

The onset and duration of sensory and motor block between intrathecal 0.75% ropivacaine with fentanyl and 0.5% bupivacaine with fentanyl for lower limb surgeries

¹Dr. Arjun Nair, ²Dr. Pramod Kohli, ³Dr. Sachin Kumar, ⁴Dr. Maitree Pandey,
⁵Dr. Prashantha Kumar

¹Assistant Professor, Department of Anesthesia, Maulana Azad Medical College, New Delhi, India

²Retd. Professor, Department of Anesthesia, Lady Hardinge Medical College, New Delhi, India

³Assistant Professor, Department of Anesthesia, AIIMS, New Delhi, India

⁴HOD, Department of Anesthesia, Lady Hardinge Medical College, New Delhi, India

⁵Assistant Professor, Department of anesthesia, The Oxford Medical College, Bangalore, Karnataka, India

Corresponding Author:

Dr. Maitree Pandey

Abstract

Regional anaesthesia techniques have seen numerous modifications over the last few decades with the advent of many newer and safer local anaesthetics. Even with a variety of drugs available, the search for a safer anaesthetic agent has always been given prime importance in all anaesthesia related practices. Till date 0.5% hyperbaric bupivacaine is the most commonly used drug for orthopedic surgeries in spinal anaesthesia. The study was carried out after approval by the institutional ethical committee in the department of Anaesthesiology. Randomization was done using a random number table generated from computer software and divided into 2 groups of 40 each. Group B: 2.5 ml of 0.5% hyperbaric bupivacaine with 25 µg fentanyl, Group R: 2.5 ml of 0.75% isobaric ropivacaine with 25 µg fentanyl. The quality of anaesthesia, as graded by the surgeons, was excellent in 96.66% in both the groups. In only one patient in group R, poor quality of anaesthesia was reported by the surgeon. This patient was well built and there was some difficulty in muscle retraction. Since the patient was comfortable, no supplementation was given and surgery was completed uneventfully.

Keywords: Ropivacaine, bupivacaine, fentanyl

Introduction

Combined spinal epidural (CSE) anaesthesia is a commonly used method for anaesthesia for major lower limb surgeries. Its advantage is its ability to combine the rapidity, density, and reliability of the subarachnoid block with the flexibility of continuous epidural block, prolong the duration of anesthesia and deliver postoperative analgesia.

Regional anaesthesia techniques have seen numerous modifications over the last few decades with the advent of many newer and safer local anaesthetics. Even with a variety of drugs

available, the search for a safer anaesthetic agent has always been given prime importance in all anaesthesia related practices. Till date 0.5% hyperbaric bupivacaine is the most commonly used drug for orthopedic surgeries in spinal anaesthesia. Bupivacaine is available in a commercial preparation as a racemic mixture (50:50) of its two enantiomers, levobupivacaine, S (-) isomer and dextro bupivacaine, R (+) isomer. Ropivacaine, the pure (S)-enantiomer, is a relatively new long acting amide local anaesthetic. It is structurally closely related to bupivacaine. Extensive clinical data have shown that ropivacaine is effective and safe for regional anaesthetic techniques such as epidural and brachial plexus block ^[1].

Severe central nervous system (CNS) and cardiovascular adverse reactions reported in the literature have been linked to the R (+) isomer of bupivacaine. Ropivacaine has pharmacodynamic and pharmacokinetic properties resembling those of bupivacaine ^[2, 3] but has lesser neurotoxicity and cardio toxicity ^[4]. Ropivacaine is about 40% less potent than bupivacaine ^[4]. The differential blocking effect of ropivacaine provides analgesia with less motor block than comparable concentrations of bupivacaine ^[5, 6]. Dose of ropivacaine and bupivacaine are found to be equipotent in the ratio 3:2 in orthopedic surgeries ^[7]. Use of ropivacaine for spinal anaesthesia has been described for orthopedic lower limb surgeries. Further, doses of intrathecal local anaesthetics can be reduced by combining with opioids (e.g. fentanyl, sufentanyl) which also improves the quality of anaesthesia and analgesia ^[8].

There are still queries on the clinical efficacy, beneficial effects and potential harms of ropivacaine and whether ropivacaine can be used as a safe & effective alternative to bupivacaine intrathecally for orthopedic surgeries. Beneficial effects of ropivacaine as an intrathecal local anaesthetic have been investigated in a number of studies. There is a wide variation in the results of different workers with respect to the onset and duration of sensory block.

Hence the present study was designed to compare the clinical efficacy of 0.75% isobaric ropivacaine and 0.5% hyperbaric bupivacaine with fentanyl when administered intrathecally for orthopedic lower limb surgeries.

Methodology

Place of study

The study was carried out after approval by the institutional ethical committee in the department of Anaesthesiology.

Study design

A randomized controlled study.

Sample size

To detect a significant difference in mean duration of sensory block between groups B (Bupivacaine with fentanyl) and group R (Ropivacaine with fentanyl) with $\alpha = 0.05$ & power = 80% the minimum number of 40 cases was required in each group. Randomization was done using a random number table generated from computer software and divided into 2 groups of 40 each.

Group B: 2.5 ml of 0.5% hyperbaric bupivacaine with 25 μ g fentanyl.

Group R: 2.5 ml of 0.75% isobaric ropivacaine with 25 μ g fentanyl.

Study population

Adult patients scheduled for lower limb surgeries.

Inclusion criteria

- Age 20-65 years of both sexes.
- ASA grade 1 and 2.
- Patients scheduled for lower limb surgeries.

Exclusion criteria

- Patients with ASA grade 3 and 4.
- History of known hypersensitivity to any drugs being used.
- Mental disturbances.
- Contraindications to neuraxial blockade.
- BMI ≥ 40 kg/m².
- Surgery lasting for > 2 hours.

After a detailed pre-anaesthetic checkup, informed written consent was taken.

The patients were kept fasting for 8 hours before the surgery.

On arrival in the OT following baseline observations were recorded-

- Heart rate, blood pressure, SpO₂, ECG.
- They were co-loaded with 10-12 ml/kg ringer lactate solution IV.
- All patients in the sitting position received a combined spinal epidural anaesthesia by a needle through needle technique using a 18 gauge Tuohy's needle through which a 27 gauge pencil point spinal needle was introduced in the sub-arachnoid space at L₃-L₄ level or one space below.
- The study drug was injected as per the group designated.

Group B: 2.5 ml of 0.5% hyperbaric bupivacaine with 25 µg fentanyl.

Group R: 2.5 ml of 0.75% isobaric ropivacaine with 25 µg fentanyl.

- The study drug was given after which the spinal needle was withdrawn, epidural catheter was put through the Tuohy's needle and the patient was made to lie supine on the operating table.
- Surgery was allowed after level of block reaches T₁₀ dermatome.

Results

Table 1: Characteristics of sensory block

Parameter	Group B (Mean ± S.D) (min)	Group R (Mean ± S.D) (min)	p-Value
Onset of sensory block	1.45 ± 0.53	2.61 ± 0.58	(S)***
Time taken to achieve Max Level	7.68 ± 0.83	8.71 ± 1.64	(S)***

(NS): $p > 0.05$ -Non-significant, (S)*: $p \leq 0.05$ -Significant, (S)**: $p \leq 0.01$ -Highly significant, (S)***: $p \leq 0.001$ -Very highly significant.

The onset of sensory block to T₁₀ dermatome level was longer in group R as compared to group B. Similarly the time taken to achieve the maximum level of sensory block was longer in Group R as compared to Group B. The differences between the two groups statistically were very highly significant for both the sensory block characteristics.

Table 2: Highest level of sensory block achieved

Highest level achieved	Group B	Group R	p-Value
	No. of patients (%)	No. of patients (%)	
T ₂	5 (12.5)	0 (0)	(S)*
T ₃	0 (0)	0 (0)	-
T ₄	14 (35)	3 (7.5)	(S)**
T ₅	1(2.5)	2(5)	(NS)
T ₆	20(50)	29(72.5)	(S)*
T ₇	0(0)	1(2.5)	(NS)
T ₈	0(0)	5(12.5)	(NS)

(NS): $p > 0.05$ -Non-significant, (S)*: $p \leq 0.05$ -Significant, (S)**: $p \leq 0.01$ -Highly significant, (S)***: $p \leq 0.001$ -Very highly significant.

Although the median highest level of sensory block was T₆ in both the groups, but the striking difference was that the range of highest level was T₆ dermatome and above in group B (T₂-T₆), whereas it was T₄ dermatome and below in group R (T₄-T₈).

T₆ dermatome level was achieved in 73% of patients in group R and 50% of the patients achieved the same in group B.

Table 3: Duration of Sensory Block and Effective Analgesia

Parameter	Group B	Group R	p-Value
	Mean \pm S.D.	Mean \pm S.D.	
Duration of Sensory Block (min)	203.75 \pm 13.27	189.23 \pm 13.33	(S)***
Duration of Effective Analgesia (min)	216.85 \pm 11.79	204.15 \pm 13.30	(S)***

(NS): $p > 0.05$ - Non-significant, (S)*: $p \leq 0.05$ -Significant, (S)**: $p \leq 0.01$ -Highly significant, (S)***: $p \leq 0.001$ - Very highly significant.

The duration of sensory block was found to be higher in group B as compared to group R, the difference being highly statistically significant. Similarly, the duration of effective analgesia was also higher in group B as compared to group R and was highly statistically significant.

Table 4: Characteristics of Motor Block

Parameter (Modified Bromage Scale)	Group B	Group R	p-Value
	Mean \pm S.D.	Mean \pm S.D.	
Onset time (Bromage 1) (min)	4.28 \pm 0.91	7.95 \pm 1.15	(S)***
Time to achieve maximum blockade (Bromage 3) (min)	7.99 \pm 0.99	11.23 \pm 1.00	(S)***

(NS): $p > 0.05$ -Non-significant, (S)*: $p \leq 0.05$ -Significant, (S)**: $p \leq 0.01$ -Highly significant, (S)***: $p \leq 0.001$ -Very highly significant.

Complete motor block of the lower extremities (modified Bromage scale 3) was obtained in all the patients in both the groups.

The time taken for the onset of motor block was almost double in group R (7.95 \pm 1.15 min) as compared to group B (4.11 \pm 0.86 min) & the time taken to achieve maximum motor block was also much longer in group R (11.23 \pm 1.00 min) than group B (7.99 \pm 0.99 min). The differences were highly statistically significant.

Table 5: Duration of motor block

Parameter	Group B Mean \pm S.D.	Group R Mean \pm S.D.	p-Value
Duration of Motor Block (min.)	181.95 \pm 12.90	158.55 \pm 11.45	(S)**

(NS): $p > 0.05$ -Non-significant, (S)*: $p \leq 0.05$ -Significant, (S)**: $p \leq 0.01$ -Highly significant, (S)***: $p \leq 0.001$ -Very highly significant.

In group B, the duration of motor block was longer as compared to group R. This difference was statistically highly significant ($p < 0.01$).

Table 6: Quality of anaesthesia

Parameter	Group B No. of patients (%)	Group R No. of patients (%)	p-Value
Excellent	38(96.66)	38(96.66)	(NS)
Good	2(3.33)	1(1.67)	
Poor	0(0)	1(1.67)	

(NS): $p > 0.05$ -Non-significant, (S)*: $p \leq 0.05$ -Significant, (S)**: $p \leq 0.01$ -Highly significant, (S)***: $p \leq 0.001$ -Very highly significant.

The quality of anaesthesia, as graded by the surgeons, was excellent in 96.66 % in both the groups. In only one patient in group R, poor quality of anaesthesia was reported by the surgeon. This patient was well built and there was some difficulty in muscle retraction. Since the patient was comfortable, no supplementation was given and surgery was completed uneventfully.

Discussion

In our study the mean onset time of sensory block with bupivacaine was found to be 1.45 ± 0.53 min.

The onset of sensory block as found in studies conducted by Singh *et al.* [9] and Chung *et al.* [10] were 2.5 ± 1.3 min and 2.5 ± 1 min respectively. Nuray *et al.* [11], Pala *et al.* [12] and Osama *et al.* [13] have also made similar observations, but with a different dose and baricity of bupivacaine. While Nuray *et al.* found the mean onset of sensory block to be 2.7 ± 1.8 min with 10 mg of 0.5% bupivacaine, Pala *et al.* reported the time to be 2.04 ± 2.81 min with 5 mg 0.5% hypobaric bupivacaine and Osama *et al.* observed the onset time to be 1.96 ± 1.18 min with 11.25 mg hyperbaric 0.5% bupivacaine.

Contrary to our observations, Ogun *et al.* [14] reported a much shorter onset time (0.4 ± 0.9 min) of sensory block with 15 mg of 0.5% plain bupivacaine.

A few studies have found the onset time of sensory block to be much higher than our study. The median sensory onset time was found to be 5 min by Lee *et al.* [15] and also by Luck *et al.* [16] with 10 mg of isobaric and 15 mg of hyperbaric solution of 0.5% bupivacaine respectively. Mantouvalou *et al.* [17] found it to be 13 ± 9 min with 15 mg of 0.5% bupivacaine and Malinovsky *et al.* [7] found the same to be 11 ± 7 min with 10 mg isobaric 0.2% bupivacaine.

In the present study the mean onset of sensory block with ropivacaine was found to be 2.61 ± 0.58 min.

Ogun *et al.* [14] reported a mean sensory onset time (0.3 ± 1 min), less than that of present study with the use of 15 mg of 0.5% isobaric ropivacaine.

A higher mean onset time of sensory block has been observed by Malinovsky *et al.* [7] (13 ± 8

min) and Mantouvalou *et al.* [17] (12 ± 7 min), each with 15 mg of isobaric ropivacaine.

In the present study the onset of sensory time with intrathecal bupivacaine was found to be shorter than with intrathecal ropivacaine. Our findings are supported by the findings of Chung *et al.* [10], Malinovsky *et al.* [7], Singh *et al.* [9].

A faster onset of sensory block with intrathecal ropivacaine as compared to bupivacaine has been reported by Mantouvalou *et al.* [17] ($p > 0.05$). This is contrary to the observations of the present study.

In total contrast to the above, the onset of sensory block was found to be same between ropivacaine and bupivacaine by Pala *et al.* [12], Osama *et al.* [13], Lee *et al.* [15], Ogun *et al.* [14] and Luck *et al.* [16].

The differences observed in the above studies from our study may be attributed to the difference in the total volume of the intrathecal solution, comparison between non-equipotent doses, different baricity of drugs and additives used as compared to the present study. Also, these differences might be because different authors had defined different levels of sensory block for onset.

The time to peak level of sensory block with bupivacaine was 7.68 ± 0.83 min. This was similar to observations of Singh *et al.* (7.9 ± 2.3 min) and Chung *et al.* (8.1 ± 2.0 min). Nuray *et al.* and Ogun *et al.* also found the time to peak levels of sensory block to be 8.1 ± 4.1 min and 7.3 ± 4.2 min with 10 mg and 15 mg of 0.5% plain bupivacaine respectively.

Gautier *et al.* [18] reported a much higher time to reach peak sensory level at 14 ± 9 min with 8 mg isobaric bupivacaine, others like Reddy *et al.* and Osama *et al.* have reported a much shorter time to reach the same which was 4 min and 4.8 ± 2.17 min with 15mg and 11.25 mg of 0.5% hyperbaric bupivacaine respectively. Pala *et al.* [12] also reported the time to reach peak level of sensory block to be 3.7 ± 1.08 min with 5 mg of hypobaric bupivacaine.

The peak level of sensory block was reached with ropivacaine in 8.71 ± 1.64 min in our study.

Singh *et al.* [9] and Nuray *et al.* [11] found the time to peak level of sensory block to be 9.8 ± 3.1 min and 11.6 ± 5.6 min with plain solutions of 24 mg and 15 mg of 0.75% ropivacaine respectively. Ogun *et al.* [11] used 15 mg of 0.5% plain ropivacaine for caesarean surgeries and reported the time to peak levels of sensory block to be 7.2 ± 4.0 min. Chung *et al.* [11] with 18 mg of 0.5% hyperbaric ropivacaine found the same to be 10.6 ± 2.2 min.

Reddy *et al.*, Pala *et al.* found the time to peak levels to be faster than the present study. Reddy *et al.* reported the time to be 6 min with the use of 3 ml 0.75% plain bupivacaine, while Pala *et al.* and Osama *et al.* found the time to be 4.19 ± 1.3 min and 4.79 ± 1.95 min with the use of hypobaric ropivacaine 7.5 mg and 15 mg of hyperbaric ropivacaine.

In our study there was a significant difference in the time to reach peak level of sensory block between the two groups. The findings in our study were supported by the findings of Nuray *et al.* and Chung *et al.*

Contrary to our observations Reddy *et al.*, Singh *et al.*, Pala *et al.*, Osama *et al.*, Gautier *et al.* and Ogun *et al.* found no difference between both the groups for the same.

The difference in result may be because of difference in baricity, volumes of the two drugs and additives used in our study compared to the reference studies.

The median peak sensory level of T₆ was seen in our study in both the groups. Reddy *et al.* and Pala *et al.* also reported the same in their studies with 3 ml of 0.75% plain ropivacaine and 7.5 mg hypobaric ropivacaine respectively.

A higher median peak sensory level of T₃ has been reported by chung *et al.* with 0.5% hyperbaric ropivacaine (18 mg) which is in contrast to our study where the median peak level was T₆.

However Ogun *et al.* [14] observed the peak level at T₄ with 15 mg each of 0.5% isobaric bupivacaine and ropivacaine, while Lee *et al.* [15] observed the peak level to be at T₅ with 10 mg each of the above two isobaric solutions.

The difference in the present study compared to other studies may be because different authors used different total volumes of drug and because of the disparity in baricity of the drugs and the additives that have been used.

Motor blockade was achieved with bupivacaine at 4.28 ± 0.91 min in our study.

Studies with similar time to onset of motor block with that of the present study were done by The difference in the present study from other studies may be explained by the different volumes of the total solutions and the different additives used in the various studies. Also the drugs used by various authors were not in equipotent dose and of different baricity.

Both the time to two segment regression (203.75 ± 13.27 min) and effective analgesia (216.85 ± 11.79 min) were significantly higher in group B compared to group R; 189.23 ± 13.33 min and 204.15 ± 13.30 min respectively. ($p < 0.001$).

Similar observations have been made by Reddy *et al.*, Singh *et al.*, Nuray *et al.*, Pala *et al.*, Mantouvalou *et al.*, Osama *et al.*, Boztug *et al.*, Danelli *et al.*, Gautier *et al.*, Malinovsky *et al.* and Luck *et al.*

Chung *et al.* [10] however have commented that while the time to two segment regression between bupivacaine (12 mg of 0.5% hyperbaric solution) and ropivacaine (18 mg of hyperbaric 0.5% solution) is statistically insignificant, the duration of sensory block with bupivacaine (122.9 ± 21.6 min) was significantly longer than that of ropivacaine (115.8 ± 20.6 min).

Contrary to the observation in our study, Ogun *et al.* [14] found no significant difference between the two segment regression ($p > 0.05$) and the duration of effective analgesia ($p > 0.05$) with 15 mg each of 0.5% plain bupivacaine (74.8 ± 11.5 min; 170 ± 28.1 min) and 0.5% plain ropivacaine (72.8 ± 20.8 min; 165.2 ± 37 min), with 150 μ g morphine added to both the groups.

In total contrast to the present study, Nuray *et al.* [11] found both the time for two segment regression and effective analgesia to be significantly higher with 15 mg of 0.75% isobaric ropivacaine (135 ± 32.1 min and 162.5 ± 32.5 min) than 10 mg of 0.5% plain bupivacaine (118.2 ± 24.2 min; 145 ± 28.1 min), 25 μ g fentanyl and 100 μ g morphine added to both the groups.

The difference in the studies by Ogun *et al.* and Nuray *et al.* could be because of the difference in the concentration, baricity of drugs and adjuvants used. The drugs used by Ogun *et al.* were not in equipotent doses and the dermatomal level for onset of sensory block and effective analgesia was different from the present study.

A statistically very highly significant difference was noted in the duration of motor block between group R (158.55 ± 11.45 min) and group B (181.95 ± 12.90 min).

In contrast Malinovsky *et al.* [7] has reported a comparable duration of motor block between 10 mg 0.5% isobaric bupivacaine and 15 mg of 0.3% isobaric ropivacaine (184 ± 59 min and 165 ± 62 min; $p > 0.05$).

The difference in the study by Malinovsky *et al.* could be because of the difference in the total volume, concentration and baricity of the drugs and the additives used in the present study.

Conclusion

1. Both the drugs are safe and the quality of anaesthesia equally good with both ropivacaine and bupivacaine.
2. Bupivacaine differs from ropivacaine in-
 - Earlier onset and time to peak effect of sensory & motor blockade.
 - Higher cephalic spread seen in bupivacaine.
 - Longer duration of sensory and motor blockade and better effective post-operative analgesia.

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