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# Research Article

# Spinal Anaesthesia With 0.5% Hyperbaric Ropivacaine and 0.5% Hyperbaric Bupivacaine: A Comparative Study

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**Abstract:** One of the primary aims of anaesthesia is to render adequate pain relief, thereby permitting the performance of surgical procedures without stress and discomfort. General anaesthesia does not abolish the stress response completely. The local anaesthetics when used intrathecal or epidural, abolishes the response to a great extent, particularly in lower abdominal operations. The present study designed to compare the clinical efficacy of hyperbaric solution of Ropivacaine (0.5%) with that of hyperbaric Bupivacaine (0.5%) in spinal anaesthesia. The aims and objectives of this study were to study the characteristics of spinal blockade in terms of sensory and motor blockade (onset, extent, regression and duration), hemodynamic stability, the recovery profile and side effects of both the drugs if any. In present randomized double blind prospective comparative study, after approval of ethical committee, 100 patients of either sex, ASA grade I and II, aged 20 - 60 years scheduled for different surgical procedures on abdomen, genitourinary region and lower extremity were included in this study. The sample size was determined by power analysis. The patients were randomly allocated into two groups. Pre-anaesthetic evaluation was done one day prior to surgery and all necessary investigations done. An informed consent was taken. Group R - Received inj. Ropivacaine 3 ml of 0.5% hyperbaric (in glucose 8.3%) solution. Group B - Received injection Bupivacaine 3 ml of 0.5% hyperbaric (glucose 8%) solution. Following observations were made - Time of onset of sensory block, maximum cephalic spread (dermatome), time to maximum cephalic spread, two segment regression time (min) and total duration of sensory block. Degree of motor block was assessed by Bromage scale. Intraoperatively, pulse rate, systolic and diastolic blood pressure, respiratory rate and SPO2 monitored at induction, 2, 5, 10, 15, 20, 25, 30, 45, 60 min with help of multipara monitor. In this study, for quantitative data of both groups, mean and standard deviation were calculated. To find out the significant difference between two groups Z- test was used. For qualitative data, Chi square test was used. A difference with significant level p<0.05 was considered statistically significant. The mean time for onset of sensory block was earlier in group B as compared to group R (3.28  $\pm$  1.78 vs 7.26  $\pm$  2.25 minutes) thus, the difference was statistically significant (Z >1.96, P <0.001). The mean time of maximum cephalic spread of sensory block in both groups was statistically not significant (15.96  $\pm$  4.34 vs  $17.32 \pm 4.83$  min. in Groups R and B) (p>0.05). Mean time of two segment regression in group B was higher than group R ( $66.72 \pm 12.56$  vs  $81.4 \pm 13.58$  min). This difference was statistically significant (P < 0.001). The mean total duration of sensory block in group R was  $133.52 \pm 18.69$  min. and in group B was  $188 \pm 52.23$  min. the difference in two groups was statistically significant (P < 0.001). The mean time for onset of motor block in group R was  $10.32 \pm 4.20$  minutes and in group B was  $6.28 \pm 1.64$  min. The difference in two groups was statistically significant (P<0.001). The mean time of total duration of motor blockade in group R and group B was  $69.74 \pm 50.36$  and  $120 \pm 61.72$  min. the difference in two groups was statistically significant. (p<0.001). The mean duration of surgery in both groups was almost similar (62.37  $\pm$  28.56 and 72.34  $\pm$  32.98 min in groups R and B). The difference in was statistically not significant. (P>0.05). Intraoperative and postoperative side effects like nausea, vomiting, hypotension, bradycardia were minimal and comparable in both the groups. Hypotension was seen in more number of patients in group B than in group R.( P < 0.05) this difference was statistically significant. No side effects were seen in 40 (80%) patients of group R and 26 (52%) patients of group B i.e. side effects were seen in more number of patients in group B than in group R. (Z value 2.266 and P value 0.0235). Z > 1.96 and P < 0.05, this difference was statistically significant.

Keywords: Ropivacaine, Bupivacaine, spinal anaesthesia, comparison, side effects.

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# Introduction

Since the introduction of spinal anaesthesia in 1898 by Dr. August Bier, who described the intrathecal administration of cocaine, spinal anaesthesia is preferred over general anaesthesia, particularly in surgical procedures of lower abdomen and lower limbs (DC Simone, 2008) The main reason for extensive use of spinal anesthesia in general are simplicity of equipments, low cost, profound analgesia, adequate muscle relaxation, less blood loss and less metabolic alterations.

General anaesthesia does not abolish the stress response completely. The local anaesthetics when used intrathecal or epidural, abolishes the response to a great extent, particularly in lower abdominal operations (Dr. Manorama Singh, 2003). Spinal anaesthesia has the definitive advantage that profound nerve block can be produced in a large part of the body by the relatively simple injection of a small amount of local anaesthetic. However, the greatest challenge of the technique is to control the spread of that local anaesthetic through the cerebrospinal fluid (CSF) to provide the block that is adequate (in both extent and degree) for the proposed surgery but without producing unnecessarily extensive spread and so increasing the complications(Hocking G,2004). Local anaesthetics are drugs that produce transient and reversible loss of sensation or feeling in a circumscribed area of the body without loss of consciousness (Courtney KR, 1987). Newer local anaesthetics are introduced with the goal of reducing local tissue irritation, minimizing systemic, cardiac and central nervous system toxicity, achieving faster onset and longer duration of action (Courtney KR, 1987).

Bupivacaine has been in clinical use for more than 30 years and is available commercially as a racemic mixture containing equal proportions of the S (-) and R (-) isomers. It is widely used because of its long duration of action and beneficial ratio of sensory to motor block. However, Bupivacaine is also associated with a number of side effects, including motor weakness, urinary retention, cardiovascular and central nervous system toxicity. In particular, there have been reports of death attributable to Bupivacaine induced cardio-toxicity in adults after accidental intravenous injection (D.A.H. deBeer, 2003).

Ropivacaine is a new long acting amino-amide local anaesthetic. It is the monohydrate of the hydrochloride salt of 1-propyl- 2', 6'- pipecoloxylidide (McClure JH, 1996). It was synthesized simultaneously with Bupivacaine by Ekenstam almost 50 years ago and was launched in 1996, being the first pure S (-) enantiomeric local anaesthetic to be clinically introduced. The reason for introducing Ropivacaine was the need for a long acting local anaesthetic that is less cardio toxic than Bupivacaine (H Kokki, 2005).

Ropivacaine produces a greater degree of differential block at low concentration and a property of producing frequency dependent block, offers considerable clinical advantage in providing analgesia with minimum motor blockade (McClure JH, 1996). Looking at this property, in the past year Ropivacaine has been one of the most studied drug, used in ambulatory spinal anesthesia, but Ropivacaine has not offered clear advantage over Bupivacaine about reliability, side effects or faster recovery (D. Malhotra, 2008). However, Ropivacaine has been extensively used for local infiltration, epidural, brachial plexus and peripheral nerve blocks in children and clinical data showed that Ropivacaine is also effective and safe for regional anaesthesia in children (H Kokki, 2005). It is approximately half as potent as Ropivacaine in spinal anesthesia when used in hyperbaric solution (A Claudio, 2002). Hyperbaric Ropivacaine produced more predictable and reliable sensory and motor block, with faster onset than a plain solution. Plain solution of Ropivacaine is associated with a less favourable pattern of block (A Claudio, 2005).

#### **Aims and Objectives**

- 1. To evaluate the efficacy and safety of 0.5% Ropivacaine 3 ml (heavy) and 0.5% Bupivacaine 3 ml (heavy) for intraoperative analgesia, predictability and reliability of sensory and motor block,
- 2. To find out characteristics of sensory and motor blockade produced by both the drugs when injected intrathecally.
- 3. Hemodynamic stability and the recovery profile.
- 4. To compare untoward effects of Ropivacaine and Bupivacaine if any.

# MATERIAL AND METHODS

The present randomized, double blind, prospective, comparative study done on 100 patients of either sex, ASA grade I and II, aged 20 - 60 years scheduled for different elective surgical procedures on lower abdomen, genitourinary region and on lower extremity were included in this study. They were randomly divided into two groups of 50 each, after obtaining approval from the institutional ethical committee. Pre-anaesthetic evaluation was done in each patient a day before surgery. All Patients were explained about the procedure and an informed consent taken for the same. A detailed history of any major diseases and previous operative history elicited. Patients with hypertension, who are haemodynamically stable with antihypertensive therapy and non IHD patients included in study. Patients with uncontrolled hypertension, IHD, psychiatric and neurological disorder, known allergy, sensitivity to anaesthetics, contraindications to spinal anaesthesia, such as infection at the site of lumbar spine, septicemia, platelet disorders and clotting abnormalities who are on anticoagulant therapy were excluded from the study.

Routine investigations like haemoglobin percentage, urine analysis for sugar and albumin done in every patient. Kidney and liver function tests, ECG, X- ray chest done whenever indicated. Their weight and height documented and nil by mouth status confirmed.

The sample size determined by power analysis. The patients randomly allocated into two groups. In group R and group B Randomization done by picking random lots from a sealed bag. All patients were blinded to spinal medication administered. Senior resident not participating in study who prepared all medications. According to randomization, the volume to be injected in spinal block was prepared in syringe with label indicating only the serial number of the patients. The residents observing the patient intraoperatively and in the recovery room were blinded to the drugs administered.

On table, a good intravenous line was secured with intravenous cannula and preloading was done with Ringers lactate, 20 ml /kg body weight.

Monitors like multipara were attached and basal reading of pulse rate, blood pressure, respiratory rate and SPO2 were noted. All patients were premedicated with injection ranitidine 1 mg/kg IV, injection Ondansetron 0.08 mg/kg IV, and injection Midazolam 0.02 mg/kg IV.

Under all aseptic precautions, Lumber puncture was done in L3 – L4 or L4-L5 interspace with 23 gauge Quincke spinal needle. After obtaining free, clear and continuous flow of cerebrospinal fluid, intrathecal administration of drugs was done as follows.

# Group R:

Received injection Ropivacaine 3 ml of 0.5% hyperbaric (in glucose 8.3%) solution. The Ropivacaine solutions were prepared aseptically immediately before injection (by adding 2 ml of Ropivacaine 0.75% plus 1 ml glucose 25%).

#### **Group B:**

Received injection Bupivacaine 3 ml of 0.5% hyperbaric (glucose 8%) solution. The hyperbaric Bupivacaine solutions were commercially available. Patients were turned immediately on their back and sensory analgesia was assessed by pinprick at every two minutes interval up to 30 minutes.

#### **Following Observations Were Made:**

- 1. Time of onset of sensory block (minutes)
- 2. Maximum cephalic spread (dermatome)
- 3. Time to maximum cephalic spread (minutes)
- 4. Two segment regression time (minutes)
- 5. Total duration of sensory block (minutes)

# The Characteristics Of Motor Block Were Assessed By Following Observations:

1. Degree of block assessed by Bromage scale

Grade 0 =Able to raise the whole limb at hip

Grade 1 = Able to flex knee but unable to raise the lower limb at hip

Grade 2 = Able to flex the ankle but unable to flex knee

Grade 3 = No movement of lower limb

- 2. Time to maximum degree of block i.e. Bromage grade 3 (minutes)
- 3. Time to complete regression of motor block grade 3 0 (minutes)

After achieving the adequate level of anaesthesia, surgeons were allowed to operate. The time of beginning of surgery was noted. Intra-operatively, pulse rate, systolic and diastolic blood pressure, respiratory rate and SPO2 monitored at induction, 2, 5, 10, 15, 20, 25, 30, 45, and 60 minutes with help of multipara monitor. Any hypotension (>30% fall from basal blood pressure) was treated with injection Mephentermine 7.5 mg IV and with loading Ringer lactate solution. Bradycardia (pulse rate below 60 beat / minute) was treated with injection Atropine 0.6 mg IV. Analgesics and sedatives were supplemented when required. General anaesthesia given if no level of anaesthesia were achieved. All patients received adequate intravenous fluids. Other side effects like nausea, vomiting, pruritus drowsiness, respiratory depression if occur were noted.

Time of completion of surgery was noted and duration of surgery was calculated. A person unknown to both groups, observed the patients in recovery room. In recovery room pulse rate, blood pressure, respiratory rate and SPO2 were monitored at arrival, 15, 30, 45, and 60 minutes with help of multipara monitor. Time taken for regression below L1 and duration of motor block (Bromage scale up to 0) was noted. The total duration of sensory block and motor block defined as interval from intrathecal administration to point of complete regression of sensory block or to the point in which the Bromage score was back to zero. The patients were shifted to ward with written instruction to withhold any analgesic or sedative in postoperative period, unless the patients complained of moderate pain and to note downfirst time of micturition. Patients were watched for side effects like nausea, vomiting, pruritus, hypotension, bradycardia, drowsiness, respiratory depression (respiratory rate < 10 breaths/minute).

#### **Statistical Analysis:**

For quantitative data of both groups, mean and standard deviation were calculated. To find out the significant difference between two groups Z- test was used. For qualitative data, Chi square test was used. A difference with significant level < 0.05 was considered statistically significant and p< 0.001 as highly significant.

# RESULTS

**Table No 1:** Shows sex wise distribution of patients between both groups

| Gender         | Number of pati | ents     | X2    | P value |  |
|----------------|----------------|----------|-------|---------|--|
|                | Group R        | Group B  |       |         |  |
| Male           | 34(68%)        | 37(74%)  |       |         |  |
| Female         | 16(32%)        | 13(26%)  | 0.192 | 0.66    |  |
| Total patients | 50(100%)       | 50(100%) |       |         |  |

Patients of both sexes were included in the study. In group R, 68% of the patients were male while only 32% patients were females. In group B, 74% of the patients were male while 26% patients were females. The numbers of male patients were more since the conditions for which the operations done were common in male than in female.

By using Chi square test for statistical analysis, chi square value was 0.192. Therefore, the P value was 0.66. Thus, the difference was statistically not significant (X2 = 0.198, P > 0.05).

**Table no. 2:** Shows mean age distribution of patients in both groups

| Parameters  | Group R<br>Mean ± SD | Group B<br>Mean ± SD | P value |  |
|-------------|----------------------|----------------------|---------|--|
| Age (years) | $46.5 \pm 15.65$     | $42.82 \pm 15.36$    | 0.81    |  |

All patients were in the age group of 20-60 years. The mean age of patient's in group R was  $46.5\pm15.65$  years and in group B was  $42.82\pm15.16$  years. Z value was 0.23 and P value was 0.81. There was no

statistically significant difference in age distribution as far as demographic profile was concerned (Z<1.96, P>0.05).

**Table no 3:** Shows mean height and weight distribution of patients in both groups.

| Parameters  | Group R           | Group B           | P value |
|-------------|-------------------|-------------------|---------|
|             | Mean $\pm$ SD     | Mean $\pm$ SD     |         |
| Height (cm) | $156.21 \pm 7.24$ | $154.24 \pm 6.49$ | 0.73    |
| Weight (kg) | $57.14 \pm 6.86$  | $56.46 \pm 7.62$  | 0.96    |

The mean height of patient's in group R was  $156.21 \pm 7.24$  cms and in group B was  $154.24 \pm 6.49$  cms. (Z value 0.34 & P value 0.73). The difference in two groups was statistically not significant (Z<1.96, P>0.05). The mean weight of patient's in group R was

 $57.14 \pm 6.86$  kg and in group B  $56.62 \pm 7.98$  kg. (Z value 0.08 & P value 0.94).

Thus, the difference was statistically not significant (Z<1.96, P>0.05).

Table no 4: Shows distribution of patients according to type of surgery in both groups

| Two of surgery       | No. of patients | No. of patients |  |
|----------------------|-----------------|-----------------|--|
| Type of surgery      | Group R         | Group B         |  |
| Hernia repair        | 09 (18%)        | 07 (14%)        |  |
| Appendicectomy       | 07 (14%)        | 06 (12%)        |  |
| DHS                  | 04 (08%)        | 05 (10%)        |  |
| OR with plating      | 05 (10%)        | 03 (06%)        |  |
| Orchidectomy         | 03 (06%)        | 05 (10%)        |  |
| Vaginal hysterectomy | 07 (14%)        | 09 (18%)        |  |
| Total abdominal      | 05 (10%)        | 07 (14%)        |  |
| hysterectomy         | 03 (10%)        | 07 (1470)       |  |
| Tubal ligation       | 08 (16%)        | 08 (16%)        |  |
| Rectal polypectomy   | 02 (04%)        | 00 (00%)        |  |
| Total                | 50 (100%)       | 50 (100%)       |  |

A total 10 surgical procedures had carried out on 100 patients of both groups.

**Table no 5:** Shows mean time of onset of sensory block in both groups

|                       | Table no 3. Shows mean time of offset of sensory block in both groups |                        |         |  |  |
|-----------------------|---|------------------------|---------|--|--|
| Sensory block         | Group R<br>Mean ± S.D   | Group B<br>Mean ± S.D. | P-value |  |  |
| Mean onset time (min) | $7.26 \pm 2.25$   | $3.28 \pm 1.78$        | 0.0000  |  |  |

The mean time for onset of sensory block was found to be  $7.26 \pm 2.25$  minutes in group R while  $3.28 \pm 1.78$  minutes in group B. The onset of sensory block was earlier in group B as compared to group R. The Z

value was 9.10 and P value was 0.0000. Thus, the difference was statistically significant (Z > 1.96, P <0.001).

Table no 6: Shows mean time to maximum cephalic spread in both Groups

| Sensory block                              | Group R<br>Mean ± S.D | Group B<br>Mean ± S.D. | P-value |  |
|--|-----------------------|------------------------|---------|--|
| Mean time to maximum cephalic spread (min) | $15.96 \pm 4.34$      | $17.32 \pm 4.83$       | 0.29    |  |

The mean time of maximum cephalic spread of sensory block in group R was  $15.96 \pm 4.34$  minutes and in group B was  $17.32 \pm 4.83$  minutes. Time required to reach maximum dermatome level was earlier in group R than in group B, as it blocks one dermatome level below than group B. However, this difference in two groups was statistically not significant. (Z value 1.04 and P value 0.29) (Z <1.96, P >0.05).

Maximum cephalic spread in group R was T6 dermatome in 12 (24%) patients and in group B was T5 dermatome in 16 (32%) patients.

This difference in two groups was statistically significant, Chi square test value was 43.71 and P value was 0.001 (P < 0.05).

**Table no 7:** Shows mean time of two segment regression in both Groups

| Sensory block                     | Group R<br>Mean ± S.D | Group B<br>Mean ± S.D. | P-value |  |
|-----------------------------------|-----------------------|------------------------|---------|--|
| Two segment regression time (min) | 66.72 ± 12.56         | $81.54 \pm 13.58$      | 0.0000  |  |

Mean time of two segment regression in group R was  $66.72 \pm 12.56$  min and in group B was  $81.4 \pm 13.58$  minutes. Duration of regression was more rapid

in group R than in group B. (Z value 4.77, P value 0.000). This difference was statistically significant. (Z >1.96, P <0.001).

**Table no 8:** Shows mean total duration of sensory block in both groups

| Sensory block                         | Group R<br>Mean ± S.D | Group B<br>Mean ± S.D. | P-value |  |
|---------------------------------------|-----------------------|------------------------|---------|--|
| Total duration of sensory block (min) | $133.52 \pm 18.69$    | $188 \pm 52.23$        | 0.0000  |  |

The mean time total duration of sensory block in group R was  $133.52 \pm 18.69$  minutes and in group B was  $188 \pm 52.23$  minutes. Total duration of sensory block was shorter in group R as compared to group B. Z

value was 8.11 and P value was 0.0000. Thus, the difference in two groups was statistically significant (Z > 1.96, P < 0.001).

**Table no 9:** Shows mean time for onset of motor block in both Groups

| motor block                             | Group R<br>Mean ± S.D | Group B<br>Mean ± S.D. | P-value |
|---|-----------------------|------------------------|---------|
| Mean time of onset of motor block (min) | $10.32 \pm 4.20$      | $6.28 \pm 1.64$        | 0.0000  |

The mean time for onset of motor block i.e. time to reach maximum degree of Bromage scale in

group R was  $10.32 \pm 4.20$  minutes and in group B was  $6.28 \pm 1.64$  minutes. (Z value 5.35 while P value is

0.0000). The difference in two groups was statistically significant (Z>1.96, P<0.001). The onset of motor block

was delayed in group R than in group B.

**Table no 10:** Shows Bromage scale for motor block in both Groups

| Bromage scale | No. of patients<br>Group R | No. of patients<br>Group B | X2    | P value |
|---------------|----------------------------|----------------------------|-------|---------|
| 0             | 03                         | 0                          |       | 0.0000  |
| 1             | 07                         | 0                          | 21.00 | 0.0000  |
| 2             | 15                         | 04                         | 21.88 |         |
| _ 3           | 25                         | 46                         |       |         |

Quality of motor block was assessed by Bromage scale. In group R, out of 50 patients, 3 (6%) developed grade 0 block, 7(14%) patients developed grade 1 block, 13 (30%) patients developed grade 2 block, 25 (50%) patients developed grade 3 block.

In group B, out of 50 patients, 4 (8%) patients developed grade 2 block, 46 (88%) patients developed grade 3 block. The difference in two groups was statistically significant (Chi square test:  $x^2 = 21.88$ , P < 0.01).

**Table no 11:** Shows mean time of total duration of motor blockade in both groups

| Motor block                         | Group R<br>Mean ± S.D | Group B<br>Mean ± S.D. | P-value |
|-------------------------------------|-----------------------|------------------------|---------|
| Total duration of motor block (min) | $69.74 \pm 50.36$     | $120 \pm 61.72$        | 0.0000  |

The mean time of total duration of motor blockade in group R was  $69.74 \pm 50.36$  minutes and in group B was  $120 \pm 61.72$  minutes. The total duration of motor block was shorter in group R than in group B.

The Z value was 8.56, while P value was 0.0000. Thus, the difference in two groups was statistically significant (Z > 1.96, P < 0.001).

Table no 12: Shows mean duration of surgery in both groups

| Parameters                        | Group R Mean ± S.D | Group B<br>Mean ± S.D | P value |  |
|-----------------------------------|--------------------|-----------------------|---------|--|
| Average duration of surgery (min) | $62.37 \pm 28.56$  | $72.34 \pm 32.98$     | 0.98    |  |

The mean duration of surgery in patients in group R was  $62.37 \pm 28.56$  minutes and in group B was  $72.34 \pm 32.98$  minutes. Z value was 0.026 and P value was 0.98. The difference in two groups was statistically not significant. ( Z<1.96, P>0.05).

# **Haemodynamic Changes**

Intraoperative and postoperative mean pulse rate changes in both groups at various intervals.

Mean pulse rate of patients in group R at induction was 72.58  $\pm$  8.62 beats/minute and in group B was74.36  $\pm$  8.85 beats/minute which was comparable in both groups.

At 2 Min it was  $79 \pm 9.59$  and  $82.28 \pm 9.84$ ; at 5 Min  $75.92 \pm 10.89$  and  $76.96 \pm 8.75$ ; at 10 Min  $73.92 \pm 11.11$  and  $71.76 \pm 11.45$ ; at 15 Min  $72.56 \pm 11.84$  and  $72.68 \pm 8.84$ ; at 20 Min  $72.16 \pm 9.66$  and  $71.56 \pm 9.34$ ; at 25 min  $73.16 \pm 9.41$  and  $70.76 \pm 8.60$ ; at 30 Min  $73.28 \pm 9.03$  and  $70.92 \pm 8.08$ ; at 45 Min  $73.8 \pm 8.52$  and  $71.72 \pm 7.76$ ; at 60 Min  $74.96 \pm 8.35$  and  $72.24 \pm 7.85$  respectively in groups R and B.

When patients were transferred to recovery room, the pulse rate changes were  $78 \pm 7.07$  and 73.58

 $\pm$  7.73 min; at 15 Min 75.88  $\pm$  7.05 and 74.96 and 7.71; at 30 Min 77.04  $\pm$  6.92 and 77.24  $\pm$  7.29; at 45 Min 77.88  $\pm$  7.28 and 78.88  $\pm$  7.15 and at 60 Min 79.92  $\pm$  7.74 and 78. 62  $\pm$  13.12 0.5485 respectively in groups R and B.

It is clear from above that after spinal anaesthesia mean pulse rate is decreased from 5 minutes onwards in both groups. It is found that there were no falls in pulse rate in postoperative periods in recovery room.

Intraoperative and postoperative mean systolic blood pressure changes in both groups at various intervals

Mean systolic blood pressure of patients in groups R at induction was  $116.28 \pm 9.42$  mmHg and in group B was  $119.2 \pm 9.96$  mmHg which was comparable in both groups. After spinal anesthesia mean systolic blood pressure of patients in groups R and in group B intraoperatively was  $118.84 \pm 9.68$  mmHg and  $120.6 \pm 8.56$  mmHg at 2 minutes,  $108.22 \pm 6.72$  mmHg and  $112.32 \pm 9.68$  mmHg at 15 min,  $115.28 \pm 12.32$  mmHg and  $111.38 \pm 12.27$ mmHg at 20 minutes,  $119.65 \pm 12.67$  mmHg and  $116.38 \pm 11.38$ 

mmHg at 45 minutes,  $123.42 \pm 9.93$  mmHg and  $121.48 \pm 11.02$  mmHg at RR 45 minutes,  $128.16 \pm 9.58$  mmHg. This difference in two groups was statistically not significant (Z < 1.96, P>0.05).

When patients were transferred to recovery room, the mean systolic blood pressure was  $122 \pm 10.7$  and  $114.04 \pm 10.89$  mmHg, at 15 minutes,  $124.36 \pm 10.25$  and  $117.08 \pm 10.87$ mmHg, at 30 minutes  $126.56 \pm 9.90$  and  $120.64 \pm 11.07$  mm of Hg at 45 minutes,  $127.4 \pm 9.93$  and  $123.38 \pm 11.23$  and at 60 minutes  $128.16 \pm 9.58$  and  $124.96 \pm 11.13$  in groups R and B respectively. This difference in two groups was statistically significant (Z test : Z > 1.96, P<0.05).

From above, it is clear that mean systolic blood pressure decreased in both groups from 5 minutes onwards and in postoperatively in recovery room also.

That difference in mean systolic blood pressure in two groups was statistically significant. (Z test: Z > 1.96,P<0.05).

Intraoperative and postoperative mean diastolic blood pressure changes in both groups

Mean diastolic blood pressure of patients in group R at induction was  $72.96 \pm 5.67$  mmHg and in group B was  $74.8 \pm 5.62$  mmHg which was comparable in both groups.

This difference in two groups was statistically non significant (Z test -Z > 1.96, P>0.05). It is clear from above table that after spinal anaesthesia mean diastolic blood pressure is decreased from 5 minutes onwards and postoperatively in recovery room also in both groups.

**Table no 13:** Shows comparison of side effects in both groups

| Contract of the contract of th |         |         |         |  |
|--|---------|---------|---------|--|
| Side effects   | Group R | Group B | P value |  |
| Nausea   | 02      | 04      | 0.53    |  |
| Vomiting   | 01      | 02      | 0.56    |  |
| Hypotension  | 05      | 12      | 0.023   |  |
| Bradycardia  | 02      | 06      | 0.75    |  |
| No side effects  | 40      | 26      | 0.024   |  |

Nausea was seen in 2 (4%), patients in group R and 4 (8%) patients in group B (Z value 0.620 and P value 0.53) Z < 1.96 and P > 0.05, this difference was statistically not significant.

Vomiting was seen in 1(2%), patients in group R and 2 (4%) patients in group B i.e. vomiting was seen in more number of patients in group B than in group R. (Z value 0.587 and P value 0.5572). Z< 1.96 and P > 0.05, this difference was statistically not significant.

#### Pruritus was not seen in any patient of both groups.

Hypotension (blood pressure fall >30% of baseline value) was seen intraoperatively in 5 (10%) patients in group R and 12 (24 %) patients in group B i.e. hypotension was seen in more number of patients in group B than in group R. (Z value 2.266 and P value 0.0235). Z > 1.96 and P < 0.05, this difference was statistically significant.

Bradycardia (pulse rate < 60 beats per minutes) was seen intraoperatively in 2 (4%) patients of group R and 6(12%) patients of group B i.e. bradycardia was seen in more number of patients in group B than in group R. (Z value 0.32 and P value 0.7490). Z <1.96 and P >0.05, this difference was statistically not significant.

Respiratory depression and drowsiness was not seen in any patient of both groups.

No side effects were seen in 40 (80%) patients of group R and 26 (52%) patients of group B i.e. side effects were seen in more number of patients in group B than in group R. (Z value 2.266 and P value 0.0235). Z > 1.96 and P < 0.05, this difference was statistically significant.

Table no 14: Shows comparison of mean time of first micturition in both groups

| Parameters                       | Group R<br>mean • } S.D | Group B<br>mean • } S.D | P value |  |
|----------------------------------|-------------------------|-------------------------|---------|--|
| Time of 1st micturition(minutes) | $235.65 \pm 36.73$      | $326 \pm 78.55$         | 0.0000  |  |

Time of first micturition was  $235.65 \pm 36.73$  minutes in group R and  $326 \pm 78.55$  minutes in group B. This means patients in group R were able to pass urine sooner than those in the group B. The Z value was 7.57 and P value was 0.0000. Thus, the difference was statistically significant (Z > 1.96 and P < 0.001).

# **DISCUSSION**

# Demographic Data:

The mean age of patients in group R was 42.5  $\pm$  15.65 years and in group B was 40.82  $\pm$  15.36 years.

The mean height of patients in group R was 159.22  $\pm$  7.24 cms and in group B was 161.24  $\pm$  7.49 cms.

The mean weight of patient's in-group R was  $58.04 \pm 6.86$  kg and in group B was  $58.04 \pm 7.98$  kg. The difference observed of above demographic data was statistically not significant (Z test - Z<1.96, P>0.05).

#### 1) Onset time of sensory block (table no 5):

In present study, the mean time taken for onset of sensory block in group R was  $7.26 \pm 2.25$  minutes and in group B was  $3.28 \pm 1.78$  minutes. Thus, the difference is statistically significant (Z -9.10, P=0.0000). (P<0.001)

Gautier *et al.*, (1999) who studied intrathecal Ropivacaine for ambulatory surgery and compare plain solutions of Ropivacaine with Bupivacaine. The onset was similar (14 minutes in Bupivacaine group and 15 minutes in Ropivacaine group).Patients received volume of drug 4 ml and concentration of drug 0.2% -0.35% in all groups in their study. In present study, less volume of drugs (3 ml), more concentrations of drugs (0.5%) are used with similar doses with glucose containing solutions. These all might be reason for late onset in group R.

Kallio *et al.*, (2004), who compared plain Ropivacaine15 mg and 20 mg versus Bupivacaine 10 mg, found that median onset of analgesia to T10, was 10 minutes in all groups. They use different doses, different concentrations i.e. 1%, 0.75% and 0.5% and smaller volume (2 ml) of both drugs in their study. In addition, sample size is smaller in their study. All these might be reason for similar onset in all groups. However, in present study we used equal volume, same dose, and similar concentration in both groups. In present study, sample size is larger so results have more accuracy.

Fettes *et al.*, (2005) confirmed in their study that a hyperbaric solution of Ropivacaine produces a more consistent block than a plain one. Reason is addition of glucose lead to a more rapid onset. (10 minutes versus 5 minutes).

Osama AL Abdulhadi *et al.*, (2007) compared hyperbaric spinal Ropivacaine (15 mg) to hyperbaric spinal Bupivacaine (11.25 mg) with 0.1 mg of preservative free Morphine and 0.01 mg Fentanyl, for elective caesarean delivery and found that similar onset times for sensory block to T6. Reason is as they used additives like Morphine and Fentanyl in both solutions, so onset becomes faster and similar. Patients chosen by them were pregnant women in whom sensitivity to local anaesthetics is already increased.

J.F. Luck *et al.*, (2008) found that there were no significant differences between the groups with regard to the mean time to onset of sensory block at T10.

However the result of present study are in accordance with the study done by Chung  $et\ al.$ , (2001) who used hyperbaric Ropivacaine 0.5% 18 mg and hyperbaric Bupivacaine 0.5%, 12 mg and found that Onset time of sensory block to T10 was  $3.2\pm1.2$  minutes in the Ropivacaine group and  $2.5\pm1.0$  minutes in Bupivacaine group. Also present study coincide with Whiteside  $et\ al.$ , (2003), who used 3 ml of Ropivacaine 0.5% (glucose 5%) and 3 ml of hyperbaric Bupivacaine 0.5% (glucose 8%), found that the hyperbaric Ropivacaine produced a somewhat slower onset at T10 (2 minutes versus 5 minutes).

# Time to maximum cephalic spread (table no 6):

Time for maximum cephalic spread depend on baricity of solution, dose of drug, tilt of table and position of patients etc. As regard to mean time to maximum cephalic spread, present study showed that equal doses of hyperbaric Bupivacaine and hyperbaric Ropivacaine showed no significant difference (17.32  $\pm$  4.83 minutes in Bupivacaine group and 15.96  $\pm$  4.34 minutes in Ropivacaine group). Present study showed that equal doses of hyperbaric Bupivacaine and hyperbaric Ropivacaine showed no significant difference in regards to mean height of sensory block (T5 in Bupivacaine group and T6 in Ropivacaine group).

Whiteside *et al.*, (2003), who found that the time to maximum extent of cephalic spread was similar in both groups [Ropivacaine 20 minutes (10 - 30 minutes), Bupivacaine - 20 minutes (5 - 30 minutes)].

The present study is in accordance with the studies done by J.F.Luck *et al.*, (2008) who found, the time to maximum cephalic spread were in all groups [ Bupivacaine 25 minutes (10 - 30 minutes), and Ropivacaine 20 minutes (2 - 30 minutes)], but statistically not significant.

The present study showed results in accordance with the study of Chung *et al.*, (2001), found that time to peak level were later in the Ropivacaine group.

All above studies used hyperbaric solutions of both compared drugs, which had higher density than CSF, this is reason that present study also having similar results like them.

Present study shows results in accordance with the studies done by Gautier *et al.*,(1999), who compared equal doses of Ropivacaine 8 mg (4 ml of 0.2%) and Bupivacaine 8 mg (4 ml of 0.2%). The extent of sensory block was similar in both groups (T8). The

exact dermatome level is higher in present study as volume of drugs, dose of drugs used are different and hyperbaric solutions were used.

In addition, our results coincides with Chung *et al.*,(2001) who compared 12 mg of intrathecal hyperbaric Ropivacaine 0.5% and 18 mg of hyperbaric Bupivacaine 0.5% in cesarean section. They found that the median (range) peak level of anaesthesia was T3 (T1 - T5) in the Bupivacaine group and T3 (T1 - T4) in the Ropivacaine group.

In addition, Whiteside *et al.*, (2003) who compared 3 ml of hyperbaric Bupivacaine 0.5% in glucose 8% and 3 ml of hyperbaric Ropivacaine 0.5% in glucose 5% for elective surgery found that the Ropivacaine produced less maximum cephalic spread (T7 versus T5).

Kallio *et al.*, (2004) who compared 56 patients divided into 2 equal groups, they received either intrathecal hyperbaric Ropivacaine 15 mg or 15 mg plain Ropivacaine, found that sensory block reached the T10 dermatome level in all patients of hyperbaric group, but there were 10 patients (36%) in plain group failed to reach T10 level, the sensory block with the plain Ropivacaine spread unpredictably and the highest extent of sensory block varied widely. In addition, the highest median extent of sensory block with Ropivacaine 15 mg was significantly greater in hyperbaric Ropivacaine (T4) than in plain one. Addition of glucose improves spread of drug.

Fettes *et al.*,(2005) compared 3 ml of plain Ropivacaine 0.5% and 3 ml of hyperbaric Ropivacaine 0.5% in glucose 5%, in a direct blinded comparison between two randomized groups of patients, that a hyperbaric solution of Ropivacaine produces a higher median level of sensory block and with less variation in maximum level (T4 level) than plain one.

J. F. Luck *et al.*, (2008) compared the clinical effects of 'hyperbaric' Bupivacaine for spinal anaesthesia with those of similar preparations of Ropivacaine found that there were no significant differences between the groups with regard to the extent of spread [Bupivacaine T3(T2 -T8), and Ropivacaine T4 (T2 - T10)].

In comparison to present study Van Kleef, *et al.*, (1994) found that the individual patient maximum block height (range from L4 –T5 and median dermatomes T11) and Wahedi *et al.*, (1996) found that the block height (range from T4-T11 and median dermatomes T7). These results clearly show the influence of adding glucose. The major effect of adding glucose is to reduce the incidence of very limited blocks or producing blocks that are more extensive.

# Regression of sensory block (table no 7)

Mean time of two segment regression in group R was  $66.72 \pm 12.56$  minutes and in group B was  $81.4 \pm 13.58$  minutes. Duration of regression was more rapid in group R than in group B. (Z value 4.77 while P value 0.000). This difference was statistically significant. (Z test: Z > 1.96, P < 0.001).

The results of present study are in coincides with the studies done by Whiteside *et al.*,(.2003) who found that mean duration of sensory block at T10 was shorter in Ropivacaine group (Ropivacaine 56.5 (28 - 145) minutes; Bupivacaine 118 (80 - 238) minutes; p=0.001).

McNamee *et al.*,(2002), comparing plain Ropivacaine 5 mg/ml with Bupivacaine 5 mg/ml for major orthopedic surgery found that the median duration of sensory block at the T10 dermatome was 3 hours (range 1.5 - 4.6 hours) in Group R and 3.5 hours (2.7 - 5.2 hours) in Group B (P<0.0001).

Kallio *et al.*,(2004), prospective randomized, double-blind study included 56 patients divided into two equal groups, they received either intrathecal hyperbaric Ropivacaine 15 mg or 15 mg plain Ropivacaine, found that hyperbaric group had longer duration of analgesia at T10; [83 minutes (5 - 145 minutes ) versus 33 minutes (0 - 140 minutes )], (P=0.004).

Kalio *et al.*,(2004) in prospective randomized double-blinded study included 90 ambulatory lower extremity surgery patients who received 2 ml of Ropivacaine 1%, Ropivacaine 0.75% or Bupivacaine 0.5% found that the median duration of sensory block at T10 was significantly longer with Ropivacaine 20 mg (170 minutes) than with Bupivacaine 10 mg (140 minutes; P= 0.005). This study demonstrated that plain solutions of local anaesthetics spread unpredictably. It might be reason for their results.

Fettes *et al.*,(2005) compared 3 ml of plain ropivacaine 0.5% and 3 ml of hyperbaric Ropivacaine 0.5% in glucose 5% and found that median duration of sensory block at T10 (plain 25 minutes; hyperbaric 115 minutes; P<0.001). They concluded that addition of glucose to Ropivacaine increase duration of block.

J.F.Luck *et al.*, (2008) found that the time of sensory block regression to T10 was shorter with Ropivacaine [Bupivacaine 129 (58 - 178), and Ropivacaine 84 (45 - 145)].

Present study is also in accordance with this study as our sample size is larger so results are more reliable.

The results of the present study did not agree with the general conclusion of Chung *et al.*,(2001) who

found that time for sensory block to recede toT10 did not differ between groups. As their individual doses of drug, volume of drug given was different and patients chosen were parturient. In present study dose of both drug, volume of both drug are similar. Patients chosen are of lower abdominal and lower limb pathology.

# Total duration of sensory block (table no 8):

The mean time for total duration of sensory block in group R was  $133.52 \pm 18.69$  minutes and in group B was  $188 \pm 52.23$  minutes. Total duration of sensory block is shorter in group R than group B. This difference in two groups was statistically highly significant [(Z = 8.11 and P = 0.0000) Z test: Z>1.96, P < 0.001].

The results of present study are in accordance with the study done by Gautier *et al.*,(1999) who found that when equal doses of Ropivacaine 8 mg (4ml of 0.2%) and Bupivacaine 8 mg (4ml of 0.2%) were compared, the duration of sensory block produced was lesser with Ropivacaine (130 minutes versus 181minutes).

The result coincides with the study done by Chung *et al.*, (2001); they found that the duration of sensory block was shorter in Ropivacaine group (162 minutes versus 188 minutes).

Also present study results are in accordance with the study done by Whiteside *et al.*, (2003), who compared the hyperbaric Bupivacaine and Ropivacaine. The Ropivacaine produced a somewhat shorter duration of action (180 minutes versus 255 minutes).

McNamee *et al.*, (2002) comparing plain Ropivacaine 5 mg/ ml with Bupivacaine 5 mg/ ml for major orthopedic surgery found that, the median duration of sensory block was 3.0 hours (range 1.5-4.6 hours) in Group R and 3.5 hours (2.7-5.2 hours) in Group B.

Kallio *et al.*, (2004) concluded that spinal anaesthesia with 15 mg of hyperbaric Ropivacaine is suitable for ambulatory lower extremity surgery with great success rate of achieving sufficient analgesia (at least T10 level sensory block) and fast recovery, the sensory regression occurs after 210 minutes in hyperbaric group and after 270 minutes in plain group.

Also present study results are in accordance with the study done by Fettes *et al.*, (2005) who compared hyperbaric and plain Ropivacaine, they found that sensory regression occurs at 240 minutes in hyperbaric group and 270 minutes in plain group.

# Time of onset of motor block (table no 9 and 10):

The mean time for onset of motor block i.e. time to reach maximum degree of Bromage scale in group R was  $10.32 \pm 4.20$  minutes and in group B was

 $6.28 \pm 1.64$  minutes that was comparable in both the groups. (Z value 5.35 while P value is 0.0000). The difference in two groups is statistically highly significant (Z test: Z>1.96, P<0.001).

# The onset of motor block was delayed in group R than in group B.

Above difference may be due to less lipid solubility of Ropivacaine which causes this drug to penetrate the large myelinated A fibres more slowly than the more lipid soluble Bupivacaine.

Van Kleef *et al.*, (1994) found no significant difference between onset time of both groups. (21minutes (8.5 - 28.5) minutes in 0.5% Ropivacaine 15 mg versus 16 minutes (6 - 31) minutes in 0.75% ropivacaine 22.5 mg).

Wahedi *et al.*,(1996) found similar onset time in both groups i.e. 15 minutes.

Chung *et al.*, (2001) found similar onset time in both groups.  $6.0 \pm 1.9$  minutes in hyperbaric Bupivacaine group versus  $6.3 \pm 2.2$  minutes in hyperbaric Ropivacaine group.

Kim *et al.*, (2002), found that the rate of onset for each grade of motor block was faster in hyperbaric group 9.9 (5.3) minutes than plain group, 13.8 (5.4) minutes.

Osama AL Abdulhadio *et al.*, (2007) found similar onset time in both groups.  $6.4 \pm 0.3$  minutes in hyperbaric Bupivacaine group versus  $6.6 \pm 0.6$  minutes hyperbaric Ropivacaine group.

The study done by Whiteside, *et al.*, (2003) confirmed present study results. The onset of motor block was significantly greater in hyperbaric Bupivacaine than hyperbaric Ropivacaine (20 minutes versus 14 minutes).

J.F.Luck *et al.*, (2008), had similar result to present study, they found that onset in hyperbaric Bupivacaine group 5 (2 - 25) minutes and it was faster than hyperbaric Ropivacaine group 10 (5 - 20) minutes.

# Quality of motor block (table no 11):

The results of present study has shown that there was significant difference between Ropivacaine (group R) and Bupivacaine (group B), in which Ropivacaine gave a lesser degree of motor block. 44 (88%) out of 50 patients developed grade three block, 6 (12%) patients developed grade two block with Bupivacaine. 24 (48%) out of 50 patients developed grade three block, 12 (24%) patients developed grade two block, 9 (18%) patients developed grade one block and 5 (10%) patients developed grade zero block i.e. no motor block with Ropivacaine.

In present study, patients who developed grade one block, out of 9 patients, in 3 patients the level of spinal block was sufficient for the planned operations not required any analgesic supplementation, one patient of SPCL given injection Propofol 25-100 µg/kg/min infusion and to 5 patients given general anaesthesia.

Those patients developed grade zero blocks, out of 5, in two patients the level of spinal block was sufficient for the planned operation had no need to give supplementation of analgesia, 3 patients given general anaesthesia. The difference in two groups was statistically significant (Chi square test: x2=21.88, P<0.01).

The results of present study are in accordance with the studies done by Gautier *et al.*, (1999), who found that the degree of motor block produced was less with Ropivacaine.

McDonald *et al.*, (1999) found that, the degree of motor block produced was less with Ropivacaine. This adds to the now considerable evidence suggesting that there is a greater degree of sensory-motor separation when using Ropivacaine compared with Bupivacaine as supported by results of Brockway *et al.*, (1991) and Morrison *et al.*, (1994). In addition, these data agree with Gautier *et al.*, (1999) and McDonald *et al.*, (1999) both studies showed there is lesser degree of motor block that regressed faster than Bupivacaine.

The study done by Whiteside *et al.*, (2003) confirmed present study results partially that Ropivacaine 5 mg/ ml with glucose 50 mg/ml had a less potent effect on motor nerves with both degree and duration in comparison to hyperbaric Bupivacaine. Out of 20 patients of Ropivacaine group, 14 patients developed grade III block i.e. 70% that was comparable to our results. While out of 20 patients, who received Bupivacaine, developed grade III block in all patients 100%. No patients needed general anaesthesia.

Present study results were also comparable with Kallio *et al.*, (2004) in regards to degree of motor block (75% developed grade III block),and median full motor recovery (120 minutes), after spinal anaesthesia with 15 mg hyperbaric Ropivacaine.

Fettes *et al.*, (2005) found similar results in regards with degree of motor block, in group of hyperbaric Ropivacaine (72.5% developed grade III block).

This is general agreement that Ropivacaine has less potent effect on motor nerves. Ropivacaine is less lipophilic as compared to Bupivacaine therefore less penetrate large myelinated motor fibers- have selective action on pain transmitting A\delta & C nerves rather than  $A\beta$  fibers.

#### Total duration of motor block (table no 12 &13):

The mean time of total duration of motor blockade in group R was  $69.74 \pm 50.36$  minutes and in group B was  $120 \pm 61.72$  minutes which was comparable in both groups.

The Z value 8.56, while P value 0.0000. The difference in two groups was highly statistically significant. (Z test: Z > 1.96, P < 0.001). The total duration of motor block is shorter in group R than in group B.

As regards to the duration of motor block, the results of our study are in accordance with the studies done by McDonald *et al.*, (1999), they found that equal doses of drugs produced motor block, which regressed faster with hyperbaric Ropivacaine (104 minutes versus 143 minutes). Again, primarily on the basis of the shorter duration of action, and despite equivalence on the onset and extent of sensory block, the author concluded that Ropivacaine is less potent than hyperbaric Bupivacaine.

Gautier *et al.*, (1999), who compared intrathecal plain Bupivacaine and intrathecal plain Ropivacaine for knee arthroscopy found that Ropivacaine has a shorter duration of action than Bupivacaine (107 minutes versus169 minutes).

Also our results coincides with the study of Chung *et al.*, (2001), they found that the duration of motor block was shorter in hyperbaric Ropivacaine group (113 versus 158 minutes).

Kim *et al.*, (2002), in their study found that the duration of motor block in hyperbaric group was 144 minutes.

McNamee *et al.*, (2002) found that the median duration of complete motor block (modified Bromage Scale 3) was significantly shorter in the plain Ropivacaine group compared with the plain Bupivacaine group (2.1 versus 3.9 hours).

The present results were also comparable with the results of Fettes *et al.*, (2005) they also found that regression of motor block (120 minutes), in group of hyperbaric Ropivacaine.

#### Duration of surgery (table no 11 and 12)

In present study, the mean duration of surgery in patients in group R was  $62.37 \pm 28.56$  minutes and in group B was  $72.34 \pm 32.98$  minutes. This difference in two groups was statistically not significant (Z test – Z<1.96, P>0.05).

# HEMODYNAMICS

#### Pulse rate changes

Intraoperative and postoperative mean pulse rate changes in both groups at various intervals.

Mean pulse rate of patients in group R at induction was  $72.58 \pm 8.62$  beats/minute and in group B was  $74.36 \pm 8.85$  beats/minute which was comparable in both groups. This difference in two groups was statistically not significant when compared in intraoperative and postoperative period (Z <1.96, P>0.05).

It is clear from the observations that after spinal anaesthesia mean pulse rate was decreased from 5 minutes onwards in both groups. It is found that there were no falls in pulse rate in postoperative periods in recovery room.

Present study results have shown that, in spite of slight hypotension in both groups, there was no significant difference between both groups when compared for hemodynamic stability. In Ropivacaine group, out of 50 patients, only 6 patients developed significant lowering of systolic blood pressure and only 2 patients developed significant bradycardia. In Bupivacaine group, out of 50 patients, 15 patients developed significant lowering of systolic blood pressure and 4 patients developed bradycardia.

There was no need for sympathomimetics or anticholinergics at all in both groups in the recovery room.

Low pulse rate was exhibited by most patients during spinal anaesthesia is explained by predominance of Bainbridge reflex. Venous pooling in periphery decrease the stimulation of volume receptors in right atria this decrease outflow resulting in fall of pulse rate.

When changes in pulse rate were compared, present study results were comparable with the results of Gautier *et al.*, (1999) and McDonald *et al.*, (1999) in which there is no significant difference in regards to pulse rate changes.

In addition, same results were found in study of Casati *et al.*, (1999) who studied the frequency of hypotension during conventional or asymmetric hyperbaric spinal block, they found that bradycardia occurred in 19% in conventional group than in unilateral group.

Ogun CO *et al.*, (2003) studied the heart rate changes in twenty-five parturient receiving Ropivacaine 15 mg and Morphine 150  $\mu$ g (RM group) and twenty-five parturient received. Bupivacaine 15 mg and Morphine 150  $\mu$ g. They found that, the mean heart rate values were similar between the groups throughout the study.

In another study done by Kallio *et al.*, (2004), who compared intrathecal plain solutions containing Ropivacaine 20 or 15 mg versus Bupivacaine 10 mg.

They found that; bradycardia occur in 60%, 47% and 37% while the need for anticholinergics was 30%, 13% and 13% consequently. While in PACU bradycardia occur in 37%, 37% and 27% while the need for anticholinergics was 3%, 0% and 3% consequently.

In study done by Kallio *et al.*, (2004) found that only 4% of patients received plain Ropivacaine needed intraoperatively treatment for bradycardia while in the recovery room 4% of the hyperbaric group and 7% of the plain group received anticholinergics for bradycardia.

# **Systolic Blood Pressure**

Mean systolic blood pressure of patients in groups R at induction was  $116.28 \pm 9.42$  mmHg and in group B was  $119.2 \pm 9.96$  mmHg which was comparable in both groups. After spinal anesthesia mean systolic blood pressure of patients in groups R and in group B intraoperatively was  $118.84 \pm 9.68$  mmHg and  $120.6 \pm 8.56$  mmHg at 2 minutes,  $108.22 \pm 6.72$  mmHg and  $112.32 \pm 9.68$  mmHg at 15 min,  $115.28 \pm 12.32$  mmHg and  $111.38 \pm 12.27$ mmHg at 30 minutes,  $119.65 \pm 12.67$  mmHg and  $116.38 \pm 11.38$  mmHg at 45 minutes,  $123.42 \pm 9.93$  mmHg and  $121.48 \pm 11.02$  mmHg at 60 minutes. This difference in two groups was statistically not significant (Z < 1.96, P > 0.05).

When patients were transferred to recovery room, the mean systolic blood pressure was  $122 \pm 10.7$ and  $114.04 \pm 10.89$  mmHg, at 15 minutes,  $124.36 \pm 10.89$ 10.25 and  $117.08 \pm 10.87$ mmHg, at 30 minutes 126.56 $\pm$  9.90 and 120.64  $\pm$  11.07 mm of Hg at 45 minutes,  $127.4 \pm 9.93$  and  $123.38 \pm 11.23$  and at 60 minutes  $128.16 \pm 9.58$  and  $124.96 \pm 11.13$  in groups R and B respectively. This difference in two groups was statistically significant (Z test :Z > When we compared our results changes in arterial blood pressure, the present study results are in comparable with the studies done by Gautier et al., (1999) and McDonald et al., (1999), in which there were no significant differences in blood pressure changes. As maximum dermatome level was T8 and preloading done with intravenous fluids. In present study, also preloading done with intravenous 10 ml/kg Ringer lactate solution. The patients who achieved dermatome level T3, T4 and T5 shows hypotension. Such patients are more in group B than group R.

Present study agree with the study done by Whiteside *et al.*, (2001) in which there was hemodynamic stability in both groups as regard to hypotension (20% versus 5%).

Craig *et al.*, (2002) compared Bupivacaine versus Ropivacaine in caesarean section; they found that 37% of patients in B group received ephedrine in comparison to 35% of patients in R group. Parturient are already have physiological changes of pregnancy so

they are more prone for hypotension. Also in their study maximum dermatome level blocked was T2-T4 in both groups.

The study done by Ogun *et al.*, (2003) on Twenty-five parturient who received Ropivacaine 15 mg and Morphine 150  $\mu$ g (RM group) and twenty-five parturient received Bupivacaine 15 mg and Morphine 150  $\mu$ g. They found that there was no difference in the hemodynamics between the two groups.

The study results done by Whiteside *et al.*, (2003) in which there was hemodynamic stability in Ropivacaine group, only 15% of patients developed significant lowering of systolic blood pressure, which was comparable to present study results.

J.F. Luck *et al.*, (2008) found that cardiovascular changes were unremarkable, with no statically significant differences between the groups in heart rate, systolic arterial pressure or the incidence of hypotension.

O AL Abdulhadi *et al.*, (2007), found that the incidence of hypotension was frequent in both hyperbaric Ropivacaine and hyperbaric Bupivacaine groups (70% - 88%). The hypotension was easily treated with either ephedrine or Phenylephrine and had no maternal or foetal sequel. As they used additives like Morphine and Fentanyl so it may add more hypotension to results.

#### **Diastolic Blood Pressure**

Mean diastolic blood pressure of patients at induction in group R was  $75.96 \pm 5.97$  mm Hg and in group B was  $77.8 \pm 4.62$  mm Hg, which was comparable in both groups. This difference in two groups was statistically significant (Z test – Z >1.96, P<0.05). It is clear from above that after spinal anaesthesia mean diastolic blood pressure is decreased from 5 minutes onwards in both groups intraoperatively and postoperatively.

#### Side Effects (table no 13):

Nausea was seen in same number of patients in group R and group B.[ 2 (4%) Vs 2 (4%)]

Vomiting was seen in more number of patients in group B than in group R.[1 (2%), Vs 2 (4%)]

# Pruritus was not seen in any patients of both groups.

Hypotension was seen intraoperatively in 6 (12%) patients in group R and 15 (30%) patients in group B i.e. hypotension was seen in more number of patients in group B than in group R. (Z value 2.266 and P value 0.0235). Z > 1.96 and P < 0.05, this difference was statistically significant. Treated with injection mephentermine 7.5 mg intravenously.

Bradycardia was seen intraoperatively in two (4%) patients of group R and 4 (8%) patients of group B i.e. bradycardia was seen in more number of patients in group B than in group R. (Z value 0.32 and P value 0.7490). Z <1.96 and P >0.05, this difference was statistically not significant. Treated with injection atropine 0.6 mg intravenously. Respiratory depression and drowsiness not seen in any patient of both groups.

No side effects were seen in 40 (80%) patients of group R and 26 (52%) patients of group B i.e. side effects were seen in more number of patients in group B than in group R. (Z value 2.266 and P value 0.0235). Z > 1.96 and P < 0.05, this difference was statistically significant.

The results coincides with the study of Chung *et al.*, (2001); they found that there is no difference in regards to side effects between both groups.

In addition, the result coincides with Kim *et al.*, (2002) they found that there is no postoperative neurological symptoms in the first 24 hours.

Whiteside *et al.*, (2001) and Whiteside *et al.*, (2003) reported that Ropivacaineis safe for intrathecal administration with no reports of TNS.

In another study done by Kallio *et al.*, (2004), compared intrathecal plain solutions containing Ropivacaine 20 or 15 mg versus Bupivacaine 10 mg. They found that on the first postoperative day, 81% of the discharged patients, equally distributed among the three groups, one patient in the Bupivacaine 10 mg group complained of back pain at the puncture site. Two patients in the Ropivacaine 15 mg group complained of headache, which had ended by the evening of the day of operation. In the Ropivacaine 20 mg group, one patient complained of a slight headache, but this was managed with a non steroidal anti-inflammatory drugs.

Fettes *et al.*, (2005), all of these results reported that Ropivacaine is safe for intrathecal administration with no reports of TNS.

J.F.Luck *et al.*, (2008), found no significant difference between both groups as regard to safety profile. Only two patients (One in the Bupivacaine group and one in the Ropivacaine group) had symptoms of headache (unrelated to posture) during the first 24 hours, but these symptoms had resolved completely at the 3 - 7 days follow up.

#### Time of first micturition (table no 14)

As regards to time of first micturition, the results of present study have shown that Patients in Ropivacaine group were able to pass urine sooner than those in the Bupivacaine group. Mean time of first micturition was  $252.65 \pm 45.83$  minutes in Ropivacaine

group and 356  $\pm$  84.85 minutes in Bupivacaine group and the difference was highly significant (P < 0.001).

Present study results are similar with the study done by Whiteside *et al.*, (2003) who found that patients receiving Ropivacaine mobilized sooner (hyperbaric Ropivacaine 254 (151 - 359) minutes; hyperbaric Bupivacaine 331 (219 - 475) minutes; P= 0.0019) and passed urine sooner (Ropivacaine 276 (177 - 494) minutes; Bupivacaine 340.5 (268 - 497) minutes; P= 0.01) than those receiving Bupivacaine.

J.F.Luck *et al.*, (2008) found that the median time to micturition was shortest in the hyperbaric Ropivacaine group, although this difference did not achieve statistical significance.

In another study done by Kallio *et al.*, (2004), compared intrathecal plain solutions containing Ropivacaine 20 mg or 15 mg versus Bupivacaine 10 mg, found that time of first micturition 5.2 (4.6 - 5.7) hours ,4.8 (4 - 5.8) hours, 5 (4.4 - 5.6) hours respectively.

# **CONCLUSIONS**

After a comparative study of 0.5% hyperbaric Ropivacaine versus 0.5% hyperbaric Bupivacaine for spinal anaesthesia, following conclusions were drawn

- Ropivacaine 0.5% in glucose 8.33%, which is hyperbaric relative to cerebrospinal fluid, can provide predictable and reliable spinal anaesthesia as compared to commercially available hyperbaric Bupivacaine.
- 2. Hyperbaric Ropivacaine shows late onset of sensory blockade, equal time to reach maximum dermatome level, early regression and shorter total duration of sensory blockade as compared to hyperbaric Bupivacaine.
- 3. Hyperbaric Ropivacaine shows late onset of motor blockade, less degree and total duration of motor blockade as compared to hyperbaric Bupivacaine, still adequate for the projected surgery.
- 4. Hyperbaric Ropivacaine was more hemodynamically stable as compared to hyperbaric Bupivacaine.
- 5. Both the sensory and motor blocks are also subject to a more rapid recovery with hyperbaric Ropivacaine compared with hyperbaric Bupivacaine.
- 6. Hyperbaric Ropivacaine was not associated with any side effects intraoperatively and postoperatively.
- 7. Patients receiving hyperbaric Ropivacaine required shorter time to first micturition as compared to Bupivacaine.

The key issue is the difference in the clinical profile of the block (onset, extent, suitability for surgery, duration) produced, not the relative potencies of the two drugs. This suggest that Ropivacaine may be

suitable for short procedures where a rapid return of ambulatory function is desirable, such as in the day case setting, where its recovery profile could confer a distinct clinical advantage.

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