



Anaesthesiology

A COMPARATIVE STUDY OF PLAIN 0.75% ROPIVACAINE AND HYPERBARIC 0.75% ROPIVACAINE DRUG FOR SPINAL ANAESTHESIA IN ELECTIVE LOWER ABDOMINAL AND LOWER LIMB SURGERIES

| | |
|----------------------------|--|
| Dr. Vandana Hebbali | Senior Resident, Department of Anaesthesiology, Shimoga Institute of Medical Sciences, Shimoga, Karnataka. |
| Dr. Savita Patil | Senior Resident, Department of Anaesthesiology, Belagavi Institute of Medical Sciences, Belgaum, Karnataka. |
| Dr. Sudha Shree P* | Senior Resident, Department of Anaesthesiology, Hassan Institute of Medical Sciences, Hassan, Karnataka. *Corresponding Author |
| Dr. Shivananda P T | Associate Professor, Department of Anaesthesiology, Shimoga Institute of Medical Sciences, Shimoga, Karnataka. |
| Dr. Gurudatta K N | Professor and HOD, Department of Anaesthesiology, Shimoga Institute of Medical Sciences, Shimoga, Karnataka. |

ABSTRACT

Introduction: Spinal anaesthesia is the most common technique of regional anaesthesia used for lower abdominal and lower limb surgeries. First spinal anaesthesia was performed by August Bier in 1898 by using 0.5% cocaine. Subarachnoid block provides effective sensory and motor blockade. A wide variety of local anaesthetic drugs are available for spinal anaesthesia namely Lidocaine, Bupivacaine. Ropivacaine, is a long acting amino amide local anaesthetic structurally similar to bupivacaine. It produces effects similar to other local anaesthetics via reversible inhibition of sodium ion influx in nerve fibres.

Materials And Methods: The study was conducted over a period of years from September 2020 to August 2021. Sample size was chosen based on outcome variable i.e time to mobilize with minimum difference of 70, SD OF 75, 90% statistical power and 5% level of significance, the sample size of 50 (25 in each group) was adequate for the study. For better results, we had chosen sample size of 80 (40 in each group)

Results: In Plain ropivacaine and hyperbaric ropivacaine group, hemodynamic parameters and demographic data were comparable. The onset of block to T10 in group C 10.1 ± 1.6 min, group D 4.6 ± 0.9 (p value <0.001), mean time to maximum block in group C 13.0 ± 2.7 min, group D 8.9 ± 0.9 (p value <0.001) were statistically significant. mean duration of block at T10 in group C was 94.7 ± 24.7 min, group D 146.1 ± 31.9 (p value <0.001), duration of sensory regression in group C 291.6 ± 74.3 min, group D 239.9 ± 39.8 (p value <0.001), duration of motor regression in group C 225.4 ± 68.4 min, group D 186.0 ± 41.0 (p value <0.003) and time mobilise in group C was 309.1 ± 76.3 min, group D 251.0 ± 24.6 min (p value <0.001) which were statistically significant.

Conclusion: Hyperbaric ropivacaine has early and faster onset, spreads more to higher levels, has more denser block and is early to regress compared to plain ropivacaine.

KEYWORDS : Spinal anaesthesia, hyperbaric ropivacaine, lower abdominal and lower limb surgeries.

INTRODUCTION

Spinal anaesthesia is the most common technique of regional anaesthesia used for lower abdominal and lower limb surgeries. First spinal anaesthesia was performed by August Bier in 1898 by using 0.5% cocaine. Subarachnoid block provides effective sensory and motor blockade. A wide variety of local anaesthetic drugs are available for spinal anaesthesia namely Lidocaine, Bupivacaine.

Bupivacaine is one of the commonest local anaesthetics used which has longer duration of action and its potency is higher than lignocaine². But it can cause profound myocardial depression and even cardiac arrest when used in higher concentration or when accidentally administered intravascularly³.

Various factors can affect the distribution of local anaesthetic solutions in CSF. These include patient's age, height, anatomical configuration of spinal column, site of injection, direction of needle during injection and density of CSF, baricity, density and volume of local anaesthetic solution and position of the patient.⁴

Ropivacaine, is a long acting amino amide local anaesthetic structurally similar to bupivacaine. It produces effects similar to other local anaesthetics via reversible inhibition of sodium ion influx in nerve fibres. It is a racemate, pure S(-) enantiomer, developed for the purpose of reducing potential toxicity and improving sensory and motor block.⁵

Higher concentration of glucose free isobaric ropivacaine solutions results in variable spread of analgesia but with good quality of motor block with higher concentration, adequate for the proposed surgery.

However in comparison with bupivacaine, plain ropivacaine produces rapid postoperative recovery of sensory and motor blockade.⁵ Hence this study is undertaken to compare plain and hyperbaric solutions of ropivacaine in spinal anaesthesia in patients undergoing elective lower abdominal and lower limb surgeries.

MATERIALS AND METHODS**Source of Data:**

The study was conducted on inpatients of Shimoga Institute of Medical Science, Hospital, Shimoga.

METHOD OF COLLECTION OF DATA**Study Design:**

A Prospective randomized double blind study.

Study Period:

The study was conducted over a period of years from September 2020 to August 2021.

Sample Size:

Sample size was chosen based on outcome variable i.e time to mobilize with minimum difference of 70, SD OF 75, 90% statistical power and 5% level of significance, the sample size of 50 (25 in each group) was adequate for the study. For better results, we had chosen sample size of 80 (40 in each group).

Inclusion Criteria:

- Patient who gave written informed consent.
- Patients aged 18 - 60 yrs of either sex.
- Patients with ASA (American society of anesthesiologists) grade 1 & 2.
- Elective lower abdominal and lower limb surgeries.

Exclusion Criteria:

- Patient refusing to participate in the study.
- ASA grade 3 and above.
- Age < 18 and > 60 years.
- Patients who were morbidly obese and under nourished.
- Infection or inflammation at sites of injection/ complications that could cause bleeding (thrombocytopenia).
- History of allergy to the study drug.
- Coagulation disorders.

- h) Cardiogenic or hypovolemic shock.
- i) Respiratory insufficiency.

Anaesthetic Procedure:

After obtaining clearance and approval from Institutional Ethical Committee, patients fulfilling inclusion criteria who gave informed consent were included in the study and were randomized using numbers generated from www.random.org website and divided into two groups,

- 1. Group C (n=40): 0.75% Plain ropivacaine 3 ml + normal saline 0.4 ml
- 2. Group D(n=40): 0.75% Plain ropivacaine 3 ml + 25% dextrose 0.4 ml.

A routine pre-anaesthetic examination was conducted on the evening before the scheduled day of surgery, assessing:

- 1) History and general condition of the patient
- 2) Airway assessment by Mallampatti grading
- 3) Nutritional status, height and weight of the patient
- 4) Detailed examination of the systems like Cardiovascular system, Respiratory system and Central nervous system.
- 5) Examination of the Spine

The following investigations were done in all patients

- 1. Complete blood count
- 2. Random blood sugar
- 3. Serum electrolytes, Renal Function Tests
- 4. Urine Routine Examination
- 5. Standard 12-lead Electrocardiogram
- 6. Chest X ray

All patients were kept fasting for 8 hours on the previous day of surgery. Patients were pre medicated with tab Alprazolam 0.25 mg and tab Ranitidine 150 mg on the night before the day of surgery. On the day of surgery, in preoperative room, intravenous line was secured with 18 G IV cannula and were preloaded with 10 ml/kg of Ringer Lactate. Injection Ranitidine 50 mg was given intravenously half an hour preoperatively.

On the arrival to the operating room, Non invasive blood pressure, pulse oximeter and three lead Electrocardiogram were connected. The baseline systolic, diastolic blood pressure (SBP, DBP), heart rate (HR) and oxygen saturation (SpO2) were recorded.

Under strict aseptic precautions subarachnoid block was performed by using 25 G Quincke Babcock spinal needle in the L2- L3 interspace with patient in left lateral position. The study drug was loaded in a 5ml syringe by a senior anaesthesiologist who was not involved in the study. Just before spinal anaesthesia, syringe was handed over to the anaesthesiologist performing the subarachnoid block, who was also the observer of the study. The patients were not aware of the drug being administered to them. Thus both the observer and the patient were blinded. The study drug was injected over 10-15 seconds. The time at which injection was completed was considered as zero time of the study and all measurements were recorded from this point. Patients were made to lie down in the supine posture immediately after the subarachnoid injection of the study drug, keeping the table flat. All patients were given supplementary oxygen through a venturi mask at 6L/min.

Sensory testing was assessed by loss of pinprick sensation to 23 G sterile hypodermic needle for the onset and dermatomal levels were tested every 2 minutes until the highest level had been achieved and stabilized for four consecutive tests. Time of onset of motor block was assessed by using Modified Bromage Scale.

Haemodynamic variables were recorded every minute for first five minutes, at 5 minutes for next half an hour after the administration of subarachnoid block and at every 10 minutes thereafter upto the end of the surgery.

Hypotension was defined as 20% fall in systolic blood pressure from baseline and was treated with intravenous fluids and intravenous injection Mephenteramine 6mg. Bradycardia was defined as 20% fall in heart rate from baseline and was treated with intravenous injection Atropine 0.6 mg.

Data regarding the time to reach highest dermatomal level of sensory blockade from the time of injection, time for sensory regression at T10 were recorded. In case of failure of subarachnoid block and conversion to general anaesthesia, were excluded from the study.

After the surgery, patients were shifted to the post anaesthesia care and recovery unit where they remained until complete recovery of sensory and motor blockade was achieved. Post operatively, the hemodynamic variables and oxygen saturation were recorded up to 24 hours postoperatively. The incidence of any adverse effects such as hypotension, bradycardia, shivering, nausea, vomiting, pruritis, respiratory depression and ECG changes were noted and treated.

Modified Bromage Score

GRADE 0: Able to perform a full straight leg raise over the bed for 5 second.

GRADE 1: Unable to perform a leg raise but able can flex the leg on knee.

GRADE 2: Unable to flex knee but can flex ankle.

GRADE 3: Unable to flex ankle.

GRADE 4: Unable to move toes.

Duration Of Motor Blockade:

was defined as the time taken from the onset of motor blockade of Bromage score 1 till the complete recovery of motor blockade to Bromage score 0. Results obtained were analysed by using descriptive statistics.

Sample Size Estimation

Sample size was chosen based on outcome variable i.e time to mobilize with minimum difference of 70, SD OF 75, 90% statistical power and 5% level of significance, the sample size of 50 (25 in each group) was adequate for the study. For better results, we had chosen sample size of 80 (40 in each group).

Statistical Methods:

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Chi-square test or Fischer's exact test (for 2x2 tables only) was used as test of significance for qualitative data. P value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

RESULTS

It is a prospective randomized controlled study with 80 patients randomly divided into two groups of 40 patients each, using www.random.org. Group C - received intrathecal 0.75% plain ropivacaine. Group D-received intrathecal 0.75% hyperbaric ropivacaine Patients were evaluated for onset and duration of sensory and motor blockade, dermatomal level achieved, hemodynamic variations and side effects of the drug if any.

Demography:

Table 1: Gender Distribution Comparison Between Two Groups

| Group | | Plain Ropivacaine | | Hyperbaric Ropivacaine | |
|--------|--------|-------------------|-------|------------------------|-------|
| | | Count | % | Count | % |
| Gender | Female | 20 | 50.0% | 20 | 50.0% |
| | Male | 20 | 50.0% | 20 | 50.0% |

$\chi^2 = 0.001, df = 1, p = 1.000$

In Plain ropivacaine and hyperbaric ropivacaine group, 50% were males and 50% were females. There was no difference in Gender between two groups.

In plain ropivacaine group mean age group, 39.50 ± 11.75 years and in hyperbaric ropivacaine group mean age group, 44.18 ± 10.546 years. There was no significant difference in mean age between two groups.

Table 2: Weight (Kg) And Height (CM) Distribution Comparison Between Two Groups

| | Group | N | Mean | SD | SE |
|--------|------------------------|----|--------|-------|--------|
| Weight | Plain Ropivacaine | 40 | 62.98 | 6.306 | 0.013* |
| | Hyperbaric Ropivacaine | 40 | 59.68 | 5.274 | |
| Height | Plain Ropivacaine | 40 | 158.38 | 3.102 | 0.004* |
| | Hyperbaric Ropivacaine | 40 | 156.38 | 2.976 | |

In plain ropivacaine group mean weight was 62.98 ± 6.306 Kg and in hyperbaric ropivacaine group mean weight was 59.68 ± 5.274 Kg. There was significant difference in mean weight between two groups.

In plain ropivacaine group mean height was 158.38 ± 3.102 Cm and in hyperbaric ropivacaine group mean weight was 156.38 ± 2.976 Cm.

There was significant difference in mean height between two groups.

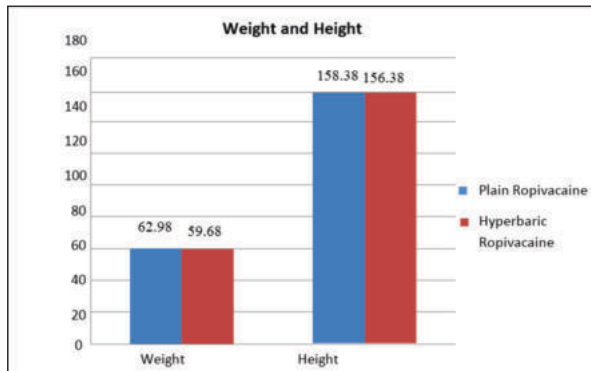


Fig 1: Bar Diagram Showing Weight And Height Distribution Comparison Between Two Groups

Table 3: ASA Grade Comparison Between Two Groups

| Group | Plain Ropivacaine | | Hyperbaric Ropivacaine | |
|-------------|-------------------|-------|------------------------|-------|
| | Count | % | Count | % |
| ASA grade 1 | 28 | 70.0% | 20 | 50.0% |
| ASA grade 2 | 12 | 30.0% | 20 | 50.0% |

$\chi^2 = 3.333, df = 1, p = 0.068$

In Plain Ropivacaine group, 70% had ASA grade 1 and 30% had ASA grade 2. In Hyperbaric Ropivacaine group, 50% had ASA grade 1 and 50% had ASA grade 2. There was no significant difference in ASA grade between two groups.

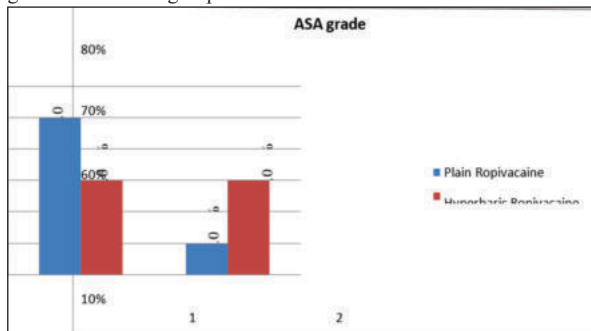


Fig 2: Bar Diagram Showing ASA Grade Comparison Between Two Groups

Table 4: Heart Rate Comparison Between Two Groups At Different Time Intervals

| HR | Group | | | | | | P value b/w two groups |
|----------|-------------------|-----|-----------------------|------------------------|-----|-----------------------|------------------------|
| | Plain Ropivacaine | | | Hyperbaric Ropivacaine | | | |
| | Mean | SD | P value with in group | Mean | SD | P value with in group | |
| Baseline | 79.6 | 8.9 | | 80.8 | 6.4 | | 0.473 |
| 1 min | 79.5 | 8.3 | 0.934 | 80.2 | 5.7 | 0.077 | 0.696 |
| 3 min | 79.6 | 8.2 | 0.855 | 79.6 | 5.6 | 0.022* | 0.975 |
| 5 min | 79.9 | 8.6 | 0.446 | 79.2 | 5.5 | 0.005* | 0.675 |
| 10 min | 79.9 | 8.3 | 0.496 | 79.6 | 5.8 | 0.064 | 0.840 |
| 15 min | 79.3 | 7.9 | 0.604 | 78.9 | 6.1 | 0.009* | 0.813 |
| 20 min | 79.5 | 7.6 | 1.000 | 78.9 | 5.3 | 0.007* | 0.657 |
| 25 min | 79.1 | 7.3 | 0.458 | 78.8 | 5.2 | 0.007* | 0.820 |
| 30 min | 79.3 | 7.4 | 0.648 | 78.8 | 5.0 | 0.007* | 0.752 |
| 40 min | 78.6 | 7.0 | 0.108 | 79.3 | 5.1 | 0.056 | 0.637 |
| 50 min | 78.8 | 7.1 | 0.176 | 79.3 | 4.9 | 0.035* | 0.729 |
| 1 hr | 78.5 | 7.3 | 0.044* | 78.6 | 5.6 | 0.001* | 0.932 |
| 2hr | 78.3 | 7.4 | 0.020* | 79.0 | 6.1 | 0.011* | 0.668 |
| 6 hr | 78.5 | 7.4 | 0.033* | 78.8 | 6.1 | 0.008* | 0.831 |
| 12 hr | 78.6 | 7.1 | 0.079 | 78.5 | 5.4 | 0.005* | 0.944 |
| 24 hr | 78.3 | 7.0 | 0.029* | 78.6 | 5.0 | 0.003* | 0.840 |

In the study there was no significant difference in mean Heart rate between two groups at all the intervals of followup.

In Plain Ropivacaine, there was significant difference in mean HR at 1 hr, 2 hr, 6 hr and 24 hr compared to baseline values.

In Hyperbaric Ropivacaine, there was significant difference in mean HR at 3 min, 5min, 15 min, 20 min, 30 min, 50 min, 1 hr, 2 hr, 6 hr, 12 hr and 24 hr compared to baseline values.

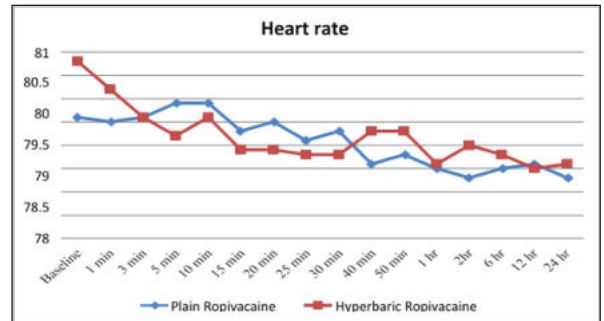


Fig 3: Line Diagram Showing Heart Rate Comparison Between Two Groups At Different Time Intervals

Table 5: SBP (Systolic Blood Pressure) Comparison Between Two Groups At Different Time Intervals

| SBP | Group | | | | | | P value |
|----------|-------------------|------|-----------------------|------------------------|------|-----------------------|---------|
| | Plain Ropivacaine | | | Hyperbaric Ropivacaine | | | |
| | Mean | SD | P value with in Group | Mean | SD | P value with in Group | |
| Baseline | 121.6 | 12.8 | | 120.2 | 21.6 | | 0.744 |
| 1 min | 120.6 | 12.4 | 0.016* | 121.5 | 13.5 | 0.611 | 0.744 |
| 3 min | 119.7 | 12.2 | 0.002* | 119.4 | 13.8 | 0.721 | 0.912 |
| 5 min | 117.5 | 11.9 | <0.001* | 117.0 | 13.7 | 0.209 | 0.869 |
| 10 min | 115.6 | 11.5 | <0.001* | 115.1 | 13.1 | 0.056 | 0.885 |
| 15 min | 113.6 | 11.4 | <0.001* | 113.3 | 13.2 | 0.011* | 0.892 |
| 20 min | 112.2 | 11.5 | <0.001* | 111.6 | 13.1 | 0.002* | 0.828 |
| 25 min | 110.7 | 11.5 | <0.001* | 111.6 | 12.9 | 0.002* | 0.743 |
| 30 min | 110.4 | 11.1 | <0.001* | 112.1 | 12.6 | 0.004* | 0.512 |
| 40 min | 110.6 | 10.9 | <0.001* | 112.8 | 12.8 | 0.007* | 0.421 |
| 50 min | 111.2 | 11.7 | <0.001* | 114.2 | 13.1 | 0.027* | 0.292 |
| 1 hr | 111.5 | 11.2 | <0.001* | 115.1 | 13.1 | 0.058 | 0.195 |
| 2 hr | 113.9 | 11.4 | <0.001* | 116.1 | 13.0 | 0.140 | 0.403 |
| 6hr | 115.5 | 10.9 | <0.001* | 117.4 | 13.5 | 0.284 | 0.507 |
| 12 hr | 116.4 | 11.4 | <0.001* | 119.3 | 12.8 | 0.710 | 0.296 |
| 24 hr | 117.0 | 10.9 | <0.001* | 119.7 | 13.4 | 0.850 | 0.321 |

In the study there was no significant difference in mean SBP between two groups at all the intervals of followup.

In Plain Ropivacaine group there was significant difference in mean SBP from 1 min to 24 hrs compared to baseline. Initially there was decrease in SBP and after 40 min SBP started to increase towards baseline value.

In Hyperbaric Ropivacaine group there was significant difference in mean SBP from 15 min to 50 min compared to baseline. Initially there was decrease in SBP and after 25min SBP started to increase towards baseline value.

Table 6: DBP (Diastolic Blood Pressure) Comparison Between Two Groups At Different Time Intervals

| DBP | Group | | | | | | P value b/w two groups |
|----------|-------------------|-----|--------------------------|------------------------|-----|--------------------------|------------------------|
| | Plain Ropivacaine | | | Hyperbaric Ropivacaine | | | |
| | Mean | SD | P value within the group | Mean | SD | P value within the group | |
| Baseline | 77.8 | 7.3 | | 81.2 | 8.6 | | 0.060 |
| 1 min | 78.0 | 8.3 | 0.557 | 80.2 | 8.8 | <0.001* | 0.269 |
| 3 min | 77.0 | 8.0 | 0.111 | 78.8 | 8.7 | <0.001* | 0.353 |
| 5 min | 75.0 | 7.2 | <0.001* | 77.1 | 8.9 | <0.001* | 0.227 |
| 10 min | 74.1 | 7.3 | <0.001* | 75.4 | 8.8 | <0.001* | 0.449 |
| 15 min | 72.3 | 6.8 | <0.001* | 73.9 | 8.9 | <0.001* | 0.385 |
| 20 min | 70.9 | 7.1 | <0.001* | 73.1 | 8.9 | <0.001* | 0.238 |
| 25 min | 69.8 | 6.9 | <0.001* | 72.7 | 8.4 | 0.002* | 0.091 |

| | | | | | | | |
|--------|------|-----|---------|------|-----|---------|--------|
| 30 min | 69.1 | 6.9 | <0.001* | 73.0 | 7.6 | 0.002* | 0.021* |
| 40 min | 69.6 | 6.6 | 0.522 | 73.6 | 7.8 | 0.002* | 0.015* |
| 50 min | 71.0 | 6.9 | <0.001* | 74.6 | 7.7 | <0.001* | 0.03* |
| 1 hr | 70.5 | 7.2 | 0.028* | 75.3 | 7.9 | <0.001* | 0.007* |
| 2 hr | 71.9 | 6.8 | 0.017* | 76.2 | 8.0 | <0.001* | 0.011* |
| 6 hr | 72.1 | 7.0 | 0.017* | 76.7 | 7.9 | <0.001* | 0.007* |
| 12 hr | 72.8 | 6.3 | 0.015* | 77.9 | 8.2 | <0.001* | 0.003* |
| 24 hr | 73.9 | 6.8 | <0.001* | 78.3 | 7.5 | <0.001* | 0.008* |

In the study there was significant difference in mean DBP between two groups from 30 min to 24 hrs. At these intervals mean DBP was significantly higher in hyperbaric ropivacaine group. At other intervals there was no significant difference in mean DBP between two groups.

In plain ropivacaine group there was significant difference in mean DBP from 5 min to 24 hrs compared to baseline. Initially there was decrease in DBP and after 40 min DBP started to increase towards baseline value.

In hyperbaric ropivacaine group there was significant difference in mean DBP from 1 min to 24 hrs compared to baseline. Initially there was decrease in DBP and after 30 min DBP started to increase towards baseline value.

Table 7: MAP (Mean Arterial Pressure) Comparison Between Two Groups At Different Time Intervals

| MAP | Group | | | | | | P value |
|----------|-------------------|------|--------------------------|------------------------|------|--------------------------|---------|
| | Plain Ropivacaine | | | Hyperbaric Ropivacaine | | | |
| | Mean | SD | P value within the group | Mean | SD | P value within the group | |
| Baseline | 91.1 | 10.5 | | 94.3 | 9.9 | | 0.171 |
| 1 min | 91.4 | 9.0 | 0.725 | 93.2 | 9.6 | <0.001* | 0.397 |
| 3 min | 90.9 | 9.1 | 0.711 | 91.8 | 9.6 | <0.001* | 0.668 |
| 5 min | 88.9 | 8.4 | 0.006* | 90.0 | 9.9 | <0.001* | 0.602 |
| 10 min | 87.8 | 8.3 | <0.001* | 88.5 | 10.0 | <0.001* | 0.734 |
| 15 min | 85.9 | 8.0 | <0.001* | 86.5 | 9.5 | <0.001* | 0.761 |
| 20 min | 84.5 | 8.2 | <0.001* | 85.5 | 9.7 | <0.001* | 0.629 |
| 25 min | 83.3 | 8.0 | <0.001* | 85.2 | 9.3 | <0.001* | 0.318 |
| 30 min | 82.5 | 8.1 | <0.001* | 85.4 | 9.0 | <0.001* | 0.133 |
| 40 min | 83.2 | 7.7 | <0.001* | 86.1 | 9.1 | <0.001* | 0.134 |
| 50 min | 84.3 | 8.2 | <0.001* | 86.9 | 9.1 | <0.001* | 0.191 |
| 1 hr | 84.0 | 8.2 | <0.001* | 87.9 | 9.3 | <0.001* | 0.048 |
| 2 hr | 85.5 | 7.9 | <0.001* | 88.9 | 9.3 | <0.001* | 0.082 |
| 6 hr | 86.7 | 8.1 | <0.001* | 89.7 | 9.2 | <0.001* | 0.123 |
| 12 hr | 87.3 | 7.8 | <0.001* | 91.0 | 9.2 | <0.001* | 0.057 |
| 24 hr | 88.3 | 7.8 | 0.004* | 91.5 | 9.3 | <0.001* | 0.099 |

In the study there was no significant difference in mean MAP between two groups at all the intervals except at 1 hr.

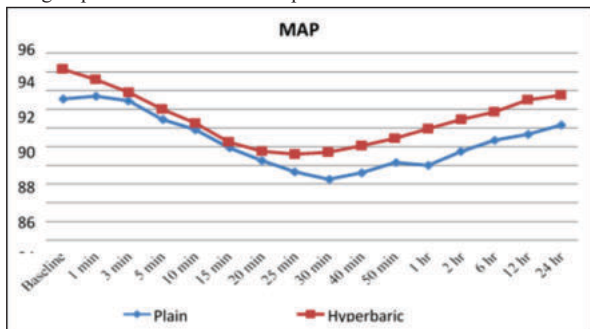


Fig 4: Line diagram showing MAP comparison between two groups at different time intervals

In plain ropivacaine group there was significant difference in mean MAP from 5 min to 24 hrs compared to baseline. Initially there was decrease in DBP and after 30 min DBP started to increase towards baseline value.

In hyperbaric ropivacaine group there was significant difference in mean MAP from 1min to 24 hrs compared to baseline. Initially there was decrease in DBP and after 25 min DBP started to increase towards baseline value.

In the study there was no significant difference in mean SpO2 between two groups at all the intervals except at 40 min.

In plain ropivacaine group there was significant difference in mean SpO2 from 1 min to 1hr compared to baseline. Initially there was increase in SpO2 and after 2hr SpO2 started to decrease towards baseline value.

In hyperbaric ropivacaine group there was significant difference in mean SpO2 at 10 min, 30 min to 50 min and at 24 hrs compared to baseline.

In the study there was significant difference in Modified Bromage Score between two groups from 1 min to 15 min and at 40 min, 50 min, 2 hrs and 6hrs. At other intervals there was no significant difference in median Bromage score.

In plain ropivacaine group there was significant difference in Median Modified Bromage Score from 1 min to 2hr compared to baseline. Initially there was increase in Modified Bromage Score and before 2hr Modified Bromage Score started to decrease towards baseline value.

In hyperbaric ropivacaine group there was significant difference in Median Modified Bromage Score from 1 min to 6hr compared to baseline. Initially there was increase in Modified Bromage Score and after 2hr Modified Bromage Score started to decrease towards baseline value.

Table 8: Durations Comparison Between Two Groups

| | Group | | | | P value |
|--------------------------------|-------------------|------|------------------------|------|---------|
| | Plain Ropivacaine | | Hyperbaric Ropivacaine | | |
| | Mean | SD | Mean | SD | |
| a) Duration of surgery (min) | 90.4 | 31.3 | 107.8 | 61.6 | 0.115 |
| b) Onset to T-10 (min) | 10.1 | 1.6 | 4.6 | 0.9 | <0.001* |
| c) Time to Maximum Block (min) | 13.0 | 2.7 | 8.9 | 0.9 | <0.001* |
| d) Duration at T10 (min) | 94.7 | 24.7 | 146.1 | 31.9 | <0.001* |
| e) Sensory Regression (min) | 291.6 | 74.3 | 239.9 | 39.8 | <0.001* |
| f) Motor Regression (min) | 225.4 | 68.4 | 186.0 | 41.0 | 0.003* |
| g) Time to mobilise (min) | 309.1 | 76.3 | 251.0 | 41.1 | <0.001* |

In plain ropivacaine group, mean duration of surgery was 90.4 ± 31.3 min and in hyperbaric ropivacaine group, mean duration of surgery was 107.8 ± 61.6. There was significant difference in mean duration of surgery between two groups.

In plain ropivacaine group, mean Onset to T-10 was 10.1 ± 1.6 min and in hyperbaric ropivacaine group, mean Onset to T-10 was 4.6 ± 0.9. There was significant difference in mean Onset to T-10 between two groups.

In plain ropivacaine group, mean time to maximum block was 13.0 ± 2.7 min and in hyperbaric ropivacaine group, mean time to maximum block was 8.9 ± 0.9. There was significant difference in mean time to maximum block between two groups.

In plain ropivacaine group, mean duration at T10 was 94.7 ± 24.7 min and in hyperbaric ropivacaine group, mean duration at T10 was 146.1 ± 31.9. There was significant difference in mean duration at T10 between two groups.

In plain ropivacaine group, mean duration for sensory regression was 291.6 ± 74.3 min and in hyperbaric ropivacaine group, mean duration for sensory regression was 239.9 ± 39.8. There was significant

difference in mean duration for sensory regression between two groups.

In plain ropivacaine group, mean duration for motor regression was 225.4 ± 68.4 min and in hyperbaric ropivacaine group, mean duration for motor regression was 186.0 ± 41.0 . There was significant difference in mean duration for motor regression between two groups.

In plain ropivacaine group, mean time to mobilise was 309.1 ± 76.3 min and in hyperbaric ropivacaine group, mean time to mobilise was 251.0 ± 41.1 . There was significant difference in mean time to mobilise between two groups.

Table 9: Median Maximum Block Comparison Between Two Groups

| | | Group | | | |
|----------------------------------|-----|-------------------|-------|------------------------|-------|
| | | Plain Ropivacaine | | Hyperbaric Ropivacaine | |
| | | Count | % | Count | % |
| Median Maximum Block (Dermatome) | T4 | 2 | 5.0% | 26 | 65.0% |
| | T5 | 1 | 2.5% | 12 | 30.0% |
| | T6 | 25 | 62.5% | 2 | 5.0% |
| | T7 | 8 | 20.0% | 0 | 0.0% |
| | T8 | 3 | 7.5% | 0 | 0.0% |
| | T10 | 1 | 2.5% | 0 | 0.0% |

$\chi^2 = 61.47$, $df = 5$, $p < 0.001^*$

In Plain Ropivacaine group, majority of subjects had Median Maximum Block at T6 (62.5%) and in Hyperbaric Ropivacaine majority of subjects had Median Maximum Block at T4 (65%). This difference in Median maximum block between two groups was statistically significant.

In Plain Ropivacaine group, majority of subjects had Median Maximum Block at T6 (62.5%) and in Hyperbaric Ropivacaine majority of subjects had Median Maximum Block at T4 (65%). This difference in Median maximum block between two groups was statistically significant.

DISCUSSION

Hemodynamic Variations:

In this study, there was no significant difference in mean heart rate between two groups at all intervals of follow up. In plain ropivacaine group, there was significant difference in mean heart rate at 1 hr, 2 hr, 6 hr and 24 hr compared to baseline values. In hyperbaric ropivacaine, there was significant difference in mean heart rate at 3 min, 5 min, 15 min, 20 min, 30 min, 1 hr, 2 hr, 6 hr, 12 hr and 24 hr compared to baseline values.

In the study there was no significant difference in mean SBP between two groups at all the intervals of follow up. In plain ropivacaine group there was significant difference in mean SBP from 1 min to 24 hrs compared to baseline. Initially there was decrease in SBP and after 40 min SBP started to increase towards baseline value. In hyperbaric ropivacaine group there was significant difference in mean SBP from 15 min to 50 min compared to baseline. Initially there was decrease in SBP and after 25 min SBP started to increase towards baseline value.

Sensory Blockade:

Onset Of Sensory Blockade

In our study, in plain ropivacaine group, mean time for onset of sensory blockade to T-10 was 10.1 ± 1.6 min and in hyperbaric ropivacaine group, it was 4.6 ± 0.9 min. Mean time of onset of sensory block at T10 is rapid in hyperbaric ropivacaine compared to plain group. There was significant difference in mean time of onset to T-10 between two groups. The previous studies conducted by **P D W Fettes et al** and **Whiteside JB et al** were similar to our study.

P D W Fettes et al in their study found that hyperbaric ropivacaine produced a more rapid onset and more extensive, but less variable sensory block compared to plain ropivacaine. The onset of analgesia to pinprick at T10 was more rapid in hyperbaric (5 min) than with plain ropivacaine (10 min) which was statistically significant. This compares well with the findings of our study.

The study of spinal anaesthesia with ropivacaine 5 mg/ml in glucose 10 mg/ml or 50 mg/ml conducted by **Whiteside JB et al** found that onset of pinprick analgesia at T10 was more rapid ($p=0.03$) with greater

concentration of glucose 50 mg/ml solution (median 5 min) than with 10 mg/ml solution (10 min) which was statistically significant.

Maximum Height Of Sensory Block

In our study, in plain Ropivacaine group, majority of subjects had median maximum block at T6 (62.5%) and in hyperbaric Ropivacaine majority of subjects had median maximum Block at T4 (65%). This difference in median maximum block between two groups was statistically significant with p value < 0.001 .

In previous study conducted by **P D W Fettes et al**, the median maximum block height was at T8 in plain Ropivacaine group and T4 in hyperbaric Ropivacaine group.

In study conducted by **J B Whiteside et al**, maximum extent of cephalad spread was same in both the groups with range T3 -T10 (median T6/7) in 10 mg/ml group and range of T3- T10 (median T6) in 50 mg/ml group. The above study compares well with the findings of our study.

Sensory Regression:

In Plain Ropivacaine group, mean duration of sensory block at T10 was 94.7 ± 24.7 min and in hyperbaric ropivacaine group, mean Duration at T10 was 146.1 ± 31.9 min. There is significant difference in mean duration of block at T10 between two groups with $p < 0.01$ which is statistically significant. In plain ropivacaine group, mean duration of complete sensory regression was 291.6 ± 74.3 min and in hyperbaric ropivacaine group, mean duration for sensory regression was 239.9 ± 39.8 min. There was significant difference in mean duration of sensory regression between two groups with p value < 0.001 which is significant.

In previously conducted studies by **Fettes et al**, median time to regression of sensory block to T10 (an indicator of useful duration for surgery) was longer in the hyperbaric group 115 min (50- 178) compared to plain ropivacaine group 25 min (0- 208). It was also shown that, median time to complete sensory regression was longer in the plain group 270 min (150- 390) compared to hyperbaric ropivacaine, 240 min (180- 270) with p value of < 0.05 which was statistically significant. Our study findings are similar to the above study.

Motor Regression:

In plain Ropivacaine group, mean duration for motor regression was 225.4 ± 68.4 min and in hyperbaric Ropivacaine group, mean duration for motor regression was 186.0 ± 41.0 . There was significant difference in mean duration for motor regression between two groups with p value of < 0.003 which is statistically significant.

In previous study conducted by **Fettes et al**, median time to complete regression of motor block were longer in the plain group 180 min(90-270) compared to hyperbaric group 120 min(30- 150) with p value of < 0.001 which was statistically significant. Our study is similar to above study.

Time to mobilise:

In Plain Ropivacaine group, mean time to mobilise was 309.1 ± 76.3 min and in hyperbaric Ropivacaine group, mean Time to mobilise was 251.0 ± 41.1 min. There was significant difference in mean Time to mobilise between two groups with $p < 0.001$ which is statistically significant.

In previous studies by **Fettes et al**, median time to complete regression of both sensory and motor block were longer in the plain group. The time to mobilise was 286 min (101- 403) in plain Ropivacaine group and 218 min (183- 347) in hyperbaric group. Patients therefore mobilized sooner in the hyperbaric group. This compares well with the findings of our study.

Side Effects:

There were no significant side effects observed in our study.

CONCLUSION

Hyperbaric ropivacaine has early and faster onset, spreads more to higher levels, has more denser block and is early to regress compared to plain ropivacaine.

REFERENCES

1. Corby MP, Bach AB. Transient radicular irritation (TRI) after spinal anaesthesia in day-care surgery. *Acta Anaesthes Scand* 1998; 42: 425-9.

2. Henderson DJ, Faccenda KA, Morrison LM. Transient radicular irritation with intrathecal plain lignocaine. *Acta Anaesthesiol Scand* 1998; 42: 376-8.
3. Casati A, Putzu M. Bupivacaine, Levobupivacaine and Ropivacaine: are they clinically different? *Best Practice and Research Clinical Anaesthesiology* 2005; 19: 247-68.
4. Reiz S, Nath S. Cardiotoxicity of local anaesthetic agents. *Br J Anaesth* 1986; 58: 736-46.
5. Gaurav Kuthiala, Geeta Chaudhary, "Ropivacaine: A review of its pharmacology and clinical use". *Ind J Anaesth* 2011; 55: 104-10.
6. McLeod GA, "Density of spinal anaesthetic solutions of bupivacaine, levobupivacaine and ropivacaine with and without dextrose". *Br J Anaesth* 2004; 547-51.
7. Van Kleef JW, Veering BT, Burm AG, "Spinal anesthesia with Ropivacaine: a double-blind study on the efficacy and safety of 0.5% and 0.75% solutions in patients undergoing minor lower limb surgery". *Anesth Analg* 1994; 78: 1125-30.
8. McName DA, Parks L, McClelland AM, et al. "Intrathecal ropivacaine for total hip arthroplasty: double-blind comparative study with isobaric 7.5 mg ml⁻¹ and 10 mg ml⁻¹ solutions". *Br J Anaesth* 2001; 87: 743-7.
9. P D W Fettes, G Hocking et al, "A comparison of plain and hyperbaric solutions of Ropivacaine for spinal anaesthesia". *BJA* 2005; issue 1: 107-11.
10. Whiteside JB, Burke D, Wildsmith JAW, "Comparison of Ropivacaine 0.5% (in glucose 5%) with bupivacaine 0.5% (in glucose 8%) for spinal anaesthesia for elective surgery". *Br J Anaesth* 2003; 90: 304-8.