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Original Research Article

Can Ropivacaine 0.75% Heavy replace Bupivacaine 0.5% Heavy for Infraumbilical Day Care Surgeries?

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Abstract:

Background: Spinal Anaesthesia is the most common type of regional anaesthesia to establish dense and reliable motor blockade in infraumbilical surgeries. The present study was aimed at evaluating the efficacy of intrathecal Ropivacaine 0.75% heavy as compared to 0.5% Bupivacaine heavy for patients undergoing infraumbilical surgeries.

Materials & Methods: The study was conducted on 100 patients. All patients were randomly allocated in to two groups of 50 each, In Group RO- Patients were given 0.75% hyperbaric ropivacaine 3ml intrathecally and in group BU- Patients were given 0.5% hyperbaric Bupivacaine 3ml intrathecally. Onset of sensory block, onset of motor blockade, duration of motor block and hemodynamic were assessed. Statistical software SPSS (Statistical Package for Social Sciences) 20.0 and graph Pad Prism 6.0 version were used for analysis of the data.

Results: It was observed that there was no statistically significant difference between these two in terms of age, gender, ASA status, weight and height. There was no statistical difference in the two groups regarding the surgical duration also. The mean time of onset of sensory block in group BU was shorter than in RO group which was significant ($p<0.05$). Mean time to achieve peak sensory block in group BU was 7.92±1.1 and in group RO was 9.5±1.1 with p value <0.05 which was significant. Motor blockade was faster in group BU than in RO group. A remarkable difference in the mean duration of motor block was observed clinically and statistically ($p<0.05$). The hemodynamic parameters including HR, MAP, RR, BP were found to be more stable in group RO as compared to group BU ($p < 0.05$).

Conclusion: The present study concluded that Intrathecal hyperbaric Ropivacaine 0.75% did show promising results in terms its efficacy, safety and analgesia as it was seen with 0.5% hyperbaric Bupivacaine but with a shorter duration of motor blockade for spinal anaesthesia in infraumbilical surgeries.

Keywords: Bupivacaine, Ropivacaine, Spinal Anaesthesia, Infraumbilical Surgeries.

Introduction

With its several associated limitations, including need of multiple drugs, risk of drug interactions, and a higher risk of intraoperative and postoperative complications, general anaesthesia always takes a second seat wherever regional/local anaesthesia is an option. Local anaesthetic agents produce reversible regional anaesthesia allowing surgical procedures to be associated with reduced pain and distress to the patients.[1] Subarachnoid block is the type of regional anaesthesia resorted to for patients undergoing lower limb and lower abdominal surgeries.[2,3] Subarachnoid block has been the gold standard for providing anaesthesia with advantages such as with rapid onset of action, being easy to perform. [4] Presently, Hyperbaric Bupivacaine 0.5% is most widely used drug for spinal anaesthesia which is the racemic mixture (50:50) of S and R enantiomers.5 Albright drew attention to the dangers of this local anaesthetic agent in re-entrant arrhythmias and cardiac depression, sometimes culminating in cardiac arrest if given intravascularly. It is more cardiotoxic due to its R enantiomer. [6] The cardiotoxic disadvantage of this drug along with neurotoxicity and prolongation of motor blockade resulted in the development of newer anaesthetic agent ' Ropivacaine'.[7] Ropivacaine, a newer amino-amide local anaesthetic (LA) agent similar to bupivacaine in chemical structure, but 30-40% less potent than bupivacaine has been well-studied for spinal anaesthesia (SA). [8-11] Ropivacaine, a pure S enantiomer, is less cardiotoxic, has shorter

duration of action, and has lesser lipid solubility than bupivacaine.[12] Ropivacaine also exhibits differential blockade property (sensory > motor), leading to early return of motor activity and postoperative ambulation. [13] Various studies till date have compared the efficacy and side effect profile of equipotent doses of intrathecal hyperbaric bupivacaine and hyperbaric or isobaric ropivacaine both with and without adjuvants in different types of surgeries. [14] The present study was aimed at evaluating and comparing the efficacy of intrathecal bupivacaine 0.5% heavy and Ropivacaine 0.75% heavy for patients undergoing infraumbilical surgeries.

Materials & Methods

Prior to study a written permission from institutional ethics committee was sought and then this prospective randomised study was carried out in department of Anaesthesiology at AFSMS & RC, Dhouj, Faridabad, over a period of one year. The study was conducted on 100 patients of either gender, posted for elective infraumbilical surgeries under subarachnoid block. Common surgeries like hernia, hydrocele, vaginal hysterectomies, hysteroscopic procedure, tubal ligation, labial cysts excision, fistula in ano, tibia fracture fixation, ankle fixation, laser ablation (EVLA), RFA etc were selected. Patients included were between 18-60 years of age group with height between 150-170 cms and of ASA Physical status of I & II. Patient who refused, ASA III and above, early pregnancy, infection at the local site, allergy to the drugs under study, on anticoagulants therapy, patients with spine deformity or previous spine surgery and any other contraindication to spinal anaesthesia were excluded from the study. All patients were randomly allocated in to two groups of 50 each using computer generated randomisation. Allocation of groups was done using sealed envelope with no way of administering anaesthetists knowing about its constituents. The technical staff and patients too were blinded to the drug being used.

In **Group BU**: Patients were given 0.5% hyperbaric Bupivacaine 3ml intrathecally

In **Group RO**: Patients were given 0.75% hyperbaric ropivacaine 3ml intrathecally

All patients were evaluated in pre-anaesthetic check-up (PAC) clinic before and were re-explained the procedure planned. They were made aware of the Visual Analogue Scale (VAS) Denoting 0 as no pain and 10 as the worst imaginable pain. All patients were kept fasting overnight (Average 8hrs) and received inj. Ranitidine 50mg I/V and tab clonazepam 0.25mg as premedication. Monitoring devices for ECG, Non-invasive blood pressure monitoring, heart rate and oxygen saturation were applied and basal parameters were noted. I/V cannula of 20G/ 18G were inserted in the peripheral vein. All the patients received 500ml of lactated ringer solution as preloading. With patient in the sitting position on OT table, under strict aseptic conditions lumbar puncture was performed in L3-L4 intervertebral space using 27 g Whitcare spinal needle. Then the study drug for the patient according to the group they belong to was injected over 20 seconds and patient was placed in supine position immediately and gently. Recording of vital parameters HR, MAP, RR, SBP was done every 3min for 15 min, every 5 min. for next 15 min. and every 15 min. till 180 min. In the intraoperative period crystalloid solution (RL) 4mg /kg/hr was infused.

Onset of sensory block was assessed by using pin prick method in midclavicular line after the administration of drug every 30 seconds using 24-gauge hypodermic needle until the level got stabilized for 4 consecutive tests. Motor blockade was assessed by loss of antigravity movements of legs by Bromage scale every 30 seconds. Parameters like onset of motor blockade (time taken in minutes from deposition of the study drug into subarachnoid space to Bromage grade- 4 complete motor block of the lower limbs), duration of motor block (Time taken in minutes from the deposition of the study drug to the regression of motor block to Bromage grade- 0) were noted. In the postoperative recovery room also thorough hemodynamic monitoring was maintained and patients were monitored for regression from motor blockade and requirement of 1st rescue analgesic when VAS>=4.

Modified Bromage scale- grading guidance.

- Patient is able to move the hip; knee, ankle
- Patient is unable to move the hip; but able to move knee & ankle
- Patient is unable to move the hip and knee but able to move the ankle
- Patient is unable to move the hip, knee and ankle but is able to move the toes
- Complete motor blockade of the lower limbs

The analgesia assessment was done as planned by VAS score to which patients were made familiar before surgery in PAC. Definition criteria for duration of analgesia being the time from deposition of study drug till the injection of first rescue analgesic when VAS was >=4.

Side effects, if any like hypotension, bradycardia, and cardiac arrhythmias were noted. A fall in blood pressure of 20% from baseline was treated with vasopressors, I/V bolus of inj Mephentermine 6mg. Bradycardia being HR<60 /min was treated with I/V bolus of Atropine in increments of 0.6mg. All observational values were analysed statistically as mean ±SD, Quantitative data analysed by t- test.

Qualitative data was analysed by Chi Square test. P<0.05 was considered statistically significant. Statistical software SPSS (Statistical Package for Social Sciences) 20.0 and graph Pad Prism 6.0 version were used for analysis of the data.

Results

Table 1 shows comparative demographic data in terms of age, gender, ASA status, weight and height. It was observed that there was no statistically significant difference between these two demographically. There was no statistical difference in the two groups regarding the surgical duration also.

Table 2 shows the mean time of onset of sensory block which was 4.10±0.64min in BU group and in group RO was 6.15±0.18 min concluding that group BU had faster onset of sensory block which was significant(p<0.05). Mean time to achieve peak sensory block in group BU was 7.92±1.1 and in group RO was 9.5±1.1 with p value <0.05 which was significant. Time for the onset of motor block in group BU was 6.5±1.0 as compared to7.8±0.89 in Group RO with a p value of <0.05, stating clearly that motor blockade was faster in group BU than in RO group. Duration of motor block was 202.84±15.44 min. in group BU as compared to 140.62±14.02 in RO group. A remarkable difference in the mean duration of block was observed clinically and statistically (p<0.05).

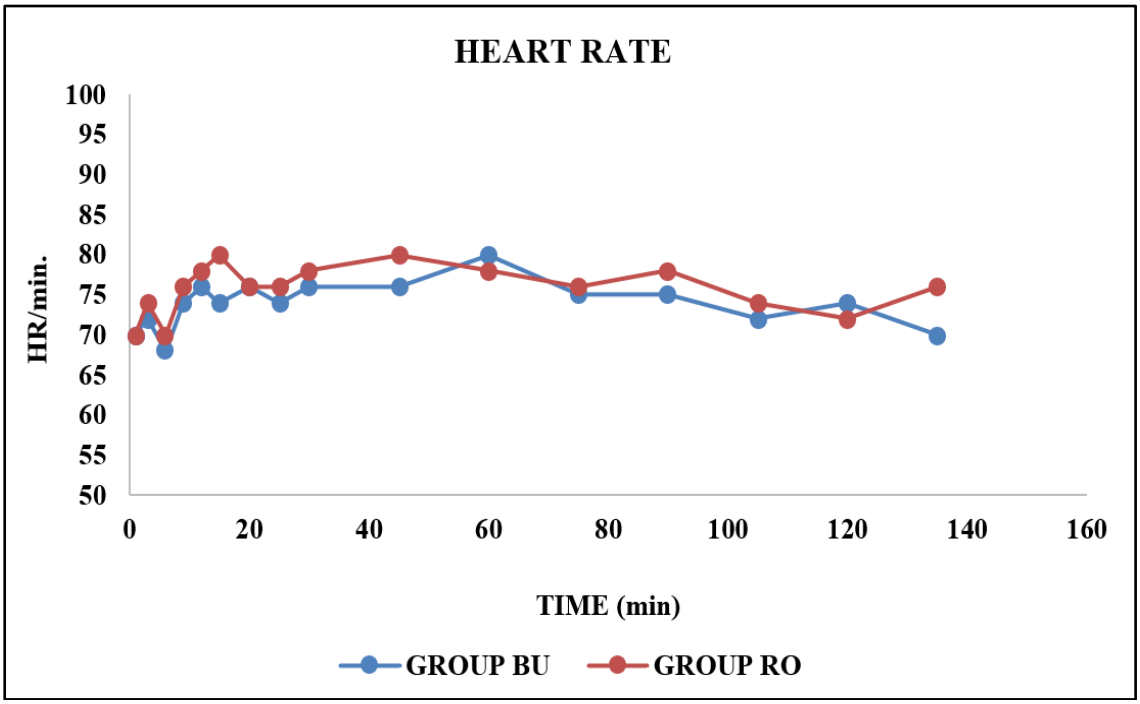
The hemodynamic parameters including HR, MAP, RR, and BP were found to be more stable in group RO as compared to group BU (p < 0.05) as depicted in graph 1, graph 2, graph 3 and table 3.

Table 1: Demographic data

Parameters	Group BU	Group RO	P value
Age	37.1 ± 12.2	40.2 ± 14.1	0.81
Sex(M/F)	23/27	21/29	>0.05
Weight	55.10 ± 7.8	56.5 ± 8.2	0.71
Height	162.65 ± 8.13	163.8 ± 7.84	0.53
Duration of Surgery	85.4 ± 14.52	83.64 ± 11.69	0.28

Table 2: Characteristics of block

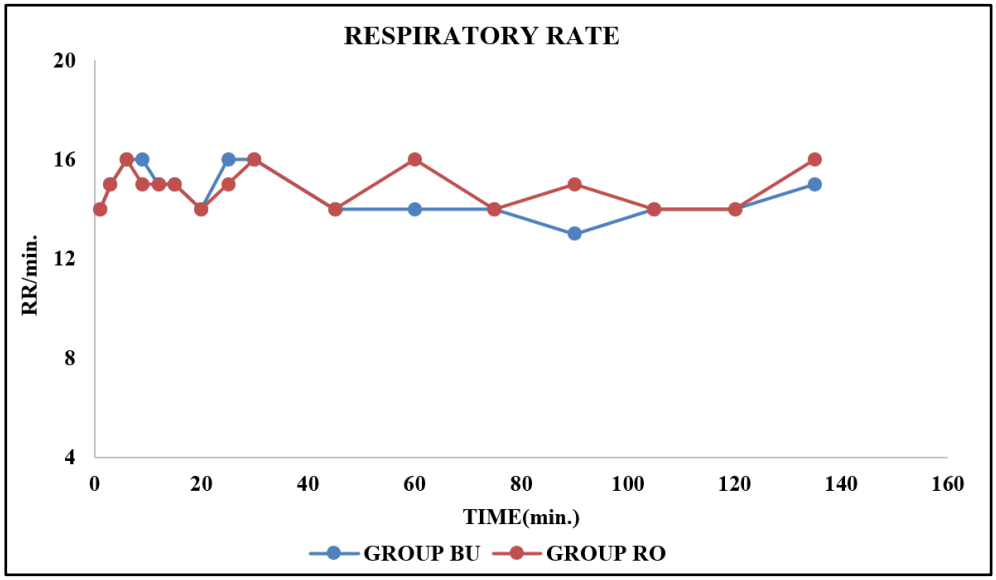
Parameter	Group BU	Group RO	P value
Onset of sensory block	4.10 ± 0.64	6.15 ± 0.18	<0.001
Time to max. sensory block level	7.92 ± 1.1	9.5 ± 1.02	<0.001
Onset of motor block	6.5 ± 1.0	7.8 ± 0.89	<0.001
Duration of motor block	202.84 ± 15.44	140.62 ± 14.02	<0.001
Total duration of sensory block	210.42 ± 12.10	205 ± 7.8	0.11



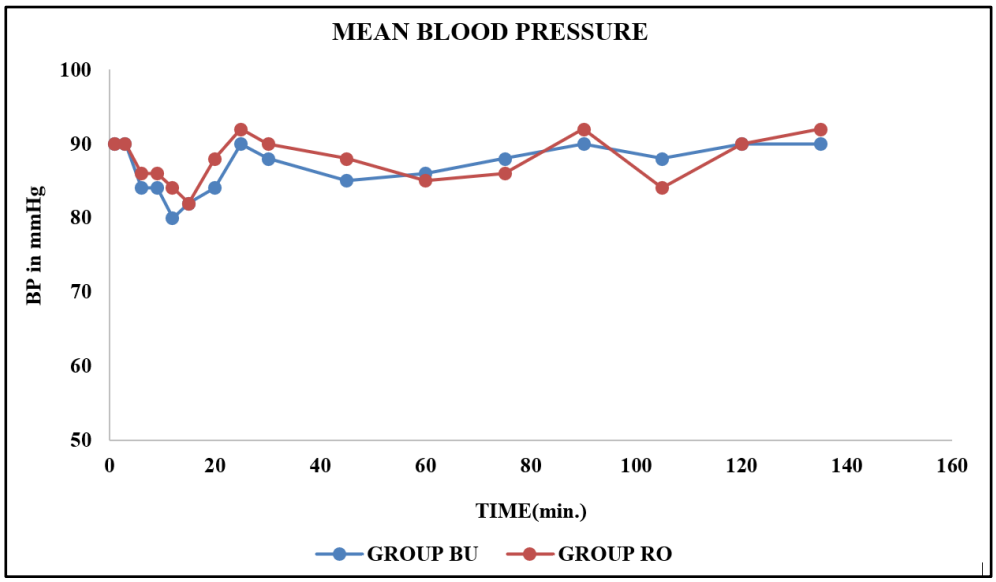
Graph 1: Comparison of mean HR between two groups

Table 3: Comparison of mean MAP between two groups

Time after Drug injected	MAP in Group BU	MAP in Group RO
1min	90mmHg	90 mmHg
3min	90mmHg	90 mmHg
6min	84mmHg	86 mmHg
9min	84mmHg	86 mmHg
12min	80 mmHg	84 mmHg
15min	82 mmHg	82 mmHg
20min	84 mmHg	88 mmHg
25min	90 mmHg	92 mmHg
30min	88 mmHg	90 mmHg
45min	85 mmHg	88 mmHg
60min	86 mmHg	85 mmHg
75min	88 mmHg	86 mmHg
90 min	90 mmHg	92 mmHg
105min	88 mmHg	84 mmHg
120min	90 mmHg	90 mmHg
135min	90 mmHg	92 mmHg



Graph 2: Comparison of mean Respiratory rate between two groups



Graph 3: Comparison of mean blood pressure between two groups

Discussion

Ropivacaine, an Senantiomer of bupivacaine, as compared to the latter, has lower potential for cardiac and central nervous systemic toxic effects and shows greater differentiation between sensory and motor blockade with more hemodynamic stability. [15] Bupivacaine is more lipophilic as compared with ropivacaine. Lesser lipophilicity is associated with reduced risk of cardiovascular toxicity with ropivacaine. [16] Overall, because of greater margin of safety than Bupivacaine, Ropivacaine can be preferred agent for spinal anaesthesia in patients undergoing surgeries of the lower limb and abdomen.

As shown in table 2, onset of sensory block was significantly faster in group BU than RO. Nema et al [17] also observed the same. No statistically significant difference was noted between the two groups in terms of highest level of sensory block achieved. From table 2 it can infer that the time to achieve a peak sensory level was significantly prolonged in RO group than in BU group and similar results were observed in a study by Chari et al [18] and Bansal et al [2].

Onset of motor blockade was significantly faster in group BU as compared to RO; similar results were seen in study by Nema et al [17], where in time of onset of motor blockade was significantly delayed in ropivacaine group 12.51±0.99min as compared to bupivacaine group 6.14±0.70min. However, in this study it was also observed that there was a significantly shorter duration of motor blockade with group RO as compared to group BU ($p<0.01$).

The result of studies done by Bhat et al [19], Kallio et al [20], Surekha et al [21]; and Malinovsky et al [22] were in accordance with our study where duration of motor blockade was significantly shorter with ropivacaine as compared to bupivacaine. The mean duration of analgesia was similar in both groups and was statistically insignificant ($p>0.05$). Serap et al23 and Chari et al [18] also showed similar results in their studies where mean duration of analgesia was similar and comparable in both the groups.

In the study by Adhikari P et al, except at 5, 15, and 90 min, there was no significant difference in the pulse rate between the two groups. At these points, the pulse rate was lower in the bupivacaine group. In the study, except at 10 min, there was no significant difference in the systolic or diastolic blood pressure between the two groups. At 10 min, systolic as well as diastolic blood pressure was lower in the bupivacaine group as compared with the ropivacaine group. The bupivacaine group was associated with a numerically higher incidence of hypotension without a significant difference between the two groups. Mean arterial pressure and SPO2 did not differ in the study groups at any time point. [24]

Conclusion

Present study brought the light the following facts:

1. Ropivacaine 0.75% heavy, no doubt did show promising results in term of its efficacy.
2. Regarding safety it scores higher (have an edge over its peers).
3. Analgesia too in equipotent doses was at par with the frequently used Bupivacaine.
4. Level of sensory block, again was in no way less than Bupivacaine.
5. But the motor blockade quality is par - excellence, albeit with the shorter duration, and to add to that was stable haemodynamic.

The pick of the property of Ropivacaine being, a drug with shorter motor duration with other observed parameters at par but scoring well in term of stable haemodynamic. Keeping this property in mind, we concluded that Ropivacaine heavy 0.75% surely can be recommended for drug of choice in patients undergoing daycare infraumbilical surgeries.

It demands further studies to corroborate over point of view.

Limitations

- All patients were either ASA I or II physical status. Results cannot be generalised to ASA III & above patients.
- Further Studies need to be undertaken to make strong recommendations.

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