

## INTRATHECAL HYPERBARIC ROPIVACAINE VERSUS BUPIVACAINE FOR AMBULATORY INFRAUMBILICAL SURGERY

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### ABSTRACT

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#### BACKGROUND

Hyperbaric ropivacaine has shown to produce a reliable and predictable anaesthesia for surgery. The present study was undertaken to compare the efficacy of hyperbaric ropivacaine with bupivacaine for spinal anaesthesia and its feasibility for ambulatory surgical procedures. Evaluation of analgesia, muscular relaxation, haemodynamic changes and clinical efficacy of intrathecally administered 0.5% hyperbaric ropivacaine in 5% glucose prepared aseptically prior to injection with commercially available 0.5% hyperbaric bupivacaine containing 8% glucose at equimiligram doses of 17.5 mg.

#### MATERIALS AND METHODS

Forty adult patients of ASA grade I-II scheduled for infraumbilical surgeries were randomly allocated to two groups to receive either 3.5 mL of 0.5% hyperbaric ropivacaine in (Group R) or 0.5% hyperbaric bupivacaine (Group B). Onset and regression of sensory and motor block, level of blockade and side effects were assessed.

#### RESULTS

Hyperbaric ropivacaine had a significant early regression of sensory and motor blockade (166.25±30.51 mins. and 155.40±30.20 mins.) than bupivacaine (270.35±40.72 mins. and 243.15±36.41 mins.). Ropivacaine had better haemodynamic stability, shorter duration of analgesia and less side effects compared to bupivacaine.

#### CONCLUSION

17.5 mg of hyperbaric ropivacaine produces a reliable spinal anaesthesia of intermediate duration for ambulatory procedures.

#### KEYWORDS

Group B- Bupivacaine Group, Group R- Ropivacaine Group, CSF- Cerebrospinal Fluid.

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#### BACKGROUND

Spinal anaesthesia is a unique and effective alternative to general anaesthesia, because infinitesimally small amount of drug injected into lumbar subarachnoid space results in anaesthesia over a wide portion of the body. In addition, different levels of block up to T5 can be achieved by altering the baricity, viscosity and the spread of an anaesthetic solution under the influence of gravity.

After the reports of cauda equina syndrome in 1993 by Schneider et al,<sup>1</sup> a quest for a local anaesthetic with a short duration of action comparable to lignocaine resulted in the development of ropivacaine.

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Apart from posture, gravity and vertebral column curves, viscosity of spinal drug plays an important role in the spread of local anaesthetic solution in the Cerebrospinal Fluid (CSF). More viscous solution produces significantly greater mean spread than others. Plain solutions are considerably less viscous than those containing glucose, which may be less miscible with CSF. The injected bolus of hyperbaric solution may thus spread farther before mixing fully with CSF, but producing a more even distribution.<sup>2</sup>

Hyperbaric bupivacaine is commercially available and popular for intrathecal use, while ropivacaine is available as isobaric. However, hyperbaric local anaesthetic solutions can be aseptically prepared by the addition of glucose to isobaric solutions. Way back in 1907, the first hyperbaric local anaesthetic solution was prepared by the addition of 5% glucose to 10% Stovaine and 85% distilled water by Barker.<sup>3</sup> In 1999, hyperbaric ropivacaine was first prepared aseptically by addition of equal volumes of 0.5% ropivacaine and 10% dextrose to obtain solutions containing 0.25% ropivacaine with 5% dextrose by McDonald et al,<sup>4</sup> which was compared with hyperbaric bupivacaine in volunteers concluding that relative potency of hyperbaric ropivacaine was less than that of hyperbaric bupivacaine and ropivacaine

did not offer any advantage over bupivacaine for its use in outpatient settings.

In an editorial by Wildsmith<sup>5</sup> in 2000 raised doubts regarding the fact that potency of a drug was related to the degree of effect produced to its dose or concentration, but not with duration and further reported that the clinical effects of ropivacaine observed by McDonald et al with lesser duration of action and significantly less motor block did not interfere with discharge criteria for outpatient procedures, however, they offered advantage in daycare settings. Since then, number of studies comparing hyperbaric ropivacaine and bupivacaine were conducted with various concentrations of the drug by adding glucose in varying percentage ranging from 10-50% to commercially available ropivacaine of 0.25-1%.<sup>4-12</sup>

Though isobaric ropivacaine also provides spinal anaesthesia of shorter duration than bupivacaine, plain solutions are less reliable for surgery above a dermatomal level of L1.<sup>12</sup> Also, fewer data is available regarding the actions, clinical relevant doses of hyperbaric ropivacaine and its preparation for intrathecal use. Among the various doses available, addition of glucose 50 mg/mL to ropivacaine 5 mg/mL increased the speed of onset, block reliability, duration of useful block for surgery and speed of recovery.<sup>10</sup> Hence, this concentration was chosen and study was done with an aim to make a direct comparison between hyperbaric solutions of ropivacaine and bupivacaine in patients receiving subarachnoid block for elective surgery.

## MATERIALS AND METHODS

This prospective randomised controlled study was undertaken from June 2011 to June 2012 for one year with

approval from our institutional ethical committee. A written and informed consent was obtained from forty patients of American Society of Anaesthesiologists (ASA) physical status grade I-II aged between 18-60 yrs. of either sex for elective surgeries below umbilicus under subarachnoid block formed the inclusion group. Patients not consenting for the study, not willing for spinal anaesthesia, sensitive to study drugs, local infection at the site of injection, failed subarachnoid block were excluded from the study.

Patients were randomly allocated into two groups using a computer-generated number to either group B (bupivacaine group, n=20) or group R (ropivacaine group, n=20). This was a single-blinded study where the care providers and then those assessing the outcome were blinded to the purpose and the drug used. All patients were subjected to preanaesthetic checkup that included medical history, physical examination and clinical laboratory tests at which they were explained about the nature of the study.

On arrival in the operating room, each patient was put on standard monitoring that included ECG, noninvasive BP, pulse oximetry (SpO<sub>2</sub>) and baseline readings were recorded. Hyperbaric ropivacaine was prepared as follows; 2 mL of 25% dextrose was diluted with 1.3 mL of normal saline to obtain 15% dextrose solution. 2 mL of this preparation was added to 4 mL of plain ropivacaine to give 0.5% hyperbaric ropivacaine in 50 mg/mL of glucose having a specific gravity of 1.020, which was similar to the hyperbaric preparation of ropivacaine by Whiteside et al.<sup>10</sup> They prepared from commercially available 1% ropivacaine by diluting with 10% glucose to obtain 0.5% ropivacaine in 5% glucose (Table 1 and 2).

| Group           | Drug Injected Intrathecally                                  | Total Drug Volume (mL) | Total Drug Dosage (mg) |
|-----------------|--------------------------------------------------------------|------------------------|------------------------|
| Group B (n=20)* | 0.5% bupivacaine + glucose 80 mg/mL (commercially available) | 3.5 mL                 | 17.5 mg                |
| Group R (n=20)* | 0.5% ropivacaine + glucose 50 mg/mL                          | 3.5 mL                 | 17.5 mg                |

**Table 1. Distribution of Study Groups**

\*n = Total number of patients enrolled in the study group.

| Drug        | Ropivacaine 7.5 mg/mL | Glucose 150 mg/mL | Bupivacaine (heavy)* | Total Volume Injected (mL) | Specific Gravity |
|-------------|-----------------------|-------------------|----------------------|----------------------------|------------------|
| Bupivacaine | 0                     | 0                 | 4                    | 3.5                        | 1.015            |
| Ropivacaine | 4                     | 2                 | 0                    | 3.5                        | 1.020            |

**Table 2. Preparation of Study Drugs**

\* Commercially available preparation.

After injecting either bupivacaine or ropivacaine solution in lateral position, patient was immediately placed supine. Primary outcome measures were the quality of sensory and motor blockade achieved. The level, duration and regression of analgesia, muscular relaxation and haemodynamics of hyperbaric ropivacaine (prepared by adding dextrose to commercially available isobaric 0.75% ropivacaine) with commercially available hyperbaric bupivacaine were

compared. The time required for onset of sensory block was defined up to T10 dermatomal level assessing by pinprick using 25G short bevel needle. The onset and degree of motor blockade was assessed according to modified Bromage scale. All durations were defined considering the time of intrathecal injection as time zero.

Secondary outcome measures included the haemodynamic stability. Noninvasive blood pressure, pulse rate and saturation of oxygen were recorded intraoperatively

every 1 min. for the initial 5 minutes followed by every 5 mins. until 30 minutes and then on every 15 mins. till the end of the surgery. Patients were discharged from the postanaesthesia care unit after sensory regression to S1 segment and modified Bromage grade 0. The mean duration of analgesia, time interval between intrathecal drug injection to first analgesic dose request by the patient were noted. Hypotension (defined as fall in blood pressure >20% of baseline value or <90 mm of Hg of systolic BP was treated with Inj. Ephedrine 6 mg intravenously), bradycardia (heart rate <60 beats/min. was treated with Inj. Atropine 0.3 mg intravenously), nausea, vomiting, dizziness were noted intraoperatively. Backache and postdural puncture headache were assessed postoperatively.

### Statistical Analysis

On simple interactive statistical analysis, sample size of minimum 18 was derived using the formula for sample size calculation for multiple comparison (two tailed) based on the assumption of  $\alpha$  (type 1 error) = 5%,  $\beta$  (type 2 error) = 0.2 and power of the study = 80%. A sample size of 18 for each group was adequate to allow power of 80 to detect a difference of 15 between the groups. To generalise the results, we selected 20 in each group. Statistical analysis was conducted with software package SPSS 16. Continuous variables were presented as Mean $\pm$ Standard deviation. The demographic data was analysed using either unpaired 't' test or Chi-square test. Categorical data were analysed by Student's t-test and a p-value of <0.05 was considered to be statistically significant.

### RESULTS

Distribution according to age, sex, BMI and type of surgery in both the study groups were comparable (Table 3).

|                            | Bupivacaine     | Ropivacaine     |
|----------------------------|-----------------|-----------------|
| Number of patients         | 20              | 20              |
| Female/male                | 7/13            | 6/14            |
| Mean Body Mass Index (BMI) | 23.8 $\pm$ 3.02 | 24.4 $\pm$ 2.85 |
| <b>Type of surgery</b>     |                 |                 |
| Lower limb                 | 6               | 4               |
| Perineal                   | 6               | 8               |
| Inguinal herniorrhaphy     | 2               | 1               |
| Cystoscopy                 | 6               | 7               |

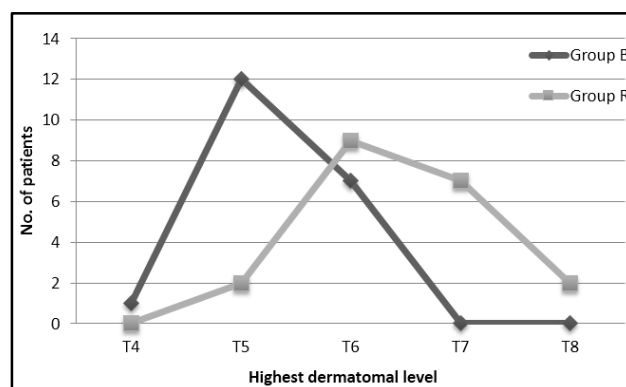
**Table 3. Patient Demographics**

The mean duration for onset of sensory block in group B was 1.59 mins. and in group R was 2.21 mins. Although, bupivacaine had a faster onset of sensory block, which was not statistically significant ( $p=0.081$ ).

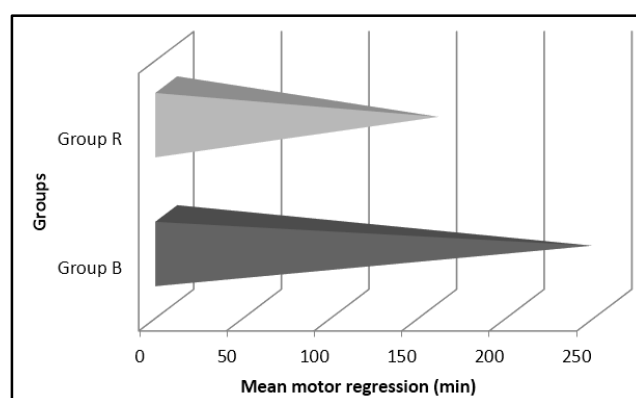
Mean duration of sensory block regression was 270.35 mins. for group B versus 166.25 mins. for group R. Highly significant early regression of sensory blockade was seen with ropivacaine ( $p=0.000$ ).

Level of sensory block reached in majority of the patients in Group B was T5 dermatomal level, while in hyperbaric

ropivacaine group it was up to T6 to T7 dermatomal level (Figure 1). Statistically, significant higher level of sensory block was noted with bupivacaine ( $p=0.002$ ).



**Figure 1. Distribution of Highest Dermatome Level of Sensory Block**



**Figure 2. Regression of Motor Blockade**

The mean time taken to reach modified Bromage grade III motor block was 1.65 mins. in group B and 2.35 mins. in group R, which was not significant ( $p=0.048$ ).

The mean regression time to modified Bromage grade 0 motor blockade was about 243.15 mins. in group B and 155.40 mins. in group R (Figure 2). Significant prolonged motor block was with bupivacaine ( $p=0.00$ ).

Modified Bromage grade III motor block occurred in all the twenty patients in group B, while only fifteen patients in group R had grade III blockade and remaining five patients had grade II block, which was statistically significant ( $p=0.017$ ).

Intergroup variations were highly significant with reference to changes in heart rate following spinal anaesthesia between the two study groups. Group R showed more stable heart rate throughout the surgery in comparison to group B ( $p=0.000$ ). There was significant statistical difference with reference to intraoperative Mean Arterial Pressure (MAP) changes. MAP fluctuations were less with ropivacaine compared to bupivacaine ( $p=0.025$ ).

The mean duration of analgesia was significantly longer with bupivacaine (259.85 mins.) compared to ropivacaine (191.50 mins.) ( $p=0.000$ ).

Intraoperatively, hypotension was observed in five patients of group B compared to two patients in group R.

Bradycardia was noted in one patient and two patients had nausea and vomiting in group B. Shivering occurred in two patients of group R as compared to one patient in group B. Incidence of side effects was statistically significant in

bupivacaine group. No side effects were observed postoperatively in both groups (Table 4).

|                                                                  | <b>Bupivacaine<br/>(n=20)</b> | <b>Ropivacaine<br/>(n=20)</b> | <b>p-value</b> |
|------------------------------------------------------------------|-------------------------------|-------------------------------|----------------|
| <b>Sensory Block</b>                                             |                               |                               |                |
| • Mean duration for sensory onset to T10 (mins.).                | 1.59±0.45*                    | 2.21±1.48*                    | 0.081          |
| • Highest dermatomal level (dermatome).                          | T 5/6                         | T 6/7                         | 0.002**        |
| • Mean duration for sensory regression (mins.).                  | 270.35±40.72*                 | 166.25±30.51*                 | 0.000**        |
| <b>Motor Block</b>                                               |                               |                               |                |
| • Grade III block, n (%).                                        | 20 (100)                      | 15 (75)                       | 0.017**        |
| • Mean duration for motor onset to reach Bromage II/III (mins.). | 1.65±0.45*                    | 2.35±1.45*                    | 0.048          |
| • Mean duration for motor regression to Bromage 0 (mins.).       | 243.15±36.41*                 | 155.40±30.20*                 | 0.000**        |
| <b>Side Effects, n (%)</b>                                       |                               |                               |                |
| • Hypotension.                                                   | 5 (25)                        | 2 (10)                        | 0.023**        |
| • Bradycardia.                                                   | 1 (5)                         | -                             |                |
| • Nausea/vomiting.                                               | 2 (10)                        | -                             |                |
| • Shivering.                                                     | 1 (5)                         | 2 (10)                        |                |
| • Postdural puncture headache.                                   | -                             | -                             |                |
| • Backache.                                                      | -                             | -                             |                |

**Table 4. Characteristics of Subarachnoid Block and Side Effects**

\*Data is expressed as mean±standard deviation.

\*\*Statistically significant.

## DISCUSSION

Hyperbaric solutions of ropivacaine have been used successfully to provide spinal anaesthesia.<sup>6-12</sup> Clinically, relevant doses of hyperbaric ropivacaine have been shown to provide predictable and reliable anaesthesia for elective surgery, albeit of a shorter duration than equal doses of bupivacaine. Hyperbaric ropivacaine produced more predictable and reliable sensory and motor block with faster onset than a plain solution.<sup>12</sup> Hence, the present study was designed to compare the clinical efficacy of hyperbaric ropivacaine over commercially available hyperbaric bupivacaine.

The mean time for onset of sensory blockade to T10 dermatomal level in the present study was 1.59±0.45 mins. for hyperbaric bupivacaine (group B) and 2.21±1.48 mins. for hyperbaric ropivacaine (group R), which was not statistically significant (p=0.081) similar to the results obtained by Carvalho et al,<sup>9</sup> Luck et al<sup>13</sup> and Chung et al.<sup>6</sup> Studies by Essam et al<sup>14</sup> and Whiteside et al<sup>10</sup> found a significant earlier onset of sensory block in bupivacaine over ropivacaine.

Highest dermatomal level of sensory block was T5, T6 in group B compared to T6, T7 levels in group R, which was highly significant (p=0.002) similar to the study by Essam et al.<sup>14</sup> No statistical significance between the groups were noted by Chung et al,<sup>6</sup> Carvalho et al,<sup>9</sup> Whiteside et al<sup>10</sup> and Luck et al.<sup>13</sup>

In the present study, the mean time for sensory regression was 270.35±40.72 mins. in group B, group R had an early regression of sensory block with 166.25±30.51

mins., which was highly significant (p=0.000) similar to the studies of Essam et al,<sup>14</sup> Carvalho et al,<sup>9</sup> Whiteside et al<sup>10</sup> and Luck et al.<sup>13</sup>

The mean value for onset of motor blockade in the present study for group B was 1.65±0.45 and 2.35±1.45 mins. for group R, which was not statistically significant (p=0.048), similar to the studies of Carvalho et al<sup>9</sup> and Chung et al.<sup>6</sup> While studies by Whiteside et al<sup>10</sup> and Luck et al<sup>13</sup> showed a significant longer onset of motor blockade time with ropivacaine compared to bupivacaine.

Overall, motor blockade in the present study showed that group R had grade II blockade in five patients and grade III blockade in fifteen patients, while all the twenty patients had grade III blockade in group B and was statistically significant (p=0.017) similar to the studies of Whiteside et al<sup>10</sup> and Luck et al.<sup>13</sup> While Carvalho et al<sup>9</sup> showed equal distribution of grade II and III motor blockade with ropivacaine and bupivacaine, all the patients had grade III motor blockade in the studies of Essam et al<sup>14</sup> and Chung et al.<sup>6</sup>

Mean motor blockade regression time in the present study was 243.15±36.41 mins. with bupivacaine compared to 155.40±30.20 mins. for ropivacaine thereby showing that ropivacaine had a highly significant early motor regression time compared to bupivacaine (p=0.000). Observations of the present study were comparable to studies of Essam et al,<sup>14</sup> Chung et al,<sup>6</sup> Whiteside et al<sup>10</sup> and Luck et al.<sup>13</sup> Carvalho et al<sup>9</sup> compared equipotent doses of hyperbaric bupivacaine and ropivacaine unlike previous studies including the present study and observed that mean motor regression time with bupivacaine (162.5±37.8 mins.) was similar to that of ropivacaine (192±50.7 mins.).

There were statistically significant changes in the intraoperative heart rate between the two groups. Ropivacaine showed more stable heart rate throughout compared to bupivacaine, which was highly significant ( $p=0.000$ ) similar to the studies of Luck et al<sup>13</sup> and Chung et al.<sup>6</sup>

In the present study, significant changes were observed in systolic blood pressure. Intraoperative fall in systolic pressure was comparatively less in ropivacaine than bupivacaine ( $p=0.001$ ) comparable to the study of Whiteside et al,<sup>10</sup> while Chung et al,<sup>6</sup> Luck et al<sup>13</sup> and Carvalho et al<sup>9</sup> reported no significant changes in systolic pressure between the study groups. Present study also showed significant intraoperative MAP changes. Ropivacaine had lesser variations in comparison to bupivacaine ( $p=0.025$ ) indicating a better haemodynamic stability.

The mean duration of analgesia was found to be  $259.85 \pm 35.52$  mins. for hyperbaric bupivacaine group compared to  $191.50 \pm 33.13$  mins. in hyperbaric ropivacaine group. Patients receiving bupivacaine had a significantly longer duration of analgesia with highly significant  $p$  value of 0.000 compared to ropivacaine comparable to the observations of Chung et al<sup>6</sup> and Carvalho et al.<sup>9</sup>

Intraoperative side effects (hypotension, bradycardia, nausea, vomiting and shivering) in the present study showed statistically significant higher incidence of side effects in group B compared to group R, ( $p=0.0236$ ) similar to the study by Whiteside et al.<sup>10</sup> However, studies by Luck et al,<sup>13</sup> Chung et al<sup>6</sup> and Carvalho et al<sup>9</sup> found no significant correlation of side effects between hyperbaric bupivacaine and ropivacaine.

In our study, although the duration of useful block for surgery was adequate, so was the speed of recovery from both sensory and motor block. Patients therefore can be mobilised more quickly after spinal anaesthesia with hyperbaric ropivacaine, something that maybe particularly useful for ambulatory surgery and any operation when a long duration of block is unnecessary or undesirable. To summarise, we found a reliable clinical profile of hyperbaric preparation of ropivacaine in terms of onset, duration and a highly favourable recovery profile in comparison to bupivacaine. This hints towards the safe practice of anaesthesia, appropriate drug selection individualised to each patient and procedure, which is the need of the hour. One of the limitation of our study is the preparation of drug prior to intrathecal injection was slightly tedious and time consuming, but the safer clinical profile of the hyperbaric preparation should be considered for its routine clinical use. Another limitation is that we compared a single concentration of hyperbaric ropivacaine, further studies with varying concentrations of hyperbaric ropivacaine might provide an ideal replacement dose for bupivacaine in future.

We suggest that this clinical profile of the drug may prove to be beneficial in selected group of patients coming for day case settings, thus replacing the commercially available hyperbaric bupivacaine used popularly these days. We also recommend that more studies with a bigger sample size are needed to validate our findings.

## CONCLUSION

In conclusion, 17.5 mg of 0.5% hyperbaric ropivacaine with 5% glucose produced a reliable spinal anaesthesia of intermediate duration compared to equal doses of commercially available 0.5% hyperbaric bupivacaine in surgeries below umbilicus. In an endeavour for searching a safe drug for ambulatory setup these days, hyperbaric ropivacaine having a lesser dermatomal level of sensory block, less intense motor blockade, significant early recovery from motor and sensory blockade with stable haemodynamic conditions compared to bupivacaine serves as better option. Thus, the suitability of hyperbaric ropivacaine for ambulatory surgery should be considered.

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