the mean density of cerebrospinal. (7) The patients of both groups were administered 2ml of the hypobaric drug via the intrathecal route in the lateral decubitus position with the operative side up so that the hypobaric drug settled in the non-dependent region. Leaving patients in the lateral position for less than 20 minutes was associated with a bilateral spread of the drug later in the intraoperative period. There was a complete unilateral block in both the groups, which can be compared to another study conducted by

Kaya M et al [8] (2010) who compared low-dose hyperbaric and hypobaric levobupivacaine in unilateral spinal anesthesia. They found unilateral sensory block in 90% of patients in the hyperbaric group and 80% in the hypobaric group in the lateral position. After 15 minutes, when patients were turned supine to redistribute the block, unilateral spinal anesthesia persisted in 60% of the hyperbaric group and 33% of the hypobaric group (P = 0.038). It can be attributed to the duration for which the patients were kept in lateral decubitus position as well as on the dose of local anaesthetic given intrathecally. The literature also suggests that giving small doses of local anaesthetics into the subarachnoid space is associated with more dense block on the operative side which was also observed in our study. [9, 10, 11, 12]. 42 Another study conducted by Kuusunami et al [13] which compared two groups who were kept in lateral positions for 20 and 30 minutes respectively showed that although sensory unilateral could be achieved in both the group equally, the unilaterality of motor block was higher in the 30 minute group. Similar results were obtained in our study. No conversion to bilateral block was observed as the patients were made supine. The spread and selectivity of block achieved with hypobaric drugs depends on the volume and concentration [14]. At lower concentrations of the drug, a more selective (preferential sensory block) block is achieved. Injecting more volume was associated with the unpredictable spread of the drug. [15] In our study groups, we administered only 2ml of hypobaric drug A and drug B. A completely unilateral block was achieved in both groups with a faster onset of sensory and motor block in the group receiving drug A as compared to the group receiving drug B ($p < 0.001$) which can be attributed to a lower concentration of the drug B (0.33%). The mean onset time for sensory block was 8.07±1.0 minutes with drug A while it was 15.9±1.15 minutes with drug B ($p<0.001$). The current evidence also supports that the height of the block depends on the dose of local anaesthetic dose given intrathecally. [16, 17] In our study, in 3 patients' maximum block height up to T12 could not be achieved and hence were excluded from the study. All these patients were given drug B and were obese with a BMI of more than 26 kg/m2. Similar observations were made concerning the duration of sensory and motor blocks in both groups. Patients who received drug A had a prolonged duration of sensory block (100.83±7.6minutes) as compared with those who received drug B (79.30±21.9 minutes). ($P<0.001$) The duration of motor block was also prolonged in those receiving drug A. ($P<0.001$). Similar observations were made by Cantürk M et al [18] in a study comparing hyperbaric and hypobaric ropivacaine (11.25mg) where it was observed that hypobaric group shows early regression of both sensory and motor block. In 4 patients who enrolled for the study, motor block up to modified Bromage scale 3 could not be achieved after 20 minutes of spinal anaesthesia with drug B and were therefore excluded from the study. As the patients were kept in lateral decubitus position such that the affected side remained non-dependent, patients were comfortable after administration of the drug. Patients remained hemodynamically stable in both the groups and there was no requirement for vasopressors in any of the groups. 19 patients who were enrolled in the study had surgeries involving the proximal femur and were required to be kept in the supine position in the fracture table which requires the unaffected limb to be kept in slight flexion, abduction and external rotation. Although the uninjured limb was properly padded 10 patients complained of discomfort in the unaffected limb. Also due to early regression of motor block in both of the group surgeries requiring proper relaxation for example amputation, communited fractures of the femur, etc. rescue methods were required in 6 patients in the form of general anaesthesia. The duration of the two-segment regression of sensory block was 105.5±21.7 minutes in the group receiving drug A as compared with 83.1±5.9 minutes in those who received drug B. ($P<0.001$).

CONCLUSION

Intrathecal administration of hypobaric solutions of ropivacaine can produce a pure unilateral block on the affected side with minimal hemodynamic disturbances. Injection of hypobaric ropivacaine 0.33% (drug B) has a slower onset of motor and sensory block as compared with hypobaric ropivacaine 0.5% (drug A). Similarly, the duration of sensory and motor block is prolonged for drug A as compared with drug B. Although both of these hypobaric solutions can produce good quality motor and sensory block, the short duration of action and early two-point regression of sensory block limits their use for lengthy procedures which is otherwise in the case of conventional hyperbaric drugs like Bupivacaine heavy.

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