

COMPARISON OF ROPIVACAINE AND BUPIVACAINE AS SINGLE-SHOT EPIDURAL ANAESTHESIA FOR ORTHOPAEDIC SURGERY

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ABSTRACT

Objective: To compare the efficacy and side-effects of 0.5% ropivacaine with that of 0.5% bupivacaine when used for single-shot epidural anaesthesia for orthopaedic surgery.

Design: Randomized controlled trial.

Place and Duration of Study: Department of Anesthesiology, Combined Military Hospital Rawalpindi, over a period of eight months from June 2013 to January 2014.

Patients and Methods: The study was carried out in 60 ASA physical status I, II or III patients undergoing elective lower extremity orthopedic surgery. Two groups of 30 patients each received single-shot epidural anaesthesia either with ropivacaine 0.5% (ropivacaine group) or bupivacaine 0.5% (bupivacaine group). Onset, time for maximum height and median height of sensory block was assessed as well as time to two segment recession. Modified Bromage scale was used for motor blockade. Total duration of motor block and common side effects were also recorded.

Results: The patients in both groups were similar in age, height, weight, gender and ASA status. There was no significant difference in onset of sensory block and time for maximum height of sensory block. The median highest level of sensory block was T6 (T5-T8) for ropivacaine group and T5 (T4-T7) for bupivacaine group. Time for two segment regression and duration of sensory block were also comparable for both groups. The total duration of motor block was significantly more in bupivacaine group (159 min vs 134.2 min, $p < 0.001$). Modified Bromage scale was also significantly higher in bupivacaine group (2.86 vs 1.96 min, $p < 0.001$). Side effects like hypotension, bradycardia, nausea, vomiting and shivering were similar in both groups.

Conclusion: Epidural administration of 0.5% ropivacaine provided effective and good quality anaesthesia. Motor blockade was of less duration as compared to equivalent dose of 0.5% bupivacaine, which may offer potential benefit of early patient mobilization after orthopaedic surgery.

Keywords: Epidural anaesthesia, Local anaesthetics, Ropivacaine.

INTRODUCTION

Ropivacaine is now available in Pakistan, marketed as Ropicaine® by Howards. This study was performed to compare the anaesthetic characteristics of epidurally administered 0.5% ropivacaine with that of 0.5% bupivacaine in equal doses for orthopaedic surgery of lower limbs. Ropivacaine is structurally closely related to a chemical group of aminoamides in present clinical use, e.g. bupivacaine and mepivacaine. The latter are racemic mixtures, whereas

ropivacaine is the pure (S)-enantiomer. The S-enantiomer produces anaesthesia of longer duration than the racemate-form¹. S enantiomers are said to have less CNS and cardiac toxicity than R enantiomers. It is because of their different affinity for different sodium, potassium and calcium ion channels². In addition, ropivacaine has been shown to have vasoconstrictor properties³. It is available as the monohydrate of the hydrochloride salt of 1-propyl^{1,2}, 6-pipecoloxylidide. In animals, ropivacaine has shown lesser CNS and cardiac toxicity than bupivacaine⁴. Initial clinical studies of epidural anaesthesia have indicated that pharmacodynamic and pharmacokinetic properties for ropivacaine are comparable to those seen with bupivacaine⁵⁻⁶. Both drugs have shown comparable onset and duration of sensory block and the anaesthesia efficacy.

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When used in equal concentrations, ropivacaine has shown less degree of motor block than bupivacaine. There are fewer chances of arrhythmias and less cardiotoxicity with ropivacaine as compared to bupivacaine⁷

Adverse events with ropivacaine have mainly been those compatible with the sympathetic block of epidural anaesthesia (hypotension, bradycardia, nausea and vomiting). The incidence of these events appears to be similar after ropivacaine and bupivacaine⁸.

METHODOLOGY

These randomized controlled trials were carried out at the Department of Anaesthesia, CMH Rawalpindi from June 2013 to January 2014 in patients undergoing lower limb orthopaedic surgery. The study was carried out in 60 patients, who were randomly divided into

taking beta adrenergic blocking medication were not included in the study. Pre anaesthetic checkup was carried out one day before and informed written consent was taken from all patients. Patients were kept nil per oral for at least 8 hours. The study solutions were prepared by a consultant anesthesiologist in identical appearing 20 ml disposable syringes so that anesthesiologist performing the procedure and later observing the effects of drugs was not aware of the identity of study drug.

All patients were preloaded with 10 ml/kg Ringer's solution. In sitting position, skin was infiltrated with 3 ml 1% lignocaine. We identified epidural space using loss of resistance at L2-3 or L3-4 interspace in the midline with a 16 or 18 gauge Tuohy needle. With the bevel of the needle directed cranially, a 3 ml dose of the study solution was

Table-1: Comparison of demographics variables between the group value.

	Ropivacaine 0.5% (n=30)	Bupivacaine 0.5% (n=30)	p-value
Age (years) Mean \pm SD	46.66 \pm 11.75	49.1 \pm 10.79	0.203
Weight (kg) Mean \pm SD	65.43 \pm 8.87	62.3 \pm 8.25	0.081
Height (cm) Mean \pm	155.9 \pm 20.0	157.36 \pm 10.46	0.361
Gender (Male/Female)	18/12	21/09	0.416
ASA Status I/II/	12/08/10	11/07/12	0.864

Table-2: Comparison of sensory block between the groups.

	Ropivacaine (n=30)	Bupivacaine (n=30)	p-value
Onset of sensory block (in min)	15.63 \pm 1.47	15.71 \pm 1.64	0.418
Time for maximum height of sensory	35.25 \pm 3.51	36.21 \pm 3.23	0.136
Time for two segment regression (min)	86.73 \pm 9.24	86.5 \pm 9.79	0.462
Time for regression of sensory block to i.e, duration of sensory block (in min)	112.182 \pm 6.81	180.46 \pm 16.76	0.315

two equal groups. Group-1(ropivacaine group) received 0.5% ropivacaine while group-2 (bupivacaine group) received 0.5% bupivacaine. Written informed consent was obtained from each patient. Patients included in the study were at least 18 years old, ASA status¹⁻³, and weight 60-90 kg. Pregnant women and those

administered and then a catheter inserted through the needle 3 - 5 cm into the epidural space. The patients were then placed supine and a further 17 ml of the study drug was administered over a three- to five-minute period. All patients received 100 mg (0.5% of 20 ml) of the study drug.

Blood pressure, pulse rate and respiratory rate were recorded at frequent time intervals. Fall in blood pressure and heart rate variation were treated and recorded. Complete loss of sensation at T10 was taken as onset of sensory block. Maximum height of block was recorded. Regression of sensory block at T12 was taken as duration of sensory block.

Complete return of normal motor and sensory function was also recorded. Modified Bromage scale was used for motor block, 0 = no motor block, 1 = inability to raise the extended

received 0.5% bupivacaine. The patients were similar regarding age, height, weight, gender and ASA status (table-1). Onset of sensory block and time for maximum height of sensory block were comparable. For ropivacaine group the median highest level of sensory block was T6 (T5-T8) and T5 (T4-T7) for bupivacaine group. Time for two segment regression and time for regression of sensory block to T12 i.e., duration of sensory block were also comparable for both groups (table-2).

For assessment of motor blockade a

Table-3: Motor block data is presented as Mean \pm SD.

	Ropivacaine	Bupivacaine	p-value
Total duration of motor block (in min)	134.2 \pm 11.29	159 \pm 10.13	< 0.001
Modified Bromage grading of motor block	1.96 \pm 0.92	2.86 \pm 0.89	< 0.001

Values are expressed as maxm \pm SD

Table-4: Most common side effects and drug interventions.

Events	Ropivacaine 0.5% (n=30)	Bupivacaine 0.5% (n=30)	p-value
Hypotension	14 (46%)	13 (43%)	0.411
Ephedrine required	10 (33%)	09 (30%)	0.770
Bradycardia	8 (26%)	7 (23%)	0.549
Atropine required	8 (26%)	7(23%)	0.744
Nausea	3 (10%)	4 (13%)	0.325
Vomiting	2 (6%)	3 (10%)	0.171
Shivering	2 (6%)	1 (3%)	0.647

Values are presented as frequency (%)

leg, 2 = inability to flex the knee, 3 = complete motor block. In case of total failure of an epidural block, the patient was withdrawn from the study and replaced by next available patient. Data was analyzed using Statistical Package for Social Sciences SPSS for Windows version 20. Descriptive statistics were used to describe the results. Independent sample t-test was used to assess the statistical significance of qualitative variables while chi-square test was used for comparison of qualitative variables between the groups. A *p*-value <0.05 was considered statistically significant.

RESULTS

Sixty patients were enrolled in the study, 30 of whom received 0.5% ropivacaine and 30

modified Bromage scale was used. Table 3 shows the total duration of motor block and modified Bromage scale in each group. The total duration of motor block was significantly higher in bupivacaine group (*p*<0.001). Similarly the modified Bromage scale was also significantly higher in bupivacaine group (*p*<0.001). Hypotension occurred in 14 patients of ropivacaine group while 13 patients of bupivacaine group exhibited of hypotension. Other side effects like bradycardia, nausea, vomiting, shivering and itching, the results were comparable. The requirement of ephedrine to treat hypotension and atropine to treat bradycardia was also similar among both groups (table-4).

DISCUSSION

Our study was aimed at comparing the anesthetic efficacy of newly introduced in Pakistani market local anaesthetic ropivacaine with that of bupivacaine, when both drugs were administered epidurally in same concentrations and same volumes. Patients under study were being operated for lower limb orthopedic surgeries. Lumbar epidural is now considered a better technique for lower limb surgery. It provides complete analgesia for as long as the epidural is continued allows the patient to mobilize early in post-operative period. It is proved that epidural techniques decrease blood loss during surgery and incidence of certain complications like respiratory infections, pulmonary embolism and post-operative ileus⁹

Bupivacaine's major disadvantage is its cardiotoxicity when used for epidural block¹⁰ To reduce the potential toxicity associated with bupivacaine, a long acting anaesthetic ropivacaine is developed¹¹⁻¹². Onset of sensory block to T10 with ropivacaine and bupivacaine was comparable in our study. Campbell¹³ and Dresner found similar results¹⁴.

In our study the maximum height of sensory block by two groups was T5. Similar results were shown by Wolff¹⁵ as well as Finegold¹⁶. We found that our results are in contrast to the results obtained by Katz et al who observed that the times to two segment regression were 162 ± 48 min with bupivacaine and 204 ± 60 min with ropivacaine, while our results were 86.73 ± 9.24 and 86.5 ± 9.79 respectively¹⁷. The time for regression of sensory block to T12 was similar for both drugs in our study. Similar results were shown by McGlade¹⁸.

We used modified Bromage scale for assessment of motor block. It was 1.96 ± 0.92 with ropivacaine and 2.86 ± 0.89 with bupivacaine. Ropivacaine is less lipophilic than bupivacaine, so less likely to penetrate the large myelinated motor fibers resulting in less intensity of motor block¹⁹. Greater degree of motor and sensory differentiation is useful when motor blockade is undesirable. Similar results have been shown by Morrison et al²⁰.

While Brown et al failed to find any difference in the intensity of motor blockade between the two drugs²¹. A less intense motor block may be an advantage in certain situations such as in obstetric or postoperative epidural analgesia.

In our study duration of motor block existed for 134.2 ± 11.29 min for ropivacaine and 159 ± 10.13 min for bupivacaine. Therefore ropivacaine's duration of motor block is less than bupivacaine. Brown et al also found similar results²¹. The common side effects were hypotension (14 vs 13) and bradycardia (8 vs 7). Ten patients in ropivacaine group while nine patients in bupivacaine group required ephedrine to correct hypotension. Similarly eight patients of ropivacaine while six patients of bupivacaine group required atropine to correct bradycardia. While a minor population of both groups suffered from side effects like nausea, vomiting, shivering and itching.

In summary, this study has not demonstrated any significant differences between the clinical effects produced by epidural ropivacaine 0.5% or bupivacaine 0.5%.

CONCLUSION

Ropivacaine is a relatively newer long acting regional anaesthetic. It produces less degree of motor block than bupivacaine which is desirable in certain situations. Additionally it has reduced potential for CNS and cardiac toxicity.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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