International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 14, No. 3, March 2025 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_14.3.2025.220

ORIGINAL RESEARCH

A prospective randomized comparative study of efficacy and safety of hyperbaric ropivacaine 0.75% versus hyperbaric bupivacaine 0.5% in infra umbilical surgeries under spinal anesthesia

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Received: 02Jan, 2025 Accepted: 03Feb, 2025

ABSTRACT
Effect of local anaesthesia is directly related to the myelination and size of the nerve fibres the more lipophilic local anaesthetics penetrance large myelinated motor fibres more effectively than the less lipophilic local anaesthetics however penetration of small unmyelinated sensory A delta and c fibres is thought to be independent to differences in lipophilicity of local anaesthetic drugs. All patients were kept nil per orally from night 10 pm the day before surgery.All patients were premedicated with Tab. Alprazolam 0.5 mg HS and Tab Ranitidine 150mg HS the previous day. On arrival in the operating intravenous line was obtained with 20G cannula and was preloaded with ringer lactate 10 ml/kg body weight half an hour before anaesthesia. The patient were connected to multi-channel monitor which records heart rate, NIBP, ECG end tidal carbon-di-oxide, oxygen saturation and temperature. Based on the available evidence, ropivacaine may not be the local anesthetic of choice for spinal anesthesia in cases with relatively longer duration. However, its faster recovery characteristics resulting in shorter duration associated with better hemodynamic profile and earlier mobilization and voiding would make it suitable for short procedures beingconducted in day care settings.

Key words: Hyperbaric ropivacaine, hyperbaric bupivacaine 0.5% in infra, spinal anesthesia

INTRODUCTION

Regional anaesthesia techniques provide excellent intra operative and post-operative pain control and shortened stay in the post anaesthesia care unit. Spinal anaesthesia is most commonly used technique for infra umbilical surgeries as it is very easy to administer with the advantage of providing surgical anaesthesia and economical[1-3].

Ropivacaine was synthesised as a pure S[-] enantiomer from the parent chiral molecule propivacain, its commercial preparation has an enantiomeric purity of 99.5%[4, 5].Ropivacaine is almost similar to Bupivacaine in chemical structure except it has a propyl group on the piperidine nitrogen atom compared to bupivacaine, which has butyl group. The length of carbon side chain on tertiary nitrogen atom is shorter in ropivacaine than that of bupivacaine. The short length of the carbon chain makes ropivacaine less lipid soluble which influences the potency of the compound[6].

Effect of local anaesthesia is directly related to themyelination and size of the nerve fibres the more lipophilic local anaesthetics penetrance large myelinated motor fibres more effectively than the less lipophilic local anaesthetics however penetration of small unmyelinated sensory A delta and c fibres is thought to be independent to differences in lipophilicity of local anaesthetic drugs[4].

Being less lipophilic ropivacaine penetrates less into large myelinated motor fibres; therefore, it has selective action on the pain transmitting A delta and C nerve rather than A beta fibres, which are involved in motor function. Thus ropivacaine shows more

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selective sensory versus motor blockade than the more lipophilic bupivacaine[7].

Due to less lipophilic property and stereo selective structure Ropivacaine has significantly higher threshold for cardiotoxicity and CNS toxicity than bupivacaine[7, 8].Hyperbaric solutions are more predictable, with greater spread in the direction of gravity and less interpatient variability[9].

The present study aimed to evaluate and compare the study of efficacy safety of 0.75% Hyperbaric Ropivacaine versus 0.5% Hyperbaric Bupivacaine in Infra umbilical surgeries under spinal anesthesia.

METHODOLOGY

STUDY POPULATION: Adult male and female patients belonging age group 20-50years and ASA I & II, coming for infra umbilical surgeries.

TYPE OF STUDY: Prospective Randomized Comparative Study.

INCLUSION CRITERIA

1. Patients belonging to age group 20-50 years with.
2. ASA grade I and grade II.
3. Elective infra umbilical surgeries.

EXCLUSION CRITERIA

1. Patients who refuse.
2. Patients with history of bleeding disorders.
3. Patients with local infection at the site of block.
4. Patients with documented neuromuscular disorders.
5. Patients with respiratory compromise/post pneumonectomy having one functional lung.
6. Patients with known allergy to local anaesthetic drugs.
7. ASA grade III and IV patients.
8. Pregnant and lactating mothers.

METHOD OF RANDOMIZATION

Computer based random selection of patients to one of the two groups will be done using a standard randomization code.

ALLOCATION TO DIFFERENT REGIMENS

GROUP R: Patients receiving 0.75% Ropivacaine 3.5ml intrathecally.

GROUP B: Patients receiving 0.5% Bupivacaine 3.5ml intrathecally.

SAMPLE SIZE

- 30 patients are taken in each group (total 60 patients).

The sample size was calculated using the previous study by Anant G *et al*., [36] using the below formula,

$$n = (Z\alpha/2+Z\beta)2 *2*\sigma2/d2$$

Where Zα/2 is the critical value of the Normal distribution at α/2 (e.g. for a confidencelevel of 95%,α is 0.05 and the critical value is 1.96),Zβ is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2and the critical value is 0.84),σ2 is the population variance, andd is the difference you would like to detect.

The sample size achieved was 29 patients in each group, which we rounded to 30 patients in each group, with total 60 participants.

ANESTHESIA PROCEDURE

Pre-anaesthetic evaluation was done on the evening before the surgery after obtaining informed written consent. A routine pre-anaesthetic examination was conducted for assessment of:

- General condition of the patientNutritional status and weight of the patient.
- A detail examination of respiratory system, cardiovascular system, central nervoussystem including musculoskeletal system.
- Other co morbid diseases.

The following investigations will be done in all the patients

- Complete blood count.
- Clotting time and bleeding time.
- Standard 12 lead electrocardiogram.
- Blood sugar/FBS/PPBS.
- Blood urea.
- Serum creatinine.
- Urine examination.

1. All patients were kept nil per orally from night 10 pm the day before surgery.
2. All patients were premedicated with Tab. Alprazolam 0.5 mg HS and Tab Ranitidine 150mg HS the previous day.
3. On arrival in the operating intravenous line was obtained with 20G cannula and was preloaded with ringer lactate 10 ml/kg body weight half an hour before anaesthesia.
4. The patient were connected to multi-channel monitor which records heart rate, NIBP, ECG end tidal carbon-di-oxide, oxygen saturation and temperature.
5. All baseline parameters were recorded and continuously monitored.
6. Patient positioned in sitting position.
7. Under aseptic precautions Subarachnoid block is performed at L3-L4 inter-space through a midline approach using 25G whitacre spinal needle after confirming the clear and free flow of CSF 0.75% hyperbaric ropivacaine 3.5ml is injected in to subarachnoid space in (Group R),0.5% hyperbaric bupivacaine 3.5ml (Group B).

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RESULTS

Table 1: Comparison of different times of onset and duration of sensory and motor block between the study groups

Group	Ropivacaine Mean±SD	Bupivacaine Mean±SD	P value
Time of onset of sensory block	3.61±0.52	4.72±0.49	<0.001
Time of peak sensory block	5.17±0.54	6.51±0.52	<0.001
Duration of sensory block	206.83±14.23	254.70±10.17	<0.001
Time of onset of motor block	5.51±0.48	6.76±0.51	<0.001
Duration of motor block	199.33±11.79	248.67±10.90	<0.001
Duration at rescue analgesia given	209.67±18.57	254.20±9.48	<0.001

Mean Time of onset of sensory block in group R was 3.61 and group B was 4.72. Mean Time of peak sensory block in group R was 5.17 and group B was 6.51. Mean Duration of sensoryblock in group R was 206.8 and group B was 254.7. Mean Time of onset of motor block in group R was 5.51 and group B was 6.76. Mean Duration of motor block in group R was 199.3 and group B was 248.6. Mean Duration at rescue analgesia given in group R was 209.6 and group B was 254.2. Therefore, it was observed that different times of onset and duration of sensory and motor block were high in group B compared to group R**.** These differences were statistically significant. (p-value <0.05).

Table 2: Comparison of VAS score between the study groups

Group	Ropivacaine Mean±SD	Bupivacaine Mean±SD	P value
VAS 4 hr	5.90±1.58	5.86±1.14	0.907
VAS 6 hr	10.00±00	10.00±00	-
VAS 8 hr	10.00±00	10.00±00	-
VAS 10 hr	10.00±00	10.00±00	-

In group Ropivacaine mean VAS score at 4 hrs was 5.9±1.5 and in group Bupivacaine mean VAS score was 5.8±1.1. The difference was not statistically significant. VAS score was 10 at 6hrs, 8 hrs and 10hrs in both the groups.

Table 3: Comparison of vitals between the groups

Vitals	Group		Total No.(%)	P value
	Ropivacaine No.(%)	Bupivacaine No.(%)		
Stable	28 (57.1)	21 (42.9)	49	0.019
Unstable	2 (18.2)	9 (81.8)	11	
Total	30 (50)	30 (50)	60	

It is observed that all 28 patients in Ropivacaine groups had stable vitals and p patients had unstable vitals. In Bupivacaine group 21 patients had stable vitals in Bupivacaine group, 9 patients had unstable vitals. This difference was significant. (p=0.038). Treated with injection Mephentaramine 6 mg stat and injection Adrpine 0.6mg.

Table 4: Nausea between the groups

Nausea	Group		Total No.(%)	P value
	Ropivacaine No.(%)	Bupivacaine No.(%)		
Yes	3 (10)	10 (33)	13	0.032
No	27 (90)	20 (67)	47	
Total	30 (50)	30 (50)	60	

It is observed that among 30 group R patients, 3 patients had nausea whereas 10 patients in group B had nausea. This difference was statastically significant. (p=0.032)

Table 5: Vomiting between the groups

Vomiting	Group		Total No.(%)	P value
	Ropivacaine No.(%)	Bupivacaine No.(%)		
Yes	3 (25)	**9 (75)**	12	0.053
No	27 (56.3)	21 (43.8)	48	
Total	30 (50)	30 (50)	60	

DOI: 10.69605/ijlbpr_14.3.2025.220

It is observed that among 30 group R patients, 3 patients had vomiting whereas 9 patients in group B had vomiting. This difference was statastically significant. (p=0.053)

Table 6: Comparison of level of sensory block and motor block at different time points between the study groups

Time	Levelof blockade	Sensory Blockade		P value	Level of blockade	Motor Blockade		P value
		Ropivacaine No.(%)	Bupivacaine No.(%)			Ropivacaine No.(%)	Bupivacaine No.(%)	
5min	T10	0 (0)	5 (16.7)	<0.001	T10	2 (6.7)	4 (13.3)	0.172
	T8	2 (6.7)	21 (70)		T8	16 (53.3)	20 (66.7)	
	T6	22 (73.3)	2 (6.7)		T6	12 (40)	5 (16.7)	
	T4	6 (20)	2 (6.7)		T4	0 (0)	1 (3.3)	
10min	T8 T7 T6 T5 T4 T2	1 (3.3) 1 (3.3) 17 (56.7) 3 (10) 8 (26.7) 0 (0)	2 (6.7) 0 (0) 21 (70) 0 (0) 6 (20) 1 (3.3)	0.302	T10 T8 T7 T6 T4	0 (0) 13 (43.3) 0 (0) 17 (56.7) 0 (0)	2 (6.7) 17 (56.7) 2 (6.7) 7 (23.3) 2 (6.7)	0.030
15 min	T8 T7 T6 T5 T4 T2	1 (3.3) 1 (3.3) 17 (56.7) 3 (10) 8 (26.7) 0 (0)	2 (6.7) 0 (0) 19 (63.3) 1 (3.3) 6 (20) 2 (6.7)	0.450	T10 T8 T7 T6 T4	0 (0) 10 (33.3) 0 (0) 20 (66.7) 0 (0)	1 (3.3) 16 (53.3) 2 (6.7) 8 (26.7) 3 (10)	0.014
20 min	T8 T7 T6 T5 T4 T2	1 (3.3) 1 (3.3) 16 (53.3) 2 (6.7) 10 (33.3) 0 (0)	2 (6.7) 0 (0) 19 (63.3) 1 (3.3) 6 (20) 2 (6.7)	0.425	T10 T8 T7 T6 T4	0 (0) 9 (30) 0 (0) 21 (21) 0 (0)	1 (3.3) 15 (50) 2 (6.7) 9 (3.) 3 (10)	0.015
30 min	T8 T7 T6 T5 T4 T2	1 (3.3) 1 (3.3) 16 (53.3) 2 (6.7) 10 (33.3) 0 (0)	2 (6.7) 0 (0) 19 (63.3) 1 (3.3) 6 (20) 2 (6.7)	0.425	T10 T8 T7 T6 T4	0 (0) 8 (26.7) 0 (0) 22 (23.3) 0 (0)	1 (3.3) 15 (50) 2 (6.7) 9 (30) 3 (10)	0.009
60 min	T8 T7 T6 T5 T4 T2	1 (3.3) 1 (3.3) 16 (53.3) 2 (6.7) 10 (33.3) 0 (0)	2 (6.7) 0 (0) 19 (63.3) 1 (3.3) 7 (23.3) 1 (3.3)	0.630	T10 T8 T7 T6 T4	0 (0) 9 (30) 0 (0) 21 (70) 0 (0)	1 (3.3) 14 (46.7) 2 (6.7) 11 (36.7) 2 (6.7)	0.056
90 min	T8	1 (3.3)	2 (6.7)	0.619	T10	0 (0)	1 (3.3)	0.311
	T7 T6 T5	2 (6.7) 20 (66.7) 1 (3.3)	0 (0) 19 (63.3) 1 (3.3)		T8 T7 T6	1 (3.3) 1 (3.3) 17 (56.7)	14 (46.7) 2 (6.7) 11 (36.7)	
	T4	6 (20)	8 (26.7)		T4	0 (0)	2 (6.7)	
120 min	T8	4 (13.3)	2 (6.7)	0.740	T10	1 (3.3)	1 (3.3)	0.515
	T7 T6 T5	1 (3.3) 18 (60) 1 (3.3)	0 (0) 19 (63.3) 1 (3.3)		T8 T7 T6	12 (40) 1 (3.3) 16 (53.3)	15 (50) 1 (3.3) 11 (36.7)	
	T4	6 (20)	8 (26.7)		T4	0 (0)	2 (6.7)	

It is observed that at 5 min, among group R patients, most of the patients had sensory block at T6 (73.3%) and motor block at T8 (53.3%), whereas among group B patients T8 was the commonest site for sensory block (70%) and motor block (66.7%).

At 10 min, among group R patients, most of the patients had sensory block at T6 (56.7%) and motor block at T6 (56.7%), among group B patients T6 was the commonest site for sensory block (70%) and T8 for motor block (56.7%).

At 15 min, most of the patients had sensory block at T6 (56.7%) and motor block at T6 (66.7%), among group B patients T6 was the commonest site for sensory block (63.3%) and T8 for motor block (53.3%).

At 20 min, most of the patients had sensory block at T6 (53.3%) and motor block at T8 (30%), among group B patients T6 was the commonest site for sensory block (63.3%) and T8 for motor block (50%).

At 30 min, most of the patients had sensory block at T6 (53.3%) and motor block at T8 (26.7%), among

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group B patients T6 was the commonest site for sensory block (63.3%) and T8 for motor block (50%).
At 60 min, most of the patients had sensory block at T6 (53.3%) and motor block at T6 (70%), among group B patients T6 was the commonest site for sensory block (63.3%) and T8 for motor block (46.7%).
At 90 min, most of the patients had sensory block at T6 (66.7%) and motor block at T6 (56.7%), among group B patients T6 was the commonest site for sensory block (63.3%) and T8 for motor block (46.7%).
At 120 min, most of the patients had sensory block at T6 (60%) and motor block at T6 (53.3%), among group B patients T6 was the commonest site for sensory block (63.3%) and T8 for motor block (50%).
There was no significant difference for level of sensory block between the groups, was observed at 10 min, 15 min, 20 min and 30 min for motor block between both the groups.

DISCUSSION

It was observed that different times of onset and duration of sensory and motor block were high in group B compared to group R. These differences were statistically significant.
Similar results observed in the study by Bhat *et al.*, were in accordance with our study where duration of motor block was significantly shorter with ropivacaine as compared to bupivacaine. The mean duration of analgesia was similar in both the groups and was statistically non-significant which is contradicting current study which significant.
Similar results were observed in the study by Nema at el where the time of onset of motor block was significantly delayed in ropivacaine group (12.51±0.99 minutes) ascompared to bupivacaine group (6.14±0.70 mins). We observed a significantly shorter duration of motor block with group R as compared to group B.
Similar results Dr.*Nazima Memon et al*.,showed that the comparison between the onset of Sensory (3.76 ± 0.53 v/s 2.28 ± 0.62) and Motor blockade (4.03 ± 0.65 v/s 3.58 ±0.63) was earlier in Group R than Group B. The differences between two groups were statistically significant. Duration of the Sensory and Motor blockade differences between two groups were statistically significant[10].
Yennawar *et al.*, showed that mean time for onset of sensory blockade revealed that the sensory blockade was significantly faster with Group B (5.21+/-1.21) than Group R (9.10 +/- 1.50 min). The difference was found to be statistically significant. Mean time for onset of motor blockade revealed that the sensory blockade was significantly faster with Group B (8.25+/-1.30) than Group R (11.50 +/- 1.75 min). The difference was found to be statistically significant[11].
Yennawar *et al*., showed that the Comparison of duration of the sensory blockade in the studied cases revealed that the mean duration of the sensory blockade was 108.75+/- 22.50 minutes in group R and 96.35 +/- 15.25 minutes. The difference was found to be statistically significant. Duration of the motor blockade in the studied cases revealed that the mean duration of the motor blockade was 148.35 +/- 32.25 minutes in group R and116.35 +/- 18.26 minutes. The difference was found to be statistically significant[11].
In a prospective study by Kumar RA *et al*.,although the start of motor blockage was faster in the Bupivacaine group, the overall length of motor blockade was comparable. The study concluded that 0.75% isobaric Ropivacaine delivers comparable duration of effectiveness with stable haemodynamics as 0.5% hyperbaric Bupivacaine[12].
In group Ropivacaine mean VAS score at 4 hrs was 5.9±1.5 and in group Bupivacaine mean VAS score was 5.8±1.1. The difference was not statistically significant. VAS score was 10 at 6hrs, 8 hrs and 10hrs in both the groups.
In study by Anant G *et al*., Only at 180 minutes did there exist a significant mean difference in VAS[13].

Comparison of vitals between the groups

It is observed that all 30 patients in Ropivacaine groups had stable vitals and 28 patients had stable vitals in Bupivacaine group, 4 patients had unstable vitals. This difference was significant.

Comparison of level of sensory block and motor block at different time points between the study groups

At 5min, 10 min, 15 min, 20 min, 30 min, 60 min, 90 min, 120 min most of the patients had sensory block at T6 and motor block at T6 in both the groups.
There was no significant difference for level of sensory block between the groups, whereas significant difference was observed at 10 min, 15 min, 20 min and 30 min for motor block between both the groups.
Yennawar *et al*., showed that the The analysis of highest segmental level of sensory blockade achieved by these 2 levels revealed, Out of 45 patients in Group B 20 patients had block up to T10 level, 15 patients had block upto the level of T8, 8 patients had highest segmental block up to T6 and remaining 2 patients showed segmental block up to the level of T4. In group R the highest segmental level was seen up to T10, T8, T6 and T4 levels in 36, 8, 1 and 0 patients respectively[11].
In study by Anant G *et al*., There was a significant mean difference in sensory blockage between groups R and B at 5 minutes, 45 minutes, 50 minutes, 55 minutes, 60minutes, and 180 minutes[13, 14].

CONCLUSION

Use of 0.75% Hyperbaric ropivacaine can be used as a possible alternative to routinely used 0.5% hyperbaric bupivacaine for spinal anaesthesia in lower abdominal surgeries as it provides similar duration of analgesia with a shorter duration of motor block, it alsoprovides adequate level of sensory block for the surgery with

DOI: 10.69605/ijlbpr_14.3.2025.220

minimal intraoperative and postoperative side effects and stable haemodynamics throughout the surgery.

Based on the available evidence, ropivacaine may not be the local anesthetic of choice for spinal anesthesia in cases with relatively longer duration. However, its faster recovery characteristics resulting in shorter duration associated with better hemodynamic profile and earlier mobilization and voiding would make it suitable for short procedures beingconducted in day care settings.

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