A Comparative Evaluation of Intrathecal 0.5% Hyperbaric Ropivacaine Versus Intrathecal 0.5% Hyperbaric Bupivacaine for Anorectal and Urological Elective Surgeries- A Randomized Comparative Study

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Abstract

Background: The growing preference for ambulatory surgeries has led to an increased utilization of subarachnoid blocks with local anesthetics, having a low incidence of side effects, a predicted regression within a reasonable time frame, and a quick commencement of motor and sensory blockage. We carried out this study to assess the effectiveness of 0.5% hyperbaric ropivacaine solution in comparison to 0.5% hyperbaric bupivacaine solution for spinal anesthesia in daycare procedures such as anorectal and urological surgeries.

Aim:

The main objective was to compare the duration of motor blockade of hyperbaric bupivacaine and hyperbaric ropivacaine.

The other objectives were to compare the onset and duration of sensory block, the onset of motor block, the time of ambulation and the hemodynamic parameters between the groups.

Method:

For this randomized comparison trial, ninety patients were included. Groups A and B, included 45 patients each and were assigned to the Ropivacaine and Bupivacaine groups, respectively. On the day of surgery, patient in sitting position, subarachnoid blockade was performed. 0.5% Hyperbaric ropivacaine of 2ml was injected intrathecally for patients in group A and 0.5% hyperbaric bupivacaine of 2ml was injected intrathecally for patients in group B. The parameters that were compared were, the onset of sensory and motor blockade, duration of sensory and motor blockade, time of ambulation and hemodynamic parameters.

Results:

Ropivacaine as compared to Bupivacaine showed a slower onset of sensory block (Group A 3.2mins, Group B 2.6mins, $P < 0.05$) , shorter time to regression (Group A 48.4mins, Group B 68.8mins, $P < 0.05$), and shorter duration of sensory block (Group A 116.4mins, Group B 159.7mins, $P < 0.05$). The onset of motor block was also slower in ropivacaine group (Group A 4.4mins, Group B 3.5mins, $P < 0.05$) and also there was a shorter duration of motor block (Group A 102.2mins, Group B 130.8mins, $P < 0.05$). Patients receiving Ropivacaine recovered faster in terms of mobilization (Group A 184.8mins, Group B 231.7mins, $P < 0.05$). Hemodynamic parameters were stable in both the groups.

Conclusion:

With minimal effects on the hemodynamics, shorter duration of motor blockade, early recovery of motor function thereby leading to shorter ambulation time, and comparable sensory block characteristics with bupivacaine, intrathecal hyperbaric ropivacaine is an attractive alternative to hyperbaric bupivacaine in daycare settings.

***Keywords*:** Hyperbaric, Bupivacaine, Ropivacaine, spinal, ambulatory procedures, anorectal and urological surgeries.

Introduction:

The principal objective of anesthesia is to enable surgical procedures to be carried out without any discomfort to the patients by providing effective pain relief. The growing preference for ambulatory surgeries has led to an increased utilization of subarachnoid blocks with local anesthetics.[1] In this setting, rapid onset and offset of anesthesia, rapid recovery of protective reflexes, mobility and micturition, and good control of postoperative pain and nausea are required.

For ambulatory surgery, the optimal intrathecal agent should have a low incidence of side effects, a predicted regression within a reasonable time frame, and a quick commencement of motor and sensory blockade[2.]

Spinal anesthesia provides a profound nerve block in a substantial body area with a small local anesthetic injection. However, the main challenge lies in regulating the distribution of the local anesthetic without excessive spread.[3]

Bupivacaine, an amino amide local anesthetic, consisting of a racemic mixture of S and R enantiomers in equal proportions, has been the preferred drug for spinal anesthesia. This choice is attributed to its extended duration and adequate motor and sensory blockade[4.] However Bupivacaine has side effects like central nervous and cardiovascular system toxicity, urinary retention and motor weakness.[5]

Ropivacaine belongs to the group pipecoloxylidides of local anesthetics and it is a pure S (−) enantiomer of propivacaine. It is different from bupivacaine in the way that the piperidine nitrogen atom is connected to a propyl group rather than a butyl group.[4] Due to its stereo-selective properties and lower lipophilicity, ropivacaine has a higher threshold for central nervous system toxicity and cardiotoxicity and thus it is now gaining popularity.[1]

The purpose of this study was to assess the effectiveness of 0.5% hyperbaric ropivacaine and 0.5% hyperbaric bupivacaine for spinal anesthesia in daycare procedures such as anorectal and urological surgeries. Pre-injection, aseptic preparations of ropivacaine solutions were made (by adding 2 ml of injection ropivacaine 0.75% plus 1 ml glucose 25%) while the commercially available solutions of hyperbaric bupivacaine were used.

Materials And Methods:

A simple randomized comparative study was conducted at Sri Manakula Vinayagar Medical College and Hospital (SMVMCH) under The Department of Anesthesiology for a period of 18 months after obtaining Institutional Ethics Committee clearance and CTRI registration.

CTRI- registration number: CTRI/2023/05/052486.

The sample size for the present study was calculated using openEpi, version 3, open source calculator-SSMean. By using the mean duration of motor block in the ropivacaine and bupivacaine group of 126.3+/ 38.3 and 148.7+/-35.4 respectively from a study done by Purohit S et al the sample size was calculated to be 86 (43 each for both study groups) at 99% confidence interval, 95% power. This sample size was rounded off to 90 (45 each for both study groups).

Randomization was done by block randomization method with block size of 10 with the help of external person not involved in the study (epidemiology unit of the community medicine department).This was done using random allocation software.

Patients were divided into two groups (Group A and Group B) of 45 each by block randomization technique.

GROUP A (Ropivacaine)- Patient receiving 2ml of 0.5% hyperbaric ropivacaine

GROUP B (Bupivacaine) - Patient receiving 2ml of 0.5% hyperbaric bupivacaine

The proposed study was a double blinded randomized study. The sub arachnoid block was made by an anesthesiologist who was not involved in the study. The investigator who recorded the data was not aware of the participant's group. The participant did not know to which group he/she was being allotted.

The sequence was handed over to the principal investigator in a sealed envelope. Decoding was done by the statistician.

Patients scheduled to undergo elective anorectal and urological surgeries under spinal anesthesia, belonging to ASA physical status I & II of either sex between the age group of >18 years or < 60 years were included in the study.

Patients of ASA physical status IlI and IV with local site infection or allergy to the drugs used, patients with psychiatric illness, coagulation abnormalities or pregnant / Lactating women and those who refused to participate in the study were excluded.

Pre op evaluation included a detailed history, basal heart rate and blood pressure, airway assessment and investigations like hemoglobin, total and differential count, renal function test, serum electrolytes, chest X-ray and ECG.

Patient Preparation:

- Nil per oral for 8 hours.
- Premedicated with tablet alprazolam 0.25mg and tablet pantoprazole 40mg on the night before surgery.
- Informed written consent for participation in the study. Written informed consent was obtained from each patient.
- Patient data was recorded in the proforma.

Based on the randomization sequence, the patients were allocated into two groups, Group A and Group B. Code number was put on the participant proforma sheet, and decoding was done at the end of the study for statistical analysis.

After checking of anesthesia machine and breathing apparatus, the patient was shifted to the Operating Theatre. Standard monitors (ECG, HR, SPO2, and NIBP were attached and baseline parameters were noted and monitored). Peripheral intravenous line was secured using an 18G cannula. All the patients were uniformly preloaded with 10ml/kg of crystalloid. The patient was placed in sitting position. Under strict aseptic precautions, lumbosacral region was painted with povidone iodine, alcohol solution and draped. The L3-L4 intervertebral space was identified using palpation. Using a 25G or 26G Quinke's spinal needle, a lumbar puncture was performed at the L3-L4 interspace following local infiltration with 2 ml of 2% lignocaine. After a free flow of cerebrospinal fluid (CSF), the assigned drug was injected intrathecally at the rate of 0.2ml/second.

The patient was placed in supine position immediately. Continuous monitoring of vitals was done every 2 minutes for first 10 minutes and then every 5 minutes till 1 hour and then every 30 minutes till 3 hours and then the 6^{th} hour and 9th hour. Following parameters were assessed: - onset of sensory block, time of highest level of sensory block, time to two segment regression, and duration of sensory block. It was scored according to a three point scale in the dermatomes.

Score 2: sharp pain

Score 1: blunt pain

Score O: no pain

The sensory block was assessed by using a 24G needle by pin prick method in the midline. Dermatome level was assessed every minute from 1 min to 6 min. Then for every 2 mins until stable for 4 successive assessments. Assessment continued every 10 mins until 2 segment regression from the maximum sensory block. Surgery will be started after achieving the T12 level.

Onset of sensory block is defined as the time interval between intrathecal injection to T12 level. The duration of sensory blockade is defined as the time taken from completion of injection of the drug until maximum level of sensory block descends to T12 level.

Motor blockade characteristics were assessed in terms of onset of motor block using a modified Bromage scale. Duration of motor blockade is defined as the time interval between intrathecal injection to MBS 0. Time for ambulation was recorded which was the time when there is full recovery of motor block (plantar flexion of the foot), sensory level to S2 with stable hemodynamics and with no pain.

Modified Bromage Scale

0 - free movement of legs and feet

1 - just able to flex knees with free movement of feet

2 - unable to flex knees, but with free movement of feet

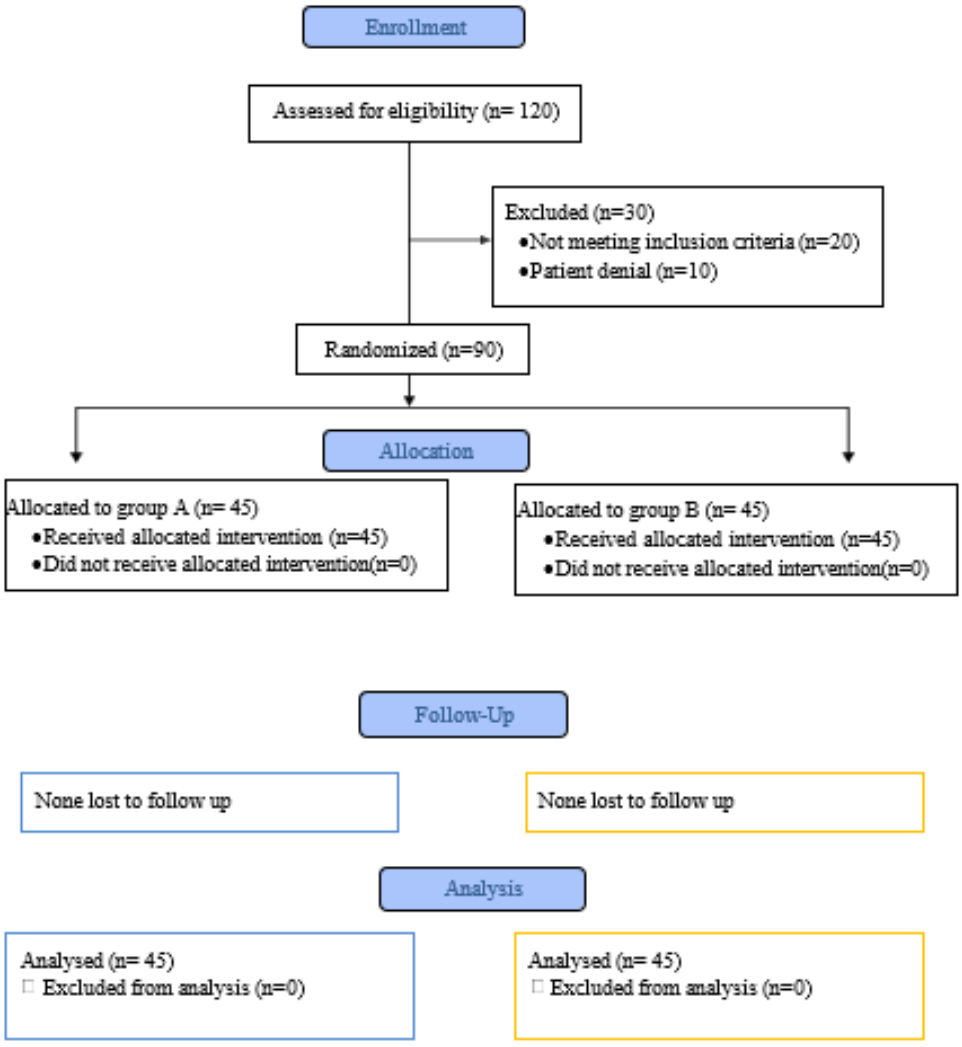
3- unable to move legs or feet.

Hemodynamic parameters - systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate, and peripheral oxygen saturation will be recorded prior to the procedure and then every 2 mins for 10 mins, and every 5 mins till 1hour and then every 30 mins till 3 hours and then 6th hour and 9th hour. Side effects of spinal anesthesia like hypotension, bradycardia, nausea, and vomiting were noted. Heart rate of less than 50 bpm was considered bradycardia and managed with injection atropine 0.6 mg intravenously. Hypotension is considered if mean arterial pressure is less than 20% from the baseline and was managed with Injection Ephedrine 6 mg intravenously bolus.

Upon completion of the surgery, patients were observed in post operative room for hemodynamic parameters (BP, HR, and MAP) and it was recorded at 30-minute intervals for 3 hours. MBS was used to measure motor block regression in the lower limbs at intervals of 0–60, 60–120, and 120–180 minutes. The pinprick method was used bilaterally in the midclavicular line to examine the sensory blockade regression time up to S2. These evaluations continued until the lower limb motor block and sensory block completely receded.

Any adverse drug reactions to the drugs were reported to the ethics committee within 24 hours of occurrence of the event.

CONSORT DIAGRAM:



Result:

Table 1: Demographic profile of the study participants in both the groups

PARAMETERS	GROUP A	GROUP B	P VALUE
AGE	41.33 ± 11.72	41.42 ± 11.63	0.97
GENDER (M/F)	36/9	35/10	0.79
HEIGHT	162.84 ± 5.56	164.24 ± 5.14	0.30
WEIGHT	64.11 ± 7.04	63.31 ± 5.17	0.54

The mean age, gender, height and weight of the participants in Group A (Ropivacaine) and Group B (Bupivacaine) was not statistically significant. Hence the two groups are comparable with age, gender, height and weight of the study participants.

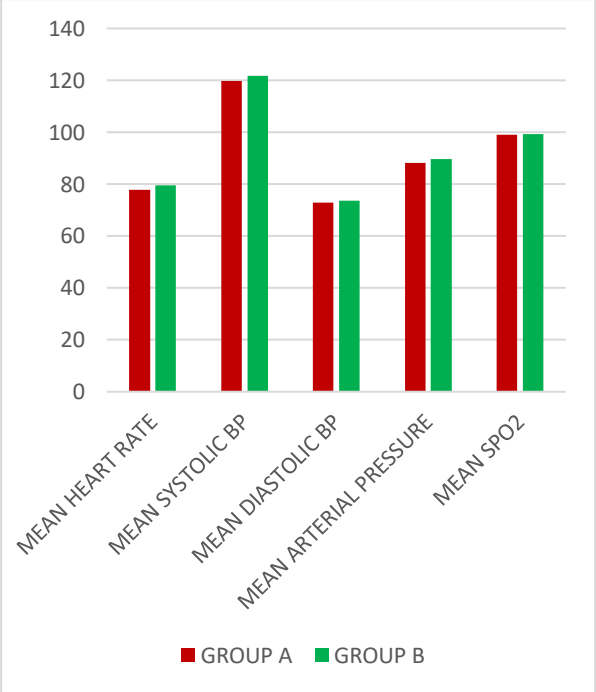
Table 2: Comparison of results of spinal anaesthesia in both the groups

PARAMETERS	GROUP A	GROUP B	P VALUE
ONSET OF SENSORY BLOCK	3.20 ± 0.89	2.64 ± 0.57	<0.001*
PEAK SENSORY BLOCK	4.36 ± 0.90	4.82 ± 0.83	0.01*
TWO SEGMENT REGRESSION	48.44 ± 7.96	68.89 ± 13.35	0.001*
DURATION OF SENSORY BLOCK	116.44 ± 18.11	159.78 ± 12.70	<0.001*
ONSET OF MOTOR BLOCK	4.47 ± 0.96	3.51 ± 1.05	0.001*
DURATION OF MOTOR BLOCK	102.22 ± 16.36	130.89 ± 14.27	0.001*
TIME OF AMBULATION	184.89 ± 28.01	231.78 ± 13.86	0.001*
SIDE EFFECTS-HYPOTENSION	1	3	0.3

*-statistically significant

Ropivacaine as compared to Bupivacaine showed a slower onset of sensory block (Group A 3.2mins, Group B 2.6mins) , shorter time to regression (Group A 48.4mins, Group B 68.8mins), and shorter duration of sensory block (Group A 116.4mins, Group B 159.7mins). The onset of motor block was also slower in ropivacaine group (Group A 4.4mins, Group B 3.5mins) and also there was a shorter duration of motor block (Group A 102.2mins, Group B 130.8mins). Patients receiving Ropivacaine recovered faster in terms of mobilization (Group A 184.8mins, Group B 231.7mins). Hemodynamic parameters were stable in both the groups.

Table 3: Comparison of hemodynamic parameters in both groups



The mean heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, SPO2 of the participants in Group A (Ropivacaine) and Group B (Bupivacaine) was not statistically significant. Hence the two groups are comparable with the mean heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, SPO2 of the study participants.

Discussion:

Daycare procedures or ambulatory procedures offer enormous potential for a quicker, safer, and more economical patient turnover in our country. These procedures improves patient satisfaction and also provides an opportunity for an economical hospital stay and reduce the disease burden by mitigating the

waiting time for in-patient care.

Ambulatory surgeries should have a faster recovery from anesthesia, which leads to an early discharge from the hospital. General anesthesia has been used in day care procedures using short-acting drugs. However, due to concerns over not having a rapid recovery of protective airway reflexes, drowsiness, early ambulation, post-operative nausea and vomiting, delirium, difficult post-operative pain control without opioids, concerns of polypharmacy, spinal anesthesia with a short-acting local anesthetic agent has become a popular alternative.

Spinal anesthesia confers its advantage over general anesthesia due to the following benefits. It provides better immediate pain control and post-operative pain management, reduced PONV, early initiation of hydration and nutrition, avoids prolonged drowsiness, thus enabling early discharge. But spinal anesthesia is not without disadvantages for day care procedures. The major reasons for not routinely using spinal anesthesia for day care surgeries is due to the motor blockade causing a delay in ambulation, urinary retention, and risk of post dural puncture headache.

With regular use of small gauge spinal needles and Whitacre dura splitting needles, the incidence of PDPH has reduced significantly allowing the patients to ambulate earlier.

But the hunt for a local anesthetic agent without the use of opioid additives which provides rapid onset and offset of motor and sensory blockade, low incidence of adverse effects thereby allowing early ambulation and early micturition still continues. Ideal agents include Lignocaine, 2-chlorprocaine, Bupivacaine, Levobupivacaine, and Ropivacaine. Lignocaine intrathecal produced an increased incidence of Transient neurological symptoms. 2-chlorprocaine with its advent showed promise but it is limited by its very short duration of action thereby not carrying the post-operative benefits Thereby leaving only Bupivacaine, Levobupivacaine, and Ropivacaine suitable for day care surgeries.

Ropivacaine is very much similar to bupivacaine and is 30-40% less potent than bupivacaine. It is less cardiotoxic when compared to bupivacaine. Intrathecal ropivacaine has been used extensively, but the commercially available solution of ropivacaine is isobaric and with isobaric preparations, the block effects were found to be unpredictable and unreliable. So ropivacaine was constituted with 25% dextrose to make it hyperbaric. Kallio[19] et al compared hyperbaric and plain ropivacaine and reported that intrathecal hyperbaric ropivacaine 15 mg resulted in a faster onset, greater success rate of analgesia at the level of T10 dermatome, and faster recovery of blocks when compared to the unpredictable non uniform block characteristics of isobaric intrathecal ropivacaine.

So, we conducted a study to compare the efficacy of intrathecal hyperbaric ropivacaine and bupivacaine for day care surgeries.

Preparation of the hyperbaric ropivacaine solution should be done with meticulous caution and strict asepsis.

In a study done by Kulkarni[16] et al, a prepared solution of hyperbaric ropivacaine (5 mg/ml and dextrose 83 mg/ml) and commercially available hyperbaric bupivacaine (5 mg/ml and dextrose 80 mg/ml) were found to have similar with the specific gravity of hyperbaric ropivacaine measuring 1.030 and hyperbaric bupivacaine measuring 1.025. In our study, we did not have the facility to measure the specific gravity or density of the prepared local anesthetic agents due to the non-availability of densitometer. However, in their study, the dose of the drugs was not titrated to day care procedures.

The onset of sensory block was slower in the ropivacaine group when compared to the bupivacaine group which was 3.20± 0.89 in Group A and 2.64± 0.57 in Group B. The higher lipid solubility of bupivacaine can be attributed to the faster onset. Though this may not be a very significant difference, but it definitely does pose a problem for time sensitive procedures like emergency LSCS where the onset plays a major role. Though the onset of sensory block was slower, it was noted that the time to peak sensory block (4.36± 0.90 in ropivacaine group and 4.82 ± 0.83 in bupivacaine group) was almost similar between the two groups and the final peak level attained with ropivacaine and bupivacaine were also similar. However, the duration of sensory block was significantly lower in the ropivacaine group when compared to bupivacaine group which was 116.44 ± 18.11 in Group A and 159.78± 12.70 minutes in Group B. These findings were similar to the study carried out by JB Whiteside[11] et al. In their study, they found the onset time for ropivacaine to be as

slow as 5 min using 3 ml of local anesthetic but in our study, the onset time was relatively shorter with ropivacaine group. The differences could be attributed to the fact that the onset time in their study was considered to be a sensory level of T10 but in our study it was T12 and that the dextrose concentration used in their study was 50 mg/ml which was lower than that used in our study 83 mg/ml. This shows that hyperbaricity significantly improves the onset of sensory block even when the dose of local anesthetic is reduced. Though the two segment regression time was faster with ropivacaine than with bupivacaine (48.44± 7.96 in Group A and 68.89± 13.35 in Group B), the duration of the block was sufficient for the conclusion of the surgery in all cases.

In our study, the onset of motor block was slower in ropivacaine group (4.47 ± 0.96 in Group A and 3.51 ± 1.05 in Group B) and the duration of motor block was shorter in the ropivacaine group when compared to the bupivacaine group (102.22 ± 16.36 in Group A and 130.89 ± 14.27 in Group B). These findings corroborated well with other studies. In a study done by Somjit Chatterjee[5] et al on patients undergoing lower limb orthopedic surgeries. The patients in the RP group received 3 ml 0.75% Ropivacaine and glucose 50%, 0.5 ml and BP group received 0.5% hyperbaric BP 3 ml and 0.9% normal saline 0.5 ml. (Total 3.5ml). The author found that onset of sensory block was 2.94±0.818 in RP group and 1.74±0.443 in BP group. Onset of motor block was 4.92±0.752 in RP group and 4.02±0.553 in BP group. Despite using a high volume of 3.5 ml, the motor block onset was slower in their study compared to our study because decreased density of local anesthetic used in their study. Duration of sensory block was 114.2±9 in RP group and 156.1±10.21 in BP group. Ropivacaine has lesser lipid solubility than bupivacaine which is responsible for the sensory motor dissociation or separation of ropivacaine as it penetrates lesser into the heavily myelinated motor fibers than the lesser myelinated sensory fibers.

The quality of motor block in our study was due to the increased density of the drug used in our study. In a study, conducted by J.F.Luck[14] et al, the motor blockade quality was lesser in ropivacaine group with only 63% of patients achieving Bromage 3. But the dextrose concentration used in their study was only 30 mg/ml. Various other studies used varying dextrose concentrations ranging from 10 mg/ml to 60 mg/ml.

In our study, intra-operative anesthesia was not distinguishable between the groups. No failure was reported in both the groups.

The shorter duration of motor block translated to a shorter time for mobilization and ambulation. In our study, the time to ambulation in ropivacaine group was 184.89 ± 28.01 minutes when compared to 231.78 ± 13.86 minutes in bupivacaine group. Shorter ambulation times meant decreased risk of Deep vein thrombosis, earlier discharge, and improved patient turnover. This was consistent with the study findings conducted by J.F.Luck[14] et al where they demonstrated that 3ml of hyperbaric 0.5% Ropivacaine provided a total duration of motor block of 90 mins when compared to hyperbaric 0.5% Bupivacaine and 0.5% Levobupivacaine which was 180 mins. Time to mobilization was 218 mins in Ropivacaine group which when compared to Bupivacaine and Levobupivacaine group was 306 mins and 286 mins respectively. Thus, ropivacaine's property of sensory-motor dissociation makes it an agent of choice when quicker recovery of motor function is desirable.

In the study done by Swetha Purohit[6] et al, Group R received 3 ml of Ropivacaine and Group B received 3 ml of Bupivacaine. They found that the time to mobilize was lesser in Ropivacaine group which was 253.3±11.1 minutes compared to Bupivacaine group which was 331±13.5 minutes). This was comparable with our study.

In our study when compared between the groups, there was no statistically significant difference in hemodynamic parameters between the groups. We found no evidence of such hemodynamic instability throughout our investigation. But clinically three patients in the bupivacaine group had hypotension and 1 patient in the ropivacaine group had hypotension even with a volume of 2 ml. All the patients improved with volume loading and no vasopressors were required in both the groups.

In the study by Leena Ingale[1] et al, 6 patients in ropivacaine group(3ml) and 15 patients in the bupivacaine group (3ml) developed significant lowering of systolic blood pressure which was treated with injection Mephentermine 7.5mg and with loading ringer lactate solution. However, the incidence of hypotension in this study was due to the

increased volume of local anesthetic when compared to our study. The difference in hemodynamic effects was attributed to R enantiomer which is absent in ropivacaine as it is a pure S enantiomer.

Time to micturition was not measured in our study.

No other complications like shivering, nausea, and vomiting were noted in either group.

Studies evaluating the use of intrathecal ropivacaine for ambulatory surgeries like the study by Mcdonald[21]et al, have reported that spinal ropivacaine offers no advantages over bupivacaine which was not consistent with our study. Ropivacaine shows a clear advantage in terms of duration of motor block and time of ambulation being quicker than bupivacaine.

Conclusion:

In our study we compared intrathecal 0.5% hyperbaric Ropivacaine and 0.5% hyperbaric Bupivacaine for anorectal and urological procedures and we conclude that with minimal effects on the hemodynamics, shorter duration of motor blockade, early recovery of motor function thereby leading to shorter ambulation time, and comparable sensory block characteristics with bupivacaine, intrathecal hyperbaric ropivacaine is an attractive alternative to hyperbaric bupivacaine in daycare settings.

Limitations:

The equipotent ratio between bupivacaine and ropivacaine is 1.5 to 1, but we have compared 0.5% ropivacaine and 0.5% bupivacaine.

Hyperbaric ropivacaine 0.5% was not commercially available.

This was a single-centered trial.

Drug dose has not been standardized to weight, height, age, and sex.

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