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ORIGINAL ARTICLE

COMPARISION OF 3.5ML BUPIVACAINE HEAVY (17.5MG) AND 3.5 ML ROPIVACAINE PLAIN (26.25 MG) FOR SUBARACHNOID BLOCK

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ABSTRACT: OBJECTIVE: Ropivacaine, have been introduced into clinical practice because of their lower toxic effects for heart and central nervous system. Ropivacaine is nearly identical to Bupivacaine in onset of action, quality and duration of sensory block, but it produces lesser duration of motor blockade and has a better safety profile when used for the purpose of spinal anesthesia. This study was aimed to compare the intrathecal efficacy and safety between 3.5 ml, 0.5% heavy Bupivacaine (17.5 mg) and 3.5 ml, 0.75% isobaric Ropivacaine (26.25 mg) for lower limb orthopedic surgeries. **MATERIALS AND METHODS:** We enrolled 60 patients of ASA (American Society of Anesthesiologists) grade I-II scheduled for elective lower limb orthopedic surgeries under spinal anesthesia for this prospective randomized double blind control trial. The patients were randomized to receive either 17.5 mg of 0.5% hyperbaric Bupivacaine or 26.25 mg of 0.75% isobaric Ropivacaine intrathecally. Intra-operative, characteristics of sensory and motor nerve block, and adverse effect (such as hypotension, bradycardia, nausea, vomiting, shivering or pruritis) were evaluated. **RESULTS:** Baseline demographic variables were comparable between two groups. 1. Time taken to achieve sensory block to L3 (3.75 minutes with SD of 0.59 vs. 5.29 minutes with SD of 0.85). 2. Mean time for the onset of complete motor block in group A was 6.14 minute with SD of 0.708, where as in group B, it was 12.51 minutes with SD of 0.994. 3. Mean duration of sensory block in group A was 204.20 minutes with SD of 8.81, while in group B it lasted for 152.23 minutes with SD of 8.17. 4. Mean duration of motor block in group a patients was 212.67 minute with SD of 11.17 where as in group B patients, the motor block lasted for a mean duration of 135.13 minutes with SD of 11.68. P value for all above mentioned four observations were calculated to be <0.001, which means it is statistically significant 5. Side effects like hypotension, bradycardia, shivering nausea and vomiting more seen in group I. **CONCLUSION:** Spinal anesthesia for lower limb orthopedic surgeries with intrathecal 26.25 mg of 0.75% isobaric Ropivacaine has characteristically having delayed onset, with shorter duration of action on the sensory as well as motor nerve roots with lesser side effects when compared to Bupivacaine and hence can be used as an effective and safe alternative to it.

KEYWORDS: Spinal Anesthesia, Isobaric Ropivacaine, Bupivacaine.

INTRODUCTION: Spinal anesthesia is widely used because of its fast onset and effective sensory and motor blockade for surgeries. Bupivacaine is available as a racemic mixture of its enantiomers, dextro-Bupivacaine and levo-bupivacaine.(1) The last few years, it's pure S-enantiomer Ropivacaine, have been introduced into clinical practice because of their lower toxic effects for heart and central nervous system.(2,3-5,) Ropivacaine is nearly identical to Bupivacaine in onset of action, quality and duration of sensory block, but it produces lesser duration of motor blockade and has a better safety profile.(6) Present study is to compare the efficacy as well as the difference between the level of

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sensory and motor blockade achieved, along with the incidence of side effects when 17.5 mg Bupivacaine heavy (0.5%) and 26.25 mg Ropivacaine (0.75%) are used intrathecally for orthopedic lower limb surgeries.

METHODS: After obtaining approval from the Hospital Ethics Committee and written informed consent from the patients, this single Centre, prospective randomized, double blind study was conducted in the Department of Anesthesiology MGM Medical College, Indore. A sample size of 60 patients with ASA Grade I and II, aged between 20 to 40 years and height more than 160 cms were scheduled for elective lower limb surgeries under spinal anesthesia. They were randomly divided into two equal groups, Group I and II. Each patient underwent a thorough pre-anesthetic checkup prior to the procedure.

This study was designed to compare the effects of intrathecal block with 3.5 ml of 0.5% Bupivacaine heavy (17.5 mg) and 3.5 ml of 0.75% isobaric Ropivacaine (26.25 mg) when used for orthopedic lower limb surgery, with respect to the onset and duration of sensory and motor block, level of sensory block along with side effects. Patients who were unwilling, posted for emergency surgeries, otherwise contraindicated for spinal anesthesia, those allergic to amide local anesthetic or any other drug, ones with a history of drug or alcohol abuse and obese patients (those with body mass index >29 kg/m ^{2}) were excluded from the study.

Before the commencement of anesthesia, patients were informed about the procedure and methods of sensory or motor assessments. Intravenous line was secured, Ringer's lactate solution (10 ml/kg) was infused for preloading before the initiation of the procedure and patients were pre-medicated with inj. Ondansetron 0.8 mg/kg (i.v.), inj. Glycopyrolate 0.004 mg/kg(i.v.). Non-invasive monitor was connected and baseline values of heart rate, blood pressure and oxygen saturation were noted before the procedure.

Under full aseptic precautions Sub arachnoid block was administered in sitting position at L_3–L_4 or L_4-L_5 intervertebral space via median approach using 25G quinke type spinal needle and then patient placed in supine position. All the patients' vitals such as NIBP, HR, SPO_2 & ECG were continuously monitored till the end of surgery. The person giving injection and the person collecting data and monitoring patient were both kept blind After the drug was injected, following observations were recorded:-

1. Onset of sensory block- Sensory block was tested by pin prick method. Absence of response to pin prick at L_3 level along mid-clavicular line was taken as onset of sensory block. The time taken from injection of drug to absence of response to pin prick at L_3 level was recorded as time of onset of sensory block.
2. Onset of motor block- This was taken as the time elapsing from injection to failure to raise the lower limb on command.
3. Level of sensory block- Maximum level at which patient could not feel pin prick sensation was taken as the level of sensory block.
4. Degree of motor block - This was tested using Bromage scale.

BROMAGE SCALE:

0 - Full flexion of knees and feet.

1 - Just able to flex knees, full flexion of feet.

2 - Unable to flex knees, but some flexion of feet possible.

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3 - unable to move legs or feet.

5. Duration of sensory block- This was recorded as time from injection to appearance of response to pin prick at L_3 dermatome level.
6. Duration of motor block- This was recorded as time from onset of motor blockade to the time when patient was able to move legs.
7. Side effects- Any side effect like bradycardia, hypotension, nausea, vomiting, respiratory depression, itching, shivering etc were also noted.

PR and BP were recorded preoperatively, immediately after injection, every 5 minutes till 30 minutes then half hourly till 2 hour.

- **PULSE RATE:** PR < 60 per minute was graded as bradycardia
  0.6 mg Atropine was kept ready if needed in any episode of bradycardia."
- **BLOOD PRESSURE:** If BP fell more than 20% from the base line, it was treated by injection Mephentermine Sulphate 0.4 mg/kg or Intravenous Fluids".

All the parameters from the pre-operative readings were recorded in the Performa. The changes in vitals such as PR, BP etc. were recorded after intra-thecal drug injection and during surgery. All data recorded was subjected to statistical tests. The Statistical analysis was done by SPSS version 15.0. The comparisons were done using chi-square test or the Fisher's exact test as deemed appropriate, with the P value reported at the 95% confidence limit, P < 0.005 was considered as significant.

RESULT: This study was conducted on 60 patients divided into two groups. Group I patients received 3.5 ml of (0.5%) Bupivacaine heavy and Group II patients received 3.5 ml of Ropivacaine (0.75%) plain. After the drug was injected, following observations were recorded:

Sl. No.	Age Group (years)	Group I Bupivacaine		Group II Ropivacaine	
		No. of patients	%	No. of Patients	%
1	20-29	19	63.33%	18	60%
2	30-40	11	36.66%	12	40%
	Total	**30**	**100%**	**30**	**100%**

Table I: SHOWING THE AGEWISE DISTRIBUTION OF GROUP I AND II

Group I 63.33% patients belong to 20-29 years of age and 33.66% patients were in between 30-40 years of age. Group II 60% patients belong to 20-29 years of age and 40% patients in between 30-40 years of age.

Sl. No.	Age Group	Group I Bupivacaine		Group II Ropivacaine	
		No. of patients	%	No. of Patients	%
1	Male	18	60%	21	70%
2	Female	12	40%	09	30%
	Total	**30**	**100%**	**30**	**100%**

Table II: SHOWING THE SEX DISTRIBUTION OF PATIENTS

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Sl. No.	Characteristics	Group I Bupivacaine		Group II Ropivacaine		P value	
		Mean (min.)	SD±	Mean (min.)	SD±		
1	Time for onset of sensory loss	3.75	0.59	5.29	0.85	<0.05	Significant
2	Time for onset of motor loss	6.14	0.70	12.51	0.99	<0.05	Significant
3	Duration of sensory block	204.20	8.81	152.23	8.17	<0.05	Significant
4	Duration of motor block	212.67	11.17	135.13	11.68	<0.05	Significant

Table III: SHOWING THE CHARACTERISTICS OF BLOCKADE (IN TWO GROUPS)

P value was significant (<0.05) with respect to time for onset and duration of sensory and motor blockade.

Motor Blockade	Group I (Bupivacine)	Group II (Ropivacine)	Total
2^0	2	5	7
3^0	28	25	53
Total	**30**	**30**	**60**

Table IV: COMPARISON OF MOTOR BLOCKADE

χ^2 =0.42. This table depicts comparison of motor blockade between the two studied groups.

Sl. No.	Levels	Group I Bupivacaine		Group II Ropivacaine	
		No. of patients	%	No. of Patients	%
1	T_{10}	20	66.66%	18	60%
2	T_9	06	20.00%	09	30%
3	T_8	04	13.3%	03	10%

Table V: MAXIMUM LEVEL ACHIEVED (DERMATOME)

Group I maximum level achieved (dermatome) was at the level of T_{10} in 66.66%, T_9 in 20% patients and T_8 in 13.3%. Group II maximum level achieved (dermatome) was at the level of T_{10} in 60%, T_9 in 30% patients and T_8 in 10%.

Sl. No.	Side Effects	Group I		Group II	
		No	%	No	%
1	Nausea & Vomiting	1	3.33%	0	0%
2	Bradycardia	2	6.66%	0	0%
3	Hypotension	4	13.3%	3	10%
4	Dizziness	0	0%	0	0%
5	Shivering	5	15%	3	10%
6	Restlessness	0	0%	0	0%
7	Resp. depression	0	0%	0	0%

Table VI: SHOWING INCIDENCE OF SIDE EFFECTS

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DISCUSSION: Sanchez et al in 2009[7] compared the effects of intrathecal isobaric Ropivacaine (IR) versus isobaric Bupivacaine (IB) in a dose ratio of 3:2 in non-ambulatory urologic and orthopedic surgery. 117 patients scheduled for surgery were randomized and assigned in a double-blind fashion to receive either 15 mg of IR (n = 58) or 10 mg of IB (n = 59). They concluded that the motor blockade was longer in the IB Group (266.5+/- 29.5) compared to the IR Groups (226.4 ± 22.3 min), $p < 0.001$. We found the duration of motor blockade to be prolonged with Bupivacaine (15 mg) when compared with Ropivacaine (21.5 mg).

In 2008, Mantouvalou et[8] al performed a study to compare the anaesthetic efficacy and safety of three local anesthetic agents: racemic Bupivacaine and its two isomers: Ropivacaine and levo Bupivacaine, in patients undergoing lower abdominal surgery. 150 patients, ASA I-III, were randomized to receive an intrathecal injection of one of three local anesthetic solutions. Group A (n = 40) received 3 ml of isobaric Bupivacaine 5 mg/ml (15 mg). Group B (n=40) received 3 ml of isobaric Ropivacaine 5 mg/ml (15 mg).

Group C (n=40) received 3 ml of isobaric levo bupivacaine 5 mg/ml (15 mg). The onset of motor block was significantly faster in the Bupivacaine group compared with that in the Ropivacaine group and almost the same of that in the levo bupivacaine group ($P < 0.05$). Ropivacaine presented a shorter duration of both motor and sensory block than Bupivacaine and levo bupivacaine ($P < 0.05$). Bupivacaine required more often the use of a vasoactive drug

In the present study, we evaluated 60 patients between age group 20-40 years all of them belonging to the ASA grade-I and II. They were divided into two groups of 30 subjects each. The patients underwent orthopaedic lower limb surgeries.

Group I: Patients received 3.5 ml of 0.5% hyperbaric Bupivacaine.

Group II: Patients received 3.5 ml of 0.75% isobaric Ropivacaine.

Baseline demographic variables were comparable between two groups.

1. Time taken to achieve sensory block to L3 (3.75 minutes with SD of 0.59 vs. 5.29 minutes with SD of 0.85).
2. Mean time for the onset of complete motor block in group A was 6.14 minute with SD of 0.708, where as in group B, it was 12.51 minutes with SD of 0.994.
3. Mean duration of sensory block in group A was 204.20 minutes with SD of 8.81, while in group B it lasted for 152.23 minutes with SD of 8.17.
4. Mean duration of motor block in group A patients was 212.67 minute with SD of 11.17 where as in group B patients, the motor block lasted for a mean duration of 135.13 minutes with SD of 11.68.
5. P value for all above mentioned four observations were calculated to be <0.001, which means it is statistically significant
6. Side effects like hypotension, bradycardia, shivering nausea and vomiting more seen in group I.

CONCLUSION: Spinal anesthesia for lower limb orthopedic surgeries with intrathecal 26.25 mg of 0.75% isobaric Ropivacaine has characteristically having delayed onset, with shorter duration of action on the sensory as well as motor nerve roots with lesser side effects when compared to Bupivacaine and hence can be used as an effective and safe alternative to it.

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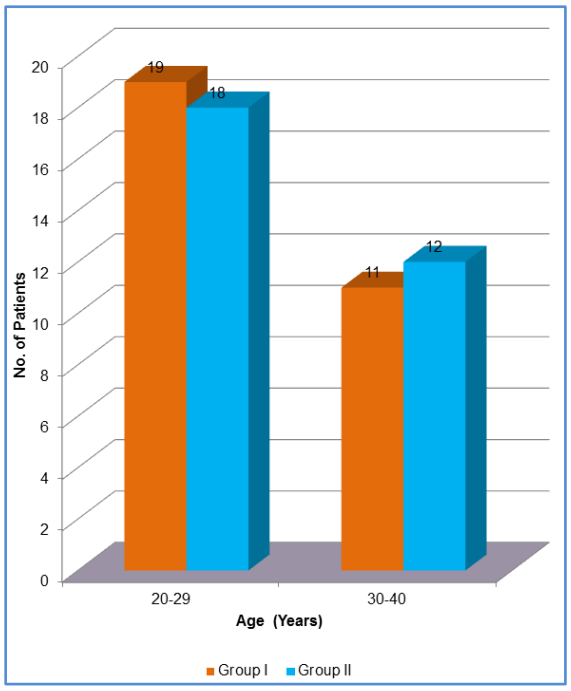

FIG. 1: AGE DISTRIBUTION

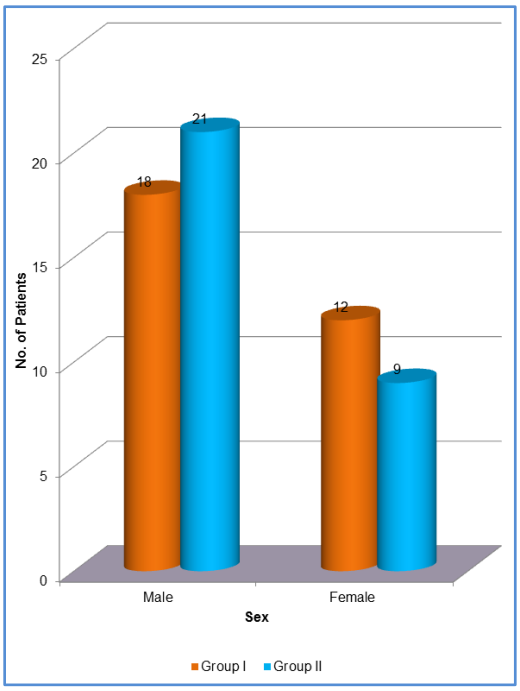

FIG. 2: SHOWING THE SEX DISTRIBUTION OF PATIENTS

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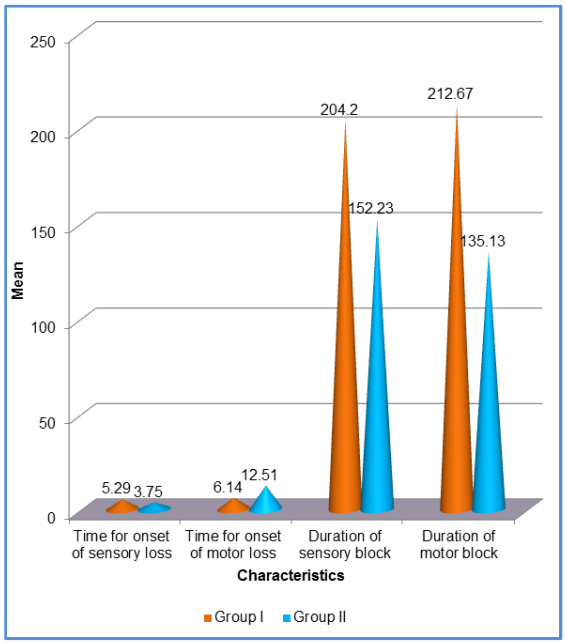

FIG. 3: SHOWING CHARACTERISTICS OF BLOCK (IN TWO GROUP)

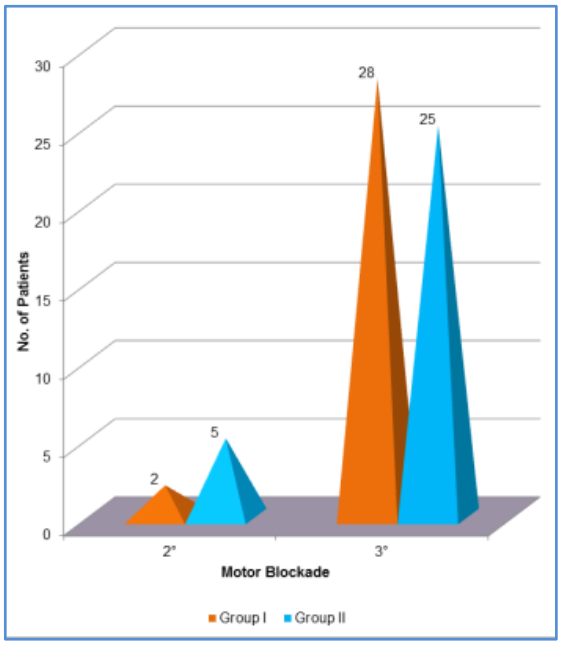

FIG. 4: COMPARISON OF MOTOR BLOCKADE

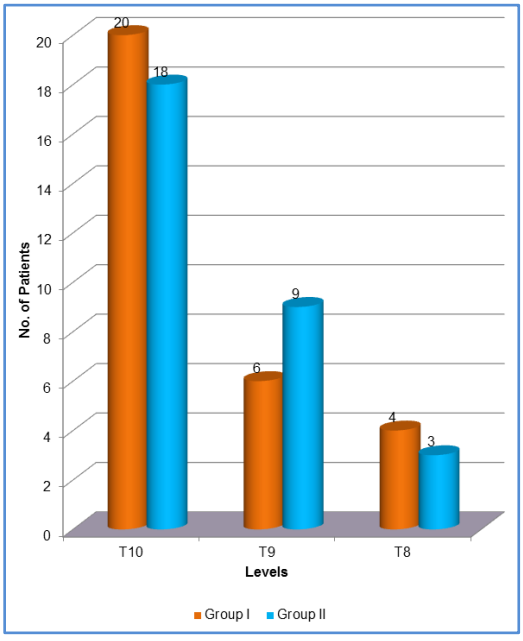

FIG. 5: MAXIMUM LEVEL ACHIEVED (DERMATOME)

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