



COMPARISON OF HYPERBARIC ROPIVACAINE AND HYPERBARIC BUPIVACAINE IN UNILATERAL SPINAL ANAESTHESIA

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ABSTRACT

OBJECTIVES: To assess and compare the onset and duration of sensory and motor block, duration of analgesia, haemodynamic changes and requirement of first analgesia in post operative period

METHODS: After obtaining approval from the Institutional Ethics Committee, this prospective, randomized, double blind study was conducted in 50 patients of ASA physical status I/II, aged between 18 to 50 years undergoing elective unilateral lower limb surgeries under unilateral SAB. Patients were randomly allocated into two groups using chit in box method.

Group B (n=25): 7.5mg of 0.375% hyperbaric inj. bupivacaine (2ml)

Group R (n=25): 10mg of 0.5% hyperbaric inj. ropivacaine (2ml).

RESULTS: The mean onset of sensory block and motor block is earlier ($p < 0.05$) in group B (sensory 2.98 ± 0.54 min, motor 2.74 ± 1.70 min) as compared to group R (sensory 5.16 ± 1.74 , motor 4.60 ± 1.979 min). Mean duration of analgesia was significantly prolonged in group B (129.28 ± 41.312 min) compared to group R (107.40 ± 30.28 min). The mean duration of motor block was significantly longer in group B (218.76 ± 64.598) as compared to group R (139.60 ± 31.02 min). Proportion of unilateral block in patients were significantly higher (80%) in group B as compared to group R (48%) according to sensory block in non operative side. First analgesia time was shorter in group R (173 ± 115.8 min) than in group B (289 ± 146.4 min).

Conclusion: The faster onset and longer duration of block was observed in the bupivacaine group, while hyperbaric ropivacaine provides a more selective unilateral block with stable haemodynamic variables.

KEYWORDS: Bupivacaine, Ropivacaine, Unilateral spinal block

INTRODUCTION: Regional anaesthesia is highly effective both for surgical procedure and post operative pain management. Spinal anaesthesia is one of the most often used modality in regional anaesthesia practice. It offers many advantages which are difficult to duplicate with general anaesthesia as it provides good pain control during post operative period and facilitates early ambulation, feeding and possibly discharge. Complication of spinal anaesthesia is preventable if administered meticulously under all aseptic precautions and skilfully in properly selected cases.

Bupivacaine (available both in isobaric and hyperbaric preparation) has been the drug of choice for spinal anaesthesia for past many years. Ropivacaine, a newer amide local anaesthetic, having almost the similar clinico-pharmacological properties as bupivacaine in terms of onset, duration and quality of block with added advantage of less cardio and neuro toxicity is being used widely nowadays.

Hyperbaric solution appeared to provide a more predictable level of block as compared to isobaric solution. It also produces a more rapid spread to a higher median level and less variation in maximum sensory and motor block and might enable a smaller dose to be used compared with plain solution.

In lower extremity surgeries, unilateral block with less sympathetic block may be advantageous. Unilateral block provides adequate analgesia and anaesthesia and reduces adverse effects in comparison to classic spinal anaesthesia.

Hence, we designed the present study to compare hyperbaric ropivacaine with hyperbaric bupivacaine in terms of onset and duration of sensory and motor blockade, duration of analgesia, more selective unilateral block in patient posted for lower Limb surgeries under unilateral spinal anaesthesia. The secondary outcomes measured were hemodynamic variables and adverse effects in both the groups.

Methods: After Institutional ethics Committee, review board approval and written informed consent from patients, 50 patients of

ASA grade I and II, age 18 to 50 years undergoing unilateral lower limb procedure of 30 to 120 minutes duration, were enrolled in this prospective, randomized double blinded clinical trial. Patient with cardiovascular, cerebrovascular, coagulation disorder, neuropathy, allergy to LA, spinal deformity, infection at injection site and patient refusal were excluded from the study.

Patients were allocated in two groups of 25 patients each; Group B received unilateral spinal anaesthesia with hyperbaric bupivacaine (7.5mg of point 0.375%) and Group R received unilateral spinal anaesthesia with hyperbaric ropivacaine (10mg of 0.5%).

After taking informed consent and confirming overnight fasting, patient was taken on OT table, all the standard monitors like NIBP, Pulse oximeter, ECG were attached and baseline parameters were recorded.

After securing 18 G IV Cannula, pre loading was done with 10 ml/kg lactated ringer solution. Patient was placed in lateral decubitus position. Lumbar puncture was performed in lateral decubitus position, operative side below, at L3- L4 interspace with 25 G Quincke needle under strict aseptic condition. The drug was given intrathecally at the rate of 0.2 ml/sec according to the allocated group. After the injection patient stayed in lateral decubitus position, operative side below for 10 minutes and then turned to supine position. Vitals were checked every 5 minutes for first 30 minutes there after every 10 minutes.

The level of sensory block was assessed every 30 sec after intrathecal injection of study drug using 25 G hypodermic needle (pin prick method) with a 3 point scale (0- sharp pain, 1- touch sensation only and 2- not even touch sensation) in both limbs until the level had stabilized for 4 consecutive tests. Onset of motor block was defined as the time taken for motor block to reach Bromage 3. (**Bromage score:** 0- full movement, 1- inability to raise extended leg, can bend knee, 2- inability to bend knee, can flex ankle and 3- no movement.) Bilateral assessment of motor block was done immediately after assessment of analgesic level. Duration of sensory block was

defined as the time taken for the sensory block to regress up to L3 level from the highest level achieved. Degree of motor block was assessed every 5 minutes till highest Bromage score was achieved and every 30 minutes postoperatively. Duration of motor block was assessed by recording the time elapsed from the 3 (no movement) to the 0 (full movement) Bromage score. Post operative monitoring including heart rate, systolic and diastolic blood pressure, SpO2 and time from intrathecal injection to the first complaint of pain (rescue analgesia) were recorded. Postoperative pain was assessed by using Visual Analogue Score (0- no pain to 10 worst imaginable pain). Intramuscular diclofenac sodium (75 mg) was given as rescue analgesic when patient complaint of pain (VAS score >6). Total rescue analgesic dose in first 24 hour was recorded.

Statistical analysis was done using SPSS version 20. The qualitative data were expressed as percentages and the quantitative data were expressed in mean ± SD. Difference in proportion were analysed by using Chi square test and difference in means were analysed via Student t- test. P value <0.05 were considered as statistically significant.

Results: Both groups were comparable with respect to age, weight, height, ASA physical status and duration of surgery (Table1). There was no statistical difference in baseline hemodynamic parameters among the both groups.

Onset of sensory blockade was faster in group B (2.98 ± 0.549) in comparison to group R (5.16 ± 1.74) in operative side (p<0.001) as well as in non operative side (9.25 ± 3.08 min in Group B and 11.5 ± 0.62 min in Group R) [P< 0.017]. Onset of motor blockade was earlier in Group B (2.74 ± 1.70) in comparison to group R (4.60 ± 1.97) in operative side(P <0.001) and in non operative side bupivacaine Vs ropivacaine (9.37 ± 2.21 & 15.00 ± 2.14 respectively) p=< 0.001. Duration of sensory block is longer in operative side (129.28 ± 41.312 and 107.40 ± 30.28) [p< 0.001] and duration of sensory block in non operative side (57.48 ± 40.82) in group B as compared to (23.28 ± 27.30) in group R which is significant (p<0.001). Proportion of the cases was significantly higher (88%) in group B as compared to group R (48%) according to sensory block in non operative side. The highest level of sensory block achieved was significantly similar in both groups. Time to achieve complete motor recovery was earlier in ropivacaine group (139 ± 31.02) in comparison to bupivacaine group (218 ± 64.59) (p<0.001) and in non operative side (61.88 ± 23.15 and 105.7 ± 54.93 respectively) [p=0.045]. Proportion of the cases were significantly higher (76%) in group B as compared to group R (32%) according to motor block onset in non operative side (p=0.005). There was a significant difference in duration of complete and effective analgesia in between both the groups. First rescue analgesic requirement was shorter in ropivacaine group (173 ± 115.8) than in bupivacaine group (289 ± 146.4) [p=0.003].

Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, oxygen saturation were comparable between groups and did not change significantly in the intra operative or post operative period. Intraoperative adverse effects like hypotension, shivering, nausea and bradycardia had no significant difference in both the groups.

Table 1: Demographic variables

VARIABLES	GROUP B	GROUP R	P value
Age (year)	38 ± 8.56	37.16 ± 9.73	0.69
Weight (kg)	55.80 ± 3.40	55.04 ± 3.17	0.418
Height (cm)	152.0 ± 2.23	152.40 ± 1.97	0.506
ASA (I/II)	45/5	46/4	
Duration of surgery (min.)	63.20 ± 17.13	62.60 ± 20.41	0.911

Table 2: Characteristics of block

PARAMETERS	GROUP B	GROUP R	P value
Onset of sensory block in operative side(min)	2.98 ± 0.54	5.16 ± 1.74	<0.001
Onset of sensory block in non-operative side	9.25 ± 3.08	11.5 ± 0.62	<0.017
Onset of motor block in operative side(min)	2.74 ± 1.70	4.60 ± 1.97	<0.001
Onset of motor block in non-operative side(min)	9.37 ± 2.21	15.00 ± 2.14	<0.001
Duration of sensory block in operative side(min)	129 ± 41.31	107.40 ± 30.28	<0.001
Duration of sensory block in non-operative side (min)	107.40 ± 30.28	23.28 ± 27.00	<0.001
First rescue analgesic requirement time(min)	289.00 ± 146.49	173.00 ± 115.81	<0.003

Table 3: Distribution of cases

PARAMETERS	GROUP B(n=25)	GROUP R(n=25)	T value
According to sensory block onset in non-operative side (%)	88%	48%	0.006
According to motor block onset in non-operative side (%)	76%	32%	0.005

Discussion:

Despite all its criticism, spinal anaesthesia is the most popular technique of regional anaesthesia because it is simple to perform, economical, produces rapid onset of anaesthesia and complete muscle relaxation. It carries high efficiency and involves fewer doses of drugs being used. Because of lidocaine induced transient neurological symptoms^(2,3,4) it was replaced by bupivacaine in last few years⁽⁴⁾. Bupivacaine has its own limitations and complications so ropivacaine, a new local anaesthetic gets attention because it is considered to be less cardio toxic on milligram basis.⁽⁵⁾ Although some clinical trials suggest that ropivacaine is less potent than bupivacaine.^(6,7)

The present study encompasses the study of unilateral spinal anaesthesia in patients undergoing lower limb surgeries in respect to onset and duration of sensory and motor blockade, duration of complete analgesia and time to complete motor recovery in operative and non operative side, hemodynamic effects, intraoperative and postoperative adverse effects. In this prospective, randomized, double-blind study we found that the onset of sensory and motor blockade is significantly earlier in patient who received bupivacaine as compared to ropivacaine. A possible explanation has lesser lipid solubility may cause delay in penetration of large myelinated A fibres than the more lipid soluble bupivacaine. Our study coincides with Chung CJ et al⁽⁸⁾ study showing early onset of sensory block with bupivacaine. Proportion of cases was significantly higher (88%) in patients received bupivacaine as compared to ropivacaine (48%) according to sensory block in non-operative side. So ropivacaine provide more selective unilateral sensory block. Our observations are consistent with Zekiye Begat et al.⁽⁹⁾ Duration of sensory block in our study was significantly shorter in ropivacaine group in operative side and in non-operative side than bupivacaine group (p< 0.001). Our study coincides with Luck JF et al⁽¹⁰⁾ and Osama Al Abdul hadi et al.⁽¹¹⁾ Study showing duration of sensory block was shorter with ropivacaine as in our study. This could be due to lesser lipid solubility of ropivacaine. These results confirm that spinal ropivacaine is less potent than bupivacaine. In our study we observed that recovery of complete motor blockade was significantly earlier in ropivacaine group in operative as well as non-operative side (p<0.001). Chung

CJ et al. ⁽¹⁰⁾ and Osama al Abdul hadi et al ⁽¹¹⁾ also found shorter duration of motor block of ropivacaine as in ours.

Proportion of the cases was significantly higher 76% in bupivacaine group as compared to ropivacaine group 32% according to motor block onset in non-operative side. Our observation also coincides with Zekiye Bigat et al. ⁽⁹⁾ So ropivacaine provides more selective motor block than bupivacaine. Possible explanation for lesser motor block with ropivacaine is its lesser potency in comparison to bupivacaine. Earlier recovery with spinal ropivacaine may be associated with more patient satisfaction. The quality of intraoperative analgesia was good in all patients. No patient in any of the group complained of discomfort on skin incision. There were no statistically significant hemodynamic changes observed in both groups. Hypotension was the most frequent adverse effect in both groups. Other adverse effects like shivering, nausea and bradycardia also occurs in few patients but they have no significant difference with either drug. Heart rate, mean arterial pressure, respiratory rate and SpO₂ were comparable between both groups intraoperatively as well as post operatively.

Conclusion:

To conclude, this study demonstrates that hyperbaric ropivacaine provides a more selective unilateral block without affecting the hemodynamic parameters and is more appropriate for intermediate duration of surgical procedures. As a result, hyperbaric ropivacaine may be a good alternative agent to hyperbaric bupivacaine during unilateral spinal anaesthesia in intermediate duration of surgical procedure.

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