

Comparison of 0.5% Bupivacaine and 0.5% Ropivacaine epidurally in lower limb orthopaedic surgeries

Ushma D. Shah*, Krunal N. Dudhwala, Mukesh S. Vakil

Department of Anaesthesiology,
Sal Hospital and Medical
Institute, Ahmedabad, Gujarat,
India

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***Correspondence to:**

Dr. Ushma D. Shah,
Email:
ushmakhushi@gmail.com

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ABSTRACT

Background: Ropivacaine in equi-potent concentrations with bupivacaine, the degree of motor blockade is less pronounced with ropivacaine, and there is a greater propensity for blocking pain transmitting A-delta and C fibres rather than A- α motor fibres. It appears to have most of the blocking characteristics of bupivacaine. So we have undertaken the study to compare ropivacaine 0.5% (20ml) and bupivacaine 0.5% (20ml) for epidural anaesthesia in patients undergoing lower limb orthopaedic surgeries.

Methods: This double-blind, randomized study involves 60 patients who were undergone orthopaedic surgery, having ASA-I or ASA-II physical status. Out of 60, 30 patients received 20 ml of 0.5% ropivacaine and 30 patients received 20 ml of 0.5% bupivacaine at the L3, 4 interspace. Parameters measured were the onset time, duration and spread of sensory block, the onset time, peak time, duration and degree of motor block, the quality of anaesthesia and the heart rate and blood pressure profile during block onset.

Results: Epidurally, Ropivacaine in comparison to Bupivacaine provides quicker onset, early peak effect and prolonged duration of sensory block and shorter duration of motor block. Ropivacaine provides prolonged effective analgesia. It reduces requirement of rescue analgesics and related side effects.

Conclusions: Ropivacaine 0.5% is safer and effective alternative to Bupivacaine in epidural anaesthesia and post operative pain relief.

Keywords: Bupivacaine, Epidural, Lower abdominal surgery, Ropivacaine

INTRODUCTION

The recognition of acute life-threatening cardiotoxicity of bupivacaine lead to the search for a local anaesthetic agent comparable with bupivacaine but with lower cardiotoxicity resulting in development of a relatively new amide, ropivacaine. Ropivacaine is produced as pure 'S' enantiomer with lower lipid solubility, easier reversibility after inadvertent intravascular injection, significant reduction in central nervous system toxicity, lesser motor block and greater differentiation of sensory and motor block.^{1,2,3} In equi-potent concentrations the degree of motor blockade is less pronounced with ropivacaine, and there is a greater propensity for blocking pain transmitting A-delta and C fibres rather than A- α motor fibres. Ropivacaine has enormous potential as a local anaesthetic agent.^{4,5,6} It appears to have most of the blocking characteristics of bupivacaine. These findings

created interest to study this new anaesthetic agent for block characteristics and safety profile and to compare this drug with commonly used drug bupivacaine and to know whether it can replace this older anaesthetic agent in future. So we have undertaken the study to compare ropivacaine 0.5% (20ml) and bupivacaine 0.5% (20ml) for epidural anaesthesia in patients undergoing lower limb orthopaedic surgeries.

METHODS

A randomized prospective clinical study of patients undergoing elective lower limb orthopaedic surgeries receiving either epidural ropivacaine or bupivacaine was undertaken after obtaining written informed consent and institutional approval. Sixty patients divided into two groups of 30 each by computer generated random number, Group R to receive 20 ml of 0.5% ropivacaine

and Group B to receive 20 ml of 0.5% bupivacaine. We included adult patients aged between 18 and 65 years of both sexes of American Society of Anaesthesiologists (ASA) physical status Grade I and II for the study. Exclusion criteria included known allergy to local anaesthetics, local infections, coagulopathy, and patients on antiarrhythmic treatment. All patients were matched for Indian height and weight. After pre anaesthetic checkup, patients were kept fasting from previous night and premedicated with Inj. Atropine 0.6mg iv and Inj. Ranitidine 50 mg iv were given and preloading was done with Inj. Ringer Lactate 10ml/kg body weight 20 minutes prior to induction. All epidural blocks were performed under strict aseptic precautions in sitting position and 18 G epidural needle was inserted in L3-4 interspace (midline approach) and epidural catheter was introduced. After 3 min of test dose of 2 ml 2% lignocaine with adrenaline 1:200,000, in absence of signs of subarachnoid and intravascular injection, 20 ml of test drug was administered over 2 min in increments, after negative aspiration for blood and cerebrospinal fluid. Time of completion of injection of drug was recorded as 0 min. In both the groups, bilateral blockade assessments were performed repeatedly at 1, 3, 5, 10, 15; 30 min then after every 30 min till surgery is over. Onset of sensory block measured as time interval from injection of drug epidurally to dull sensation on pin prick with 24G hypodermic needle at L1 Dermatome. Peak of blockade measured as Loss of sensation to pin prick (with 24 G hypodermic needle) at L1 Dermatome, Highest level of sensory block to be achieved is T10 and time to achieve the same were noted. Duration measured as Time interval between onsets of sensory block to regression of segmental sensory block to L1 dermatome again. Two segment regression of the sensory blockade from the maximum sensory segmental level (T10) as well as total duration of sensory blockade was noted too. Motor block estimated at these same intervals using the BROMAGE scale. Onset of motor block, Maximum motor block achieved, Time to achieve maximum motor block and Duration of motor block were noted. All the patients were given Inj. Midazolam 0.01-0.02 mg/kg intravenous as sedation. All the patients were monitored for vital parameters, sensory and motor blockade and complications if any. Vital parameters were monitored using multipara monitor. Pulse Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Oxygen saturation were recorded at 0, 1, 3, 5, 10, 15, 30 min and there after every 30 mins till the end of the surgery. All the patients were monitored for any intraoperative complications like - Hypotension, Bradycardia, Nausea / vomiting. Top up dose of 5 ml of group drug was given if sensory level regresses to L1 and time for the same was noted. Duration of surgery (In hours), total amount of blood loss and fluid replaced were noted. Epidural catheter was removed at the end of the surgery. The patients were monitored post operatively for vital parameters, analgesia and any complication every hourly till 8 hrs and thereafter 6 hourly till 24 hours. Pain was noted in the both the groups using visual analogue scale (VAS). A

linear visual analogue scale of 10 cm was used graded from 0-10 that is from no pain to worst pain. The patient was asked to mark the point on the scale that corresponds to his/her intensity of pain. The duration of effective analgesia was counted from epidural administration of drug to first dose of rescue analgesia. Rescue analgesia (RA) in form of Inj. Diclofenac 1.5 mg/kg intra muscular was administered when the VAS was more than and equal to 4. Inj. Diclofenac 1.5 mg/kg IM was repeated if the patient complained of pain in next 24 hours. Total no. of analgesics required in first 24 hours was noted. The patients were observed for the complications. The results of the study were tabulated and statistically analyzed using Student's t test and Chi square test after calculating mean and Standard Deviation (SD) for the individual group and the inter and intra group comparison. The P value <0.05 considered significant and P value <0.001 highly significant.

RESULTS

Demographic data in terms of age, sex, ASA physical status, mean duration of surgery, types of surgeries were comparable in both the groups. The mean time for onset of sensory block was 106.33 ± 13.51 sec in Group R and 168.66 ± 17.75 sec in Group B. The mean time for peak effect of sensory block was 3.56 ± 0.63 min in Group R and 7.66 ± 0.84 min in Group B. The mean time to achieve highest level sensory block was 7.56 ± 1.07 min in Group R and 11.73 ± 1.04 min in Group B which was achieved faster in Group R than in Group B. Thus the onset, peak effect and duration of sensory blockade were faster in Group R than in Group B. The mean duration of sensory block was 257.66 ± 14.78 min in Group R and 222 ± 20.24 min in Group B, the difference being statistically highly significant ($P < 0.001$). In both the groups, maximum height of segmental sensory block achieved was T10 in most of the patients (28 in Group R and 29 in Group B) which is comparable. The mean time for onset of motor block was 525 ± 50.29 seconds in Group R and 505 ± 56.31 seconds in Group B. The mean time for peak effect of motor block was 26.83 ± 2.07 min in Group R and 25.93 ± 1.76 min in Group B. The mean duration of motor block was 202 ± 17.49 min in Group R and 260 ± 18.19 min in Group B. Thus in Group R the onset, peak effect and duration of sensory block was faster compared to Group B. Duration of motor block was shorter in group R in comparison to Group B. Surgical anaesthesia was adequate in all the cases and there was not a single failure case in either of the two groups. None of the patients in both the groups required epidural top up dose. The intra-group and inter-group comparison did not show any significant change in mean pulse rate, systolic and diastolic BP and SpO₂ throughout the study when compared with pre-operative values. The duration of effective analgesia was counted from epidural administration of drug to when VAS score of 4 or more. Postoperatively, the mean VAS score was lower in group R (0,0.93,1.7, 2.17, 2.87, 3.47,3.93,4 at 1,2,3, 4,5, 6,7, 8 hours) than in group B (0.13,1.07,2.0, 2.53,3.47,4 at 1, 2,

3, 4, 5, 6, 7,8hours) respectively. On inter-group comparison, there showed statically significant difference in mean VAS score at 2, 3, 4 (p <0.05) and highly significant at 5, 6 hours (P<0.001). At the end of 3 hours none of the patients required rescue analgesics in both the groups (VAS score 2.0 ± 0.49 in group B Vs 1.7 ± 0.45 in group R). At the end of 4 hours, mean VAS score was 2.17 ± 0.38 but none of patients were given rescue analgesia in Group R while it was 2.53 ± 0.57 and 01 (03.33%) patient was given rescue analgesia in Group B. At the end of 5 hours, mean VAS score was 2.87 ± 0.56 and 03 (10%) patients were given rescue analgesia in Group R while it was 3.47 ± 0.51 and 14 (46.67%) patients were given rescue analgesia in Group B. At the end of 6 hours, mean VAS score was 3.47 ± 0.51 and 14 (46.67%) patients were given rescue analgesia while it was 4 in Group B and , remaining patients (100%) were given rescue analgesia At the end of 8 hours, mean VAS score was achieved 4 Group R and remaining patients (100%) were given rescue analgesia. The mean duration of analgesia was 375 ± 45.77 min in Group R as compared to 312 ± 35.76 min in Group B, thus it was prolonged in Group R, the difference being statistically highly significant. Also the analgesic requirement in 24hr post operative period was less; 2.17 ± 0.46 in Group R as compared to 2.7 ± 0.53 in Group B with 20% reduction in diclofenac requirement in Group R. There were no postoperative sequelae like headache, backache, nausea and vomiting for next 24 h.

DISCUSSION

Epidural anaesthesia reduces perioperative physiologic responses in addition to providing pain relief. Ropivacaine was identified in 1957, but not evaluated fully until 1988 after the alarming editorial by Albright observing difficult resuscitation and poor outcome after accidental intravascular injection of bupivacaine.⁷ In the present study, in patients who received ropivacaine the mean onset time of sensory block was faster than in those who received bupivacaine. The onset, peak effect and duration of sensory blockade were faster in Group R than in Group B. In a similar study, Finucane et al.⁸ found that onset time for sensory block to T12 was shorter in 0.5% ropivacaine group when compared to 0.5% bupivacaine group. The mean time for onset and peak effect of motor block was early in Group B. Duration of motor block was shorter in group R in comparison to Group B. Brockway et al.⁹ showed that motor block produced by ropivacaine was slower in onset. Time for two segment regression of sensory block in both groups was comparable. Concepcion et al.⁵ found a mean time for two segment regression as 164 ± 22 min for ropivacaine, which was comparable to present study. The mean duration of analgesia was 375 ± 45.77 min in Group R as compared to 312 ± 35.76 min in Group B, thus it was prolonged in Group R, the difference being statistically highly significant. The mean time for complete motor recovery in present study was comparable in both groups. Brown et al and Cekmen et al showed that duration of motor

block was significantly longer in the 0.5% bupivacaine group as compared to 0.5% ropivacaine. Zaric et al found that motor blockade with 0.75% ropivacaine was comparable to 0.5% bupivacaine.^{4,6,10} There were no significant changes in mean pulse rate and mean arterial pressure between two groups in present study, findings shared by other studies.^{4,5,9} There were no postoperative sequelae like headache, backache, nausea and vomiting for next 24 h which is in consonance with Brown et al.⁴

CONCLUSION

Epidurally, Ropivacaine in comparison to Bupivacaine provides quicker onset, early peak effect and prolonged duration of sensory block and shorter duration of motor block, prolonged effective analgesia. It reduces requirement of rescue analgesics and related side effects. It provides stable hemodynamics. Thus, Ropivacaine 0.5% is safer and effective alternative to Bupivacaine in epidural anaesthesia and post operative pain relief.

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