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A Comparison of Intrathecal Isobaric Ropivacaine 0.5% and 0.75% for Orthopaedic Lower Limb Surgeries and Lower Abdominal Surgeries.

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ABSTRACT

Background: Aim: This study was done to evaluate the onset, extent and duration of sensory and motor block and side effects of ropivacaine when used in spinal anaesthesia in lower limb orthopedic and lower abdominal surgery. **Methods**: A prospective randomized double blind study was conducted on 60 patients of ASA status I and II, posted for lower limb orthopaedic and lower abdominal surgery. All patients were randomly allocated into two groups of 30 each; group I received 3ml of isobaric ropivacaine 0.5%(15mg) and group II received 3ml of 0.75% (22.5mg)isobaric ropivacaine in subarachnoid block. The onset, extent, duration of sensory and motor block and side effects were recorded. **Results:** Onset of sensory block and highest level of sensory block achieved was comparable in both the groups. The duration of sensory block at T10 and total duration of sensory blockade was prolonged in-group II in comparison to group I, which was statistically significant. The onset time of motor block was comparable in both groups. Time to maximum degree of motor block was longer in group I (17.45±6.63min) compared to group II(11.04±4.26min) which was statistically significant. Total duration of motor block was longer in group II(152.60±23.02min) compared to group I(112.62±13.72min)which was statistically significant. **Conclusion**: 0.75% ropivacaine when used in spinal subarachnoid block prolonged the sensory and motor block in comparison to 0.5% ropivacaine.

Keywords: abdominal**,** intrathecal, ropivacaine, orthopaedic.

INTRODUCTION

Spinal anaesthesia is a very popular regional anaesthetic technique, with a high success rate and a good safety profile.[1] A review of the current literature suggests that ropivacaine have improved safety profile over bupivacaine, with a reduced neurotoxic and cardiotoxic potential, together with a wide clinical utility at different doses.[2] It has been shown to provide effective and prolonged surgical anaesthesia in different regional anaesthetic techniques like epidural and brachial plexus blocks.

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Epidural anaesthesia with 0.5% ropivacaine has produced similar type of sensory block like 0.5% bupivacaine but it was less potent in producing motor block for which it can be an ideal spinal anaesthetic which would provide adequate surgical anaesthesia together with early ambulation and allow early discharge.[3] Reports of transient radicular irritation after lidocaine spinal anaesthesia and neuro & cardiac toxicity of bupivacaine prompted the search for alternatives.[4] Ropivacaine could be promising in this setting in concentrations of 0.5% and 0.75%.[5-9] As few studies are available comparing 0.5% and 0.75% ropivacaine in intrathecal route ,we have studied onset of action, duration of sensory and motor block, and side effects like such as nausea, vomiting, hypotension, shivering and headache.

MATERIALS AND METHODS

Sisxty patients posted for elective orthopaedic lower limb surgeries & lower abdominal surgeries under spinal anaesthesia were included in this study. Patients of either sex, patients with ASA Grade-I &II and patients aged between 20-60 years were included in this study. Patients with severe systemic

disease, metabolic disorder, neurological, congenital or cardiovascular disease, patients with coagulation disorders, local sepsis at site of spinal injection, patients allergic to local anaesthetics and patient refused for spinal anaesthesia were excluded from this study. 60 envelopes were divided into two groups of 30 each. The drug to be given was mentioned inside the envelope. Any envelope was randomly picked up just before the surgery. The envelope was opened by an anaesthesiologist and the drug was loaded by that person. Another anaesthetist conducted the procedure of spinal anaesthesia and the observations were done by a third person who did not knew what drug was given. On the night before surgery, all the patients were visited and detailed pre-anaesthetic examination was done and the anaesthetic procedure was briefly explained to the patient. An informed written consent was obtained from the patient. The patients were kept nil orally for 6 hours before surgery. Once the patient was shifted to the operating room, the patient was connected to the routine monitors, which included non invasive blood pressure, pulse oxymeter and continuous electrocardiogram. Base line pulse rates, blood pressure, respiratory rate, SPO 2 were recorded. A wide bore intravenous access was obtained and secured. All patients were preloaded with 500ml of Ringer's lactate prior to spinal anaesthesia. Patients were allocated into two groups .Group-I: 30 patients received 3ml of isobaric ropivacaine 0.5%, Group-II: 30 patients received 3ml of isobaric ropivacaine 0.75%

Under strict aseptic precautions, lumbar puncture was performed by midline approach in sitting position by using disposable 25G Quincke spinal needle at L3–L 4 intervertebral space and all patients were made supine immediately. Patients were continuously monitored using NIBP, pulse oximeter and electrocardiogram. After spinal anaesthesia, the patient's pulse rate, systolic, diastolic and mean arterial pressure were recorded at 0, 3, 6, 9, 12, 15, 18, 21, 24, 27, 30, 45, 60, 75, 90, 120, 150 and 180 minutes. If the systolic arterial pressure decreased more than 20% below the baseline value or to less than 90 mm Hg, ephedrine 5 mg was given intravenously(IV) .Bradycardia (heart rate <50 /min) was treated with IV atropine sulphate (0.6mg). Sensory block was tested by pin-prick method using 25G needle. [9] The time of onset was taken from time of injection of the drug into the subarachnoid space to loss of pin-prick sensation up to T10 level. The time to achieve maximum sensory block was noted from time of injection of drug to loss of pin-prick sensation at highest dermatome level. The time for two segment regression from the highest point of sensory level was noted. Total duration of sensory blockade was recorded from time of onset to time of regression up to S2. Motor blockade was assessed by modified Bromage scale.[10] The time interval between injection of drug into subarachnoid space and the patient's inability to lift the straight extended leg was taken as onset time. The time to achieve maximum motor blockade was noted from time of injection of the drug to maximum degree of motor block (Bromage scale 3). Duration of motor block was recorded from onset time (Bromage scale 1) to time when the patient was able to lift the extended leg (Bromage scale 0). Modified Bromage Scale: 0 - The patient is able to move the hip, knee and ankle. 1 - The patient is unable raise extended leg. 2 – The patient is unable to move the hip and knee but able to move the ankle. 3 – The patient is unable to move the hip, knee and ankle. Sensory and motor block was assessed every 5min upto 30 min and 15 min interval upto 120 min and 30 min interval there after postoperatively. The pain scoring was done by using visual analogue scale. (0=no pain, 10=severe pain)[11]. VAS was monitored 1hrly for first 2 hrs, 2hrly for next 8 hrs and 4hrly thereafter. Injection paracetamol 1 gm IV was given as rescue analgesia when patient complained pain (VAS>5). The side effects like shivering, hypotension, bradycardia, nausea and vomiting and post spinal headache were looked for. Sample size was chosen to show a difference in height of sensory block of two dermatomes between two groups which is based on α risk of 0.05 and β risk of 0.10 using data from prior study of intrathecal ropivacaine. Results were summarised by descriptive statistics such as mean and standard deviation for numerical variables that are normally distributed and median range for those that are skewed. Numerical variables were compared between groups by 'Students unpaired t test' if normally distributed and by 'Mann Whitney U test' if skewed. 'Chi Square test' and 'Fischer's Exact Test' were used to compare frequency of adverse events and other categorical variables between groups. All statistical analysis were two tailed and a P value of <0.05 was regarded as statistically significant.

RESULTS

The patients studied across the group did not vary much with respect to age, sex, height and body weight. The type of surgeries performed were almost identical in both the groups [Table 1].

Table 1: Demographic characteristics

Variables	Group I	Group II	P value
Age (yrs.)	35.04 ±11.6	35±9.6	0.98
Sex(M/F)	23/7	22/8	0.45
Height(cm)	164.16±13.32	159±11.4	0.12
Weight(kg)	55.04±3.91	54.38±3.84	0.42
ASA Physical status(I/II)	36/14	35/15	0.57

In the present study the onset of sensory blockade in-group-I was 2.30±0.21min compared to 1.58±0.20

min in group-II which was statistically not significant. Similarly, the onset of motor blockade in group-I was 2.34±0.67 min compared to 1.64±0.22 min in group-II which was also statistically not significant. The median time to reach the highest level of analgesia was comparable in both groups. Duration of analgesia at T10 and total duration of analgesia was longer in group II in comparison to group I which was statistically significant [Table 2, Figure 1].

Table 2: Intrathecal block characteristics

Sensory Block (min)	Group-I	Group-II	P-value
Onset time of sensory block	2.30±0.21	1.58±0.20	0.054
Time to reach highest level of sensory block	17.48±5.94	18.32±6.20	0.06
Duration at T10	45.52±17.02	90.34±35.48	<0.001
Total duration	146.80±27.64	184.20±18.06	<0.001
Motor Block (min)			
Onset time of motor block	2.34±0.67	1.64±0.22	0.058
Time to maximum degree of block	17.45±6.63	11.04±4.26	0.024
Total duration of block	112.62±13.72	152.60±23.02	<0.001

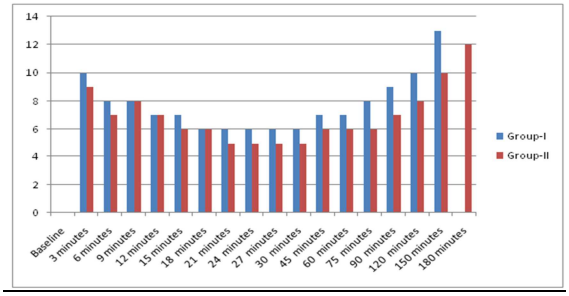

Figure 1: Sensory level block with time between the groups

(No given in y-axis is corresponding the level of sensory block as given bellow)

0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
No block	T4	T5	T6	T7	T8	T9	T10	T11	T12	L1	L2	L3	L4	L5

Side effects like shivering, hypotension, nausea, vomiting and post spinal headache was monitored and it was comparable in both groups [Table 3].

Table 3: Side effects in the study groups

Side Effects	Group I	Group II	P value
Shivering	5	4	>0.05
Hypotension	2	3	>0.05
Nausea	3	3	>0.05
Vomiting	1	1	>0.05
Bradycardia	4	5	>0.05
Post spinal headache	1	1	>0.05

Heart rate, systolic and diastolic blood pressure in both the groups did not vary significantly. Cardiovascular changes were unremarkable throughout and similar in the two groups, as were the volumes of fluid administered.[Figure 2,3]

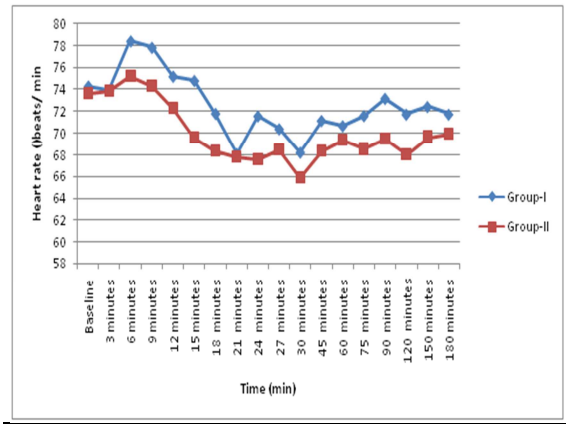

Figure 2: Heart rate variation between the groups

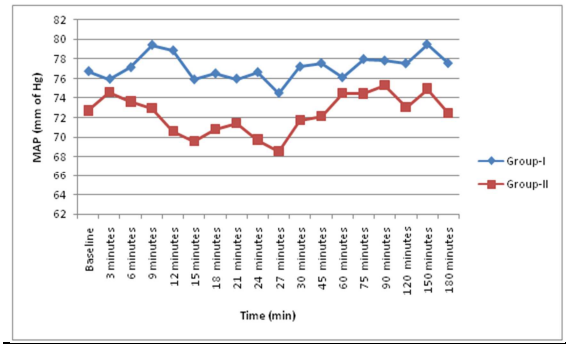

Figure 3: Mean arterial pressure (MAP) variability between the groups

DISCUSSION

Ropivacaine is an amide local anaesthetic with a high pKa value and low lipid solubility. It is considered to block sensory nerves to a greater degree than motor nerves. Because of sensory motor dissociation, ropivacaine can be a favourable local anaesthetic for day-case surgery.[12] This double blind randomized study was conducted to compare two different concentrations of intrathecal ropivacaine in orthopaedic lower limb surgeries & lower abdominal surgeries.

Jack W van Kleef et al, found that the duration of analgesia at the level of T12 was significantly longer in the 0.75% group as compared to 0.5% group. This showed that ropivacine 0.75% had a longer duration of analgesia compared to 0.5% ropivacaine. They observed that, due to its greater propensity to produce longer duration of analgesia and complete

motor block, 0.75% ropivacaine may be an ideal intrathecal anaesthetic, suitable for orthopaedic and vascular surgical procedures of intermediate duration, requiring an intense motor block.[13] There was no significant difference regarding onset of either sensory or motor block .These finding were similar to ours. Kim S Khaw et al found that the incidence of hypotension were similar in a comparison of different doses of plain ropivacaine.[14] Wong et al had observed the same, that there were no major cardiovascular changes in the two groups receiving two different doses (2.5ml and 3ml) of 0.75% ropivacaine in caesarean section. They opined that the onset of sensory and motor block were similar in two groups of ropivacaine 0.75%.[15] Helena Kallio et al studied the effects of plain ropivacaine 20mg and 15 mg. They found that there was a significantly longer duration of motor block with 20mg than 15 mg of ropivacaine. They observed that both groups receiving plain ropivacaine did not have any differences in the hemodynamic parameters.[16]

Chari et al found that the onset of motor block in 0.75% isobaric ropivacaine to be at 2.54±1.01 min which was corroborating our study. They also concluded from their study that the time to maximum degree of motor block in 0.75% isobaric ropivacaine group to be 18.92±2.41min which was corroborating our study.[17] Surekha C et. al studied with intrathecal plain ropivacaine with bupivacaine and they did not found any hemodynamic instability in the both study group.[18] Kelkar et. al in his study of 0.5% isobaric ropivacaine found that the sensory onset to be 8.40±2.94 min. which was not corroborating with our study. They found that the total duration of motor block in 0.5% of isobaric ropivacaine is 116.00±16.2 min and total duration of sensory block in 0.5% isobaric ropivacaine group is 138±17.4 min which was similar to our study.[19] Above studies also concluded that use of 15 mg or 22.5mg of ropivacaine in spinal anaesthesia caused no gross hemodynamic disturbances. In the present study, the two segment regression of sensory level to T 10 dermatome in group-I was 45.52±17.02 min. compared to 90.34±35.48 minutes in group-II which was statistically highly significant (P<0.001). Also the time to maximum degree of motor block in group-I was 17.45±6.63 minutes compared to 11.04 ±4.26 minutes in group-II which was statistically significant (P<0.05). Five patients had shivering in group I as compared to 4 patients in group II. 5 patients in Group II and 4 patients in group I had bradycardia. There were one case of post spinal headache in both group. 3 patients have nausea and one patients have vomiting in both groups. There was no statistical significance regarding any of side effects. We summarized that 3ml of intrathecal isobaric ropivacaine 0.75% (22.5mg) brought better quality and longer duration of sensory block, reliable quality of motor block and better postoperative outcome with minimum side effects than 0.5% ropivacaine (15mg).

CONCLUSION

Intrathecal administration of 22.5 mg of 0.75% isobaric ropivacaine produced better quality of sensory and motor block with negligible hemodynamic disturbances as compared to 15 mg of isobaric 0.5% ropivacaine in orthopaedic lower limb surgeries & lower abdominal surgeries of intermediate duration. 0.5% ropivacaine may be suitable for short surgical procedures when motor block is not required.

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