Comparison between Intrathecal Isobaric Bupivacaine 0.5% with Isobaric Ropivacaine 0.75% for Lower Limb Orthopaedic Surgeries: A Double Blind Randomized Controlled Study

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ABSTRACT

Introduction: Spinal anaesthesia is probably the most widely used regional anaesthetic procedure in routine clinical anaesthesiology practice. It provides rapid onset, consistent sensory blockade and adequate muscle relaxation for all types of surgery below the level of umbilicus. The present study compared effects of plain Ropivacaine 0.75% and plain Bupivacaine 0.5% on duration of sensory and motor block for lower limb orthopaedic surgery.

Material and methods: A randomized double blind prospective controlled study involving 100 patients aged 20-50 years of ASA I and II scheduled for receiving subarachnoid block for lower limb orthopaedic surgery was conducted. The patients were divided into two groups of 50 each. Group I was given 3ml, 0.5% isobaric bupivacaine (15mg) and Group II was given 3ml, 0.75% isobaric ropivacaine (22.5mg). In this study we assessed three parameters, namely- onset time, sensory regression and motor blockade, intraoperative haemodynamic parameters and complications. Result between two groups were compared using unpaird t-test. P-value <0.05 was considered significant.

Results: The duration of sensory blockade was longer and duration of motor blockade was shorter with 0.75% ropivacaine as compared to 0.5% bupivacaine. Also the 0.75% ropivacaine provide more haemodynamic stability as compared to 0.5% bupivacaine.

Conclusion: Ropivacaine 0.75% via subarachanoid block for lower limb orthopaedic surgery provides lesser duration of motor blockade while providing adequate surgical analgesia and better haemodynamic stability in short duration day care surgery.

Keywords: Isobaric Ropivacaine, 0.75% Ropivacaine, Isobaric Bupivacaine, 0.5% Bupivacaine, Lower Limb Orthopaedic Surgery

INTRODUCTION

Subarachnoid block is the most commonly practised regional anaesthetic technique for all types of surgeries below the level of umbilicus and is relatively easier, requires less equipment and very cost effective in developing countries like India. It also provides faster onset of motor and level of sensory block with adequate muscle relaxation.

Bupivacaine is the most commonly used drug for spinal anaesthesia, but also has many undesirable effects such as hypotension, bradycardia, longer duration of motor blockade, cardiotoxicity and central nervous system toxicity.1-4

Ropivacaine is a local anaesthetic with local anaesthetic properties similar to those of bupivacaine. It is an amide and pure S(-) enantiomer of propivacaine which is effective and safe for regional anaesthetic techniques such as epidural, brachial plexus block and peripheral nerve block. Ropivacaine provides effective spinal anaesthesia for lower limb orthopaedic surgery. It provides lesser duration of motor blockade and has a better safety profile.5 Which is helpful for short duration surgeries and provides early ambulation. This study was done to compare the safety and efficacy of intrathecal plain bupivacaine 0.5% and plain ropivacaine 0.75% in patients undergoing lower limb orthopaedic surgery.

MATERIAL AND METHODS

This randomized prospective controlled study was conducted after approval from institutional ethics committee. A well explained and informed consents in written form were taken. Study comprises of 100 patients both males and females aged between 20-50 years, belonging to ASA I and II physical status scheduled for lower limb orthopaedic surgery were included in the study and were divided into two groups of 50 each. Exclusion criteria: Patient’s refusal, any contraindication of spinal anaesthesia.

Randomization was done in two groups using sealed envelop method. After securing a suitable peripheral vein all patients were administered 500ml ringer lactate solution along with 50mg i.v. ranitidine and 4mg i.v. ondansetron. The parameters monitored were non invasive blood pressure, pulse rate, SpO₂ and ECG.

Under all aseptic precautions spinal anaesthesia was given in patient placed in lateral position with affected limb uppermost via midline approach in L₁- L₂ space via 25G Quincke's tip spinal needle after local infiltration with 2ml of lignocaine 2%, on confirmation of free flow of CSF 3 ml study drug was injected over 10s. Group A received plain 0.5% (3ml) Bupivacaine, Group B received 0.75% (3ml) ropivacaine. The spinal needle was removed and patient placed supine. Supplemental oxygen was given at 3l/min with oxygen mask. A close monitoring was done for pulse rate, blood pressure, respiratory rate and SpO₂ was monitored. Bradycardia defined as heart rate <60/minute was treated with i.v. atropine 0.3-0.6mg. Incidence of side effects such as respiratory depression, nausea, and vomiting was minimized.

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recorded. Sensory block level was assessed by loss of pinprick sensation using 23G needle at every 2 minutes interval and time to reach sensory block at T₁₀ dermatome was recorded. Motor block onset was assessed by modified Bromage scale and time to achieve complete motor block of lower limbs (Bromage-0) was recorded. Modified Bromage scale was scored as follows: Bromage-0: Patient unable to move hip, knee and ankle. Bromage-1: Patient unable to move the hip, but is able to move the knee and ankle. Bromage-2: Patient unable to move the hip and knee but able to move the ankle. Bromage-3: Patient unable to move the hip, knee and ankle. When T₁₀ sensory level and Bromage-3 score were attained, surgery was allowed. Meanwhile, assessment was done every 10 minutes till the time of two segment regression of block. Thereafter, assessment was done at 20 minutes interval till the block height decreased to S₉ dermatome. Data regarding time to reach T₁₀ dermatome and Bromage-3 and time to S₉ level sensory regression, and time to reach Bromage-0 were recorded and compared.

**STATISTICAL ANALYSIS**

Statistical computer software SPSS version 15 (statistical packages for Social sciences, Chicago, IL, USA) was used for statistical analysis. Data was expressed as either mean +/- Standard Deviation (SD) or number and percentage. Unpaired t-test was used to test the significance of results of quantitative variables. Chi-square test was used to test the significance of results of quantitative variables. P<0.05 was considered statistically significant.

**RESULT**

Both the groups were comparable with regard to age, sex ASA grading and duration of surgery. Onset of sensory block for plain bupivacaine and plain ropivacaine have no intergroup significance (6.36 ±1.76 and 6.16 ±1.72 minutes respectively) as summarized in Table-1. However in 0.5% bupivacaine group we found slight higher level of block i.e. up to T₇ dermatome. Level achieved in both groups was not statistically significant. Highest level of sensory block in 0.75% ropivacaine achieved was T₁₀ as shown in Graph-1.

Time to achieve complete motor blockade (modified bromage scale 3) was shorter in bupivacaine group as compared to ropivacaine group (11.50 ± 3.272 and 15.39 ± 3.166 minutes respectively) and the difference was statistically significant. Sensory regression to S₉ segment for bupivacaine and ropivacaine (296.2 ± 25 and 315 ± 38.5 minutes respectively) was prolonged in ropivacaine group and was statistically significant. Level of motor block regression to Bromage 0 was significantly prolonged in bupivacaine group as compared to ropivacaine (217.14 ± 20.158 and 161.07 ± 19.310 minutes respectively) and was statistically significant, summarized in Table – 1. Values are expressed as mean +/- SD and P value ≤0.05 is considered significant.

**DISCUSSION**

Regional anaesthesia like sub arachanoid block. has many advantage including lower incidence of pulmonary and
cardiovascular complications, better post-operative pain management, lower incidence of deep vein thrombosis and pulmonary embolism.\textsuperscript{3} Newly introduced long acting amide local anaesthetic like Ropivacaine blocks A\textsubscript{6} and C fibres (pain) more completely than A\textsubscript{a} (motor) fibres and among A\textsubscript{6} and C fibres it blocks C fibres faster than A\textsubscript{6} fibres.\textsuperscript{8}

Our study is aimed to compare relative anaesthetic efficacy and safety of plain bupivacaine vs ropivacaine for spinal anaesthesia in ASA Grade I and II between age group 20-50 years as also done by Halena Kallio et al\textsuperscript{9}, D.A. McNamee\textsuperscript{10}, A.M. McClelland et al\textsuperscript{11}, and Jack W Vankleef et al\textsuperscript{12} In our present study we performed subarachnoid block with the patient placed in lateral position with affected limb uppermost, which was also done by A.M. McClelland et al\textsuperscript{11} and M.C. Shesky et al\textsuperscript{13} and they explained that this solution is slightly hypoobaric which explain the greater cephalad spread when it is injected in lateral position with affected limb uppermost. In our study we use bupivacaine 0.5\%, 3ml (15mg) and ropivacaine 0.75\%,3ml (22.5mg) as also used by Jack VanKleef et al\textsuperscript{12} and Shesky et al\textsuperscript{13} In our present study there was slight reduction in mean arterial pressure after spinal block in both the groups, which however was significant in Bupivacaine group. There was decrease in heart rate after spinal block in both the groups however there were no significant inter group differences which were also reported by M.Mantouvalou et al\textsuperscript{14}, Shesky et al\textsuperscript{15}, Mc Namee et al.\textsuperscript{16} No change in respiratory rate were reported in two groups.

In our study onset of sensory block took 6.36±1.76 minutes for 0.5\% Bupivacaine and 6.16±1.76 minutes for 0.75\% ropivacaine and there was no intergroup significane. The highest level of sensory block in 0.75\% ropivacaine achieved was T\textsubscript{10} as also reported by Van Kieff et al.\textsuperscript{12} However in 0.5\% Bupivacaine we found slight higher level of block i.e. T\textsubscript{10} dermatome which was not statistically significant which was similar to the study done by D.A. Mc Namee et al.\textsuperscript{13}

Sensory level achieved in our study was in contrast to study done by Shesky Mc et al.\textsuperscript{17} The time to achieve complete motor blockade (Modified Bromage scale) was shorter in Bupivacaine group (11.50±3.272) than ropivacaine group (15.39±3.166). Total duration of motor block was significantly prolonged in Bupivacaine group which coincide with the study done by Van Kieff et al.\textsuperscript{12} This may be explained by, lesser lipid solubility of ropivacaine may cause this drug to penetrate the large myelinated A fibres more slowly than the more lipid soluble Bupivacaine.

Intraoperative hypotension is more in Bupivacaine group than in Ropivacaine group. No significant changes reported in heart rate, SpO\textsubscript{2}, respiratory rate, nausea and vomiting, which was also supported by studies of Mc Namee DA et al\textsuperscript{18}, Malinovsky JM et al\textsuperscript{19}, Gautier PE et al.\textsuperscript{20}

CONCLUSION

We conclude from this study that Ropivacaine 0.75\% via subarachnoid block provides lesser duration of motor blockade and more duration of sensory blockade while providing adequate surgical analgesia and better hemodynamic stability in short duration day care surgeries as compared to 0.5\% Bupivacaine.

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