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A RANDOMIZED CONTROL STUDY TO COMPARE 0.5% ROPIVACAINE WITH FENTANYL AND 0.5% BUPIVACAINE WITH FENTANYL IN EPIDURAL ANESTHESIA FOR PATIENTS UNDERGOING LOWER ABDOMINAL AND LOWER EXTREMITY SURGERIES.

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ABSTRACT **Background:** Bupivacaine is a potent local anesthetic commonly used in epidural anesthesia but has cardiotoxic effect, Ropivacaine is a new long-acting, similar to bupivacaine, but with less potential for cardiac toxicity, purpose of this study is to compare the effectiveness of ropivacaine and bupivacaine in epidural blockade for elective lower abdominal and lower extremity surgeries. **Materials And Methodology:** This is a prospective, randomized trial, with a hundred patients divided into two groups of 50 each. In Group A fifty (n=50) received 20 ml of ropivacaine 0.5% with 2microgram/ml fentanyl and Group B received 20 ml of 0.5% bupivacaine with 2microgram/ml fentanyl. The two study groups were compared with respect to onset, duration, and level of sensory block. The time for the onset of motor block, total duration of motor block, and hemodynamic changes were also recorded. Quantitative data and categorical data were analyzed using ttest and Chisquare test, respectively. $P < 0.05$ was considered statistically significant. **Results:** The time of onset of sensory block was shorter in Ropivacaine group when compared to Bupivacaine group (11.2 min vs 14.6 min, $p<0.05$). The time taken for onset of motor block (19.8 min vs 25.6 min, p,0.05) and total duration of motor block (212.5 min vs 254.7 min, $p< 0.05$) was shorter in Ropivacaine group when compared to that of Bupivacaine group. Other recorded parameters like time taken for maximum sensory block and time taken for regression up to T12 was slightly shorter in Ropivacaine when compared to Bupivacaine but statistically non-significant. The time taken for two dermatome regression and Hemodynamic changes in both groups were similar. **Conclusion:** Time taken for onset of sensory and motor block and total duration of motor block was shorter in Ropivacaine compared to Bupivacaine, other parameters and hemodynamic changes were similar in both groups. Thus, concluding Ropivacaine is better alternative to Bupivacaine in epidural anesthesia for lower abdominal and lower extremity surgeries with lesser cardiotoxic effects.

KEYWORDS : Ropivacaine, Bupivacaine, Epidural anesthesia

INTRODUCTION:

Bupivacaine is a potent local anesthetic with unique characteristics from the amide group of local anesthetics which led its wide spread use in epidural anesthesia but with the recognition of acute life-threatening cardiotoxicity of bupivacaine lead to the search for a local anesthetic agent comparable with bupivacaine but with lower cardiotoxicity resulting in development of a relatively new amide, Ropivacaine which is a medium- to long-acting local anesthetic of the amino amide class.[1-3]

Ropivacaine is produced as pure 'S' enantiomer with lower lipid solubility, easier reversibility, and has been shown to produce peripheral nerve anesthesia of longer duration than either the racemate or the R-form. Like other local anesthetics ropivacaine elicits nerve block via reversible inhibition of sodium ion influx in nerve fibres.[4] It blocks C-fibres faster than A fibers, but the blockade of A fibers is less with ropivacaine than a similar concentration of bupivacaine, whereas the degree of C-fibre block was similar with both drugs. The analgesic potency of ropivacaine is similar to that of bupivacaine while motor block is less pronounced and of shorter duration.[5-6]

The study is to compare the effectiveness of ropivacaine (0.5%) with fentanyl and bupivacaine (0.5%) with fentanyl in epidural neuraxial blockade for elective lower abdominal and lower extremity surgeries regarding the time for onset, duration and time for maximum of sensory and motor blockade, and to look for hemodynamic changes.

MATERIALS AND METHODOLOGY:

A clinical prospective and randomized control study of patients undergoing elective lower abdominal and lower extremity surgeries receiving either epidural 0.5 % ropivacaine or 0.5 % bupivacaine with fentanyl was undertaken after obtaining written informed consent and institutional approval. Hundred patients divided into two groups of 50 each by computer generated random number, Group A to receive 20 ml of 0.5% ropivacaine with fentanyl and Group B to receive 20 ml of 0.5% bupivacaine with fentanyl. 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 anaesthestic 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. With the bevel of the needle directed cranially, a 3 ml dose of the study solution was administered and then a catheter inserted through the needle 3-5 cm into the epidural space. The patient was then placed supine and a further 17 ml of the study drug was administered over a three- to five-minute period along with 2microgram/ml of fentanyl. 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 wasassessed by using the Bromage scale (0=no motor block, 1=inability to raise the extended leg, 2=inability to flex the knee, 3=complete motor block). 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 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. A 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. The 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 hours till 24 hours.

Statistical Analysis:

The sample size was determined prior to study, based on the ability to detect a difference in the primary outcome variable i.e., duration of sensory and motor blockade. With 50 patients in each group, there was 80% power and 0.05 probability. Statistical analysis was done using the statistical software Microsoft Excel sheet. Using this software range, frequencies, percentages, means, standard deviations, chi square and 'p' values were calculated. Kruskul Wallis chi-square test was used to test the significance of difference between quantitative variables. The 'p' value less than 0.05 is taken to denote significant relationship.

RESULTS

A total of 100 patients were included in this study, 50 in each group A were given ropivacaine with fentanyl and 50 in group B were given bupivacaine with fentanyl. The mean age of the patients in group A was 42.3 +/- 13.2 years and in group B was 43.8 +/- 11.8 which was not statistically significant with p value of 0.64. The mean weight of the patients in group A was 76.2 +/- 11.3 kilograms and in group B was 77.1 +/- 12.7 kilograms which was not statistically significant p value of 0.23. The mean height of the patients in group A was 168.5 +/- 9.6 cms and in group B was 167.9 +/- 8.7 kilograms which was not statistically significant p value of 0.16. Total male in group A was 28 when compared to 31 in group B. Total abdominal surgeries were 32 and 18 lower extremity surgeries in group A when compared to 35 abdominal and 15 extremity surgeries in group B. Time between injection to operation in group A was 10.5+/- 12.3 minutes and total duration of surgery was 142.5 +/- 35.8 minutes when compared to in group B for time for injection to operation was 12.3 +/- 11.8 and total duration of surgery was 156.7 +/- 42.1minutes which was not statistically significant p value of >0.05. Base line characters between ropivacaine and bupivacine depicted in Table 1.

Table 1: Baseline Characteristicsbetweeen Bupivacaine Versus Ropivacaine

CHARACTERISTICS	GROUP A (n=50)	GROUP B (n=50)	p Value
AGE (Mean +/- SD)	42.3 +/- 13.2	43.8 +/- 11.8	0.64
HEIGHT (cm Mean +/- SD)	168.5 +/- 9.6	167.9 +/- 8.7	0.16
WEIGHT (Kg Mean +/- SD)	76.2 +/- 11.3	77.1 +/- 12.7	0.23
MALE/FEMALE	28/22	31/19	0.37
ASA GRADE 1/2	41/9	38/12	0.25
NUMBER ABDOMINAL / EXTREMITY SURGERIES	32/18	35/15	0.40
TIME BETWEEN INJECTION TO OPERATION IN MINUTES	10.52 +/- 12.3	12.3 +/- 11.8	0.81
DURATION OF SURGERY IN MINUTES	142.5 +/- 35.8	156.7 +/- 42.1	0.08

Table 2: Epidural Anaesthesia Characteristics Betweeen Bupivacaine Versus Ropivacaine

PARAMETER	GROUP A (ROPIVACAINE)	GROUP B (BUPIVACAINE)	P Value
TIME TAKEN FOR ONSET OF SENSORY BLOCK (MIN)	11.2 +/- 5.8	14.6 +/- 6.2	0.03
TIME TAKEN FOR MAXIMUM SENSORY BLOCK T6 (MIN)	28.6 +/- 13.6	31.7 +/- 14.5	0.62
TIME TAKEN 2 DERMATOME REGRESSION (MIN)	168.8 +/- 24.6	167.7 +/- 31.8	0.56
TIME TAKEN FOR REGRESSION UPTO T12 (MIN)	225.7 +/- 38.9	242.6 +/- 41.7	0.06
TIME TAKEN FOR ONSET OF MOTOR BLOCK (MIN)	19.8 +/- 7.8	25.6 +/- 8.1	0.01
TOTAL DURATION OF MOTOR BLOCK (MIN)	212.5 +/- 45.2	254.7 +/- 52.8	0.01

Time taken for onset of sensory block in group A was 11.2 +/- 5.8 minutes when compared to 14.6 +/- 6.2 minutes in group B which was statistically significant with p value of 0.03 which <0.05 as in Figure 1. Time taken for maximum sensory block in group A was 28.6 +/- 13.6 minutes when compared to 31.7 +/- 14.5 minutes in group B which was not statistically significant with p value of 0.62. Time taken for 2 dermatome regression in group A was 168.8 +/- 24.66 minutes when compared to 167.7 +/- 31.8 minutes in group B which was not statistically significant with p value of 0.56. Time taken for regression up to T12 in group A was 225.7 +/- 38.9 minutes when compared to 242.6 +/- 41.7 minutes in group B which was not statistically significant with p value of 0.06. Time taken for onset of motor block in group A was 19.8 +/- 7.8 minutes when compared to 25.6 +/- 8.1 minutes in group B which was statistically significant with p value of 0.01 which <0.05 (FIGURE 2). Time taken for total duration of motor block in group A was 212.5 +/- 45.2 minutes when compared to254.7 +/- 52.8 minutes in group B which was statistically significant with p value of 0.01 which <0.05 (FIGURE3). These anesthesia characteristics between ropivacaine and bupivacien are depicted in Table 2.

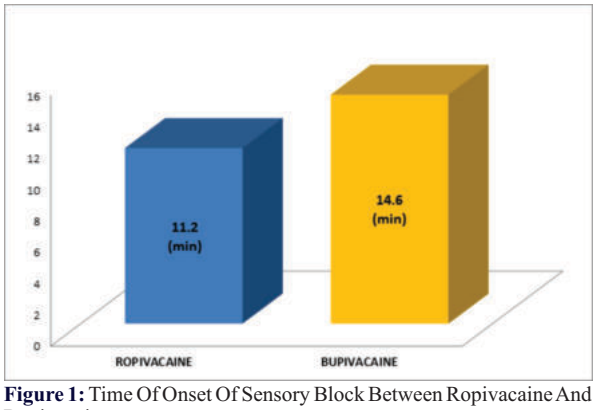

Figure 1: Time Of Onset Of Sensory Block Between Ropivacaine And Bupivacaine

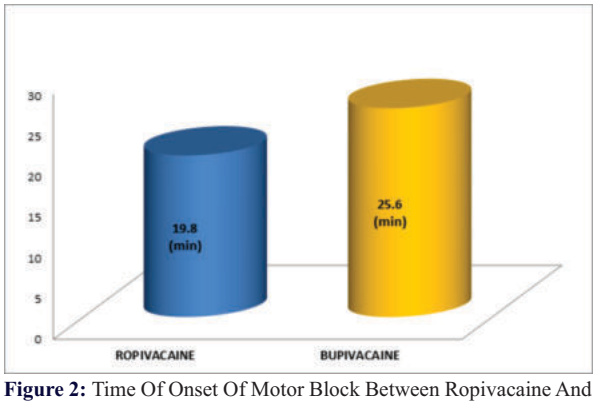

Figure 2: Time Of Onset Of Motor Block Between Ropivacaine And Bupivacaine

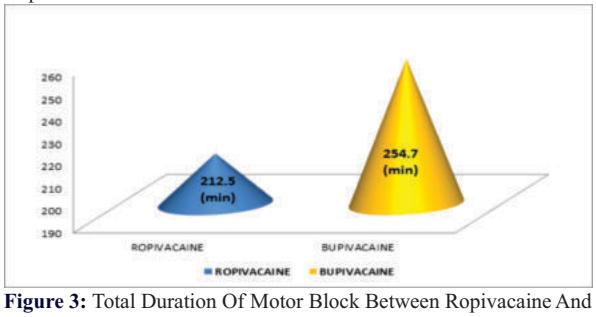

Figure 3: Total Duration Of Motor Block Between Ropivacaine And Bupivacaine

The hemodynamic character between ropivacaine and bupivacaine were comparable with not statistically significant between both groups. Heart rate in group A was 88.3 +/- 10.2 beats per minute when compared to 89.7 +/- 11.8 beats per minutes in group B which was not statistically significant with p value more than 0.05. Sytolic blood pressure (mm Hg) in group A was127.8 +/- 21.5 compared to 127.8 +/- 21.5 in group B which was not statistically significant with p value more than 0.05. Diastolic blood pressure (mm Hg) in group A was 78.4 +/- 15.2 compared to 77.9 +/- 14.7 in group B which was not statistically significant with p value more than 0.05. Baseline saturations in group A were 97.5 +/- 1.2 compared to 96.8 +/- 0.8 in group B which was not statistically significant with a p value more than 0.05 as depicted in Table 3.

Table 3: Hemodynamic Character Comparision Between Ropivacaine And Bupivacaine

PARAMETER	GROUP A (ROPIVACAINE)	GROUP B (BUPIVACAINE)	P Value
HEART RATE (BEATS/MIN)	88.3 +/- 10.2	89.7 +/- 11.8	0.36
SYTOLIC BLOOD PRESSURE (mm Hg)	127.8 +/- 21.5	126 +/- 18.9	0.42
DIASTOLIC BLOOD PRESSURE (mmHg)	78.4 +/- 15.2	77.9 +/- 14.7	0.18
BASELINE SpO2	97.5 +/- 1.2	96.8 +/- 0.8	0.89

DISCUSSION

Epidural anesthesia for abdominal and extremity surgeries is soundly established with many of the benefits which are proven to be effective. A well-managed epidural can provide excellent analgesia in the operative and postoperative period. In addition, epidural block will obtund the acute stress response to surgery. Consequently, along with the analgesic benefits, patients are less likely to suffer cardiac, respiratory, or gastrointestinal side-effects. Bupivacaine is a most commonly used in epidural anesthesia and is an amide linked local anaesthetic. It is a hydrochloride of 1-Butyl-N-(2,6-dimethylphenyl) piperidine-2-carboxamideand is present as a racemic mixture. Bupivacaine reduces cardiac output by reducing the sympathetic tone, by slowing the heart rate and by reducing the venous return. It produces a fall in arterial blood pressure but it is relatively slow and seldom is it very profound. It produces a fall in central venous pressure and this major concern about the cardiotoxicity of bupivacaine has led to the development of ropivacaine, a new long-acting amide.[7] The clinical profile of ropivacaine is similar to that of bupivacaine. It elicits nerve block via reversible inhibition of sodium ion influx in nerve fibres but produces less cardiotoxic effects.[8]The current study compares sensory and motor blockade properties OF 0.5% Ropivacaine with fentanyl and 0.5% Bupivacaine with fentanyl used as an anesthetic and administered epidurally for lower abdominal and lower extremity surgeries.

In present study time taken for onset of sensory block in group A was 11.2 +/- 5.8 minutes when compared to 14.6 +/- 6.2 minutes in group B which was statistically significant with p value of 0.03 which <0.05. Time taken for maximum sensory block in group A was 28.6 +/- 13.6 minutes when compared to 31.7 +/- 14.5 minutes in group B which was not statistically significant with p value of 0.62. In a double-blind, randomized study involves 60 patients done by Ushma D. Shah et al comparing 0.5% ropivacaine (Group R) and of 0.5% bupivacaine (Group B) had similar results with 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.[1] In a similar study, Finucane et al. which was a double-blind comparison of ropivacaine 0.5% and bupivacaine 0.5%, injected epidurally, in patients undergoing abdominal surgeries found that onset time for sensory block to T12 was shorter in 0.5% ropivacaine group when compared to 0.5% bupivacaine group.[3] In contrast to present study and above-mentioned studies, research done by Mohamad Ommid et al, D. P. McGLADE et al, C. Geetha et al comparing ropivacaine and bupivacaine in epidural surgery did not find any significant difference in onset of sensory block between the two groups.[2,5,8]

In present study time taken for 2 dermatome regression in group A was 168.8 +/- 24.66 minutes this was slightly higher when compared to 167.7 +/- 31.8 minutes in group B which was not statistically significant with p value of 0.56. These results were comparable to study done by Geetha et al where they concluded that the two-dermatome segment regression and regression up to T12 were statistically significant; it was prolonged in the case of Ropivacaine compared to Bupivacaine.[8] In a study by Katz JA et al they compared Ropivacaine with Bupivacaine and found that the time for two dermatome segment regression was of longer duration with Ropivacaine in comparison to Bupivacaine.[9]

In present study time taken for regression up to T12 in group A was 225.7 +/- 38.9 minutes was shorter when compared slightly longer in Group B with 242.6 +/- 41.7 minutes which was not statistically significant with p value of 0.06. Similar findings were observed in study done by A Chandra shekhar Reddy et al who compared Bupivacaine group (B) received 3 ml of 0.5% bupivacaine intrathecally and bupivacaine with fentanyl 2 µg/ml epidurally while Ropivacaine group (R), received 3 ml of 0.5% ropivacaine intrathecally and ropivacaine with fentanyl 2 µg/ml epidurally concluded that the duration of analgesia and the time till the need for start of epidural infusion was longer in group B (221.60 + 10.677 min) when compared to group R (198.40 + 23.216 min).[4] Similar and consistent results were found in study done by Mohamad Ommid et al where duration of action was longer in Bupivacaine when compared to Ropivacaine group and they theorized that this because of lesser lipid solubility of Ropivacaine when compared to that of Bupivacaine.[5]

In the present study time taken for onset of motor block in group A was 19.8 +/- 7.8 minutes when compared to 25.6 +/- 8.1 minutes in group B which was statistically significant with p value of 0.01 which <0.05. Time taken for total duration of motor block in group A was 212.5 +/- 45.2 minutes when compared to254.7 +/- 52.8 minutes in group B which was statistically significant with p value of 0.01 which <0.05. These results are comparable to two similar studies one done by Brockway MS et al, in their study compared Ropivacaine with Bupivacaine in 110 patients and found that Ropivacaine produced a slower onset, shorter duration and less intense motor block.[10] Morrison LMM et al in their study of clinical efficacy and kinetics of the lumbar extradural administration of 0.5% Ropivacaine and 20 ml of 0.5% Bupivacaine observed that the motor block produced by Ropivacaine was less intense and of shorter duration than Bupivacaine.[11]

In current study hemodynamic changes like heart rate, systolic blood pressure, diastolic blood pressure, and saturation levels during elective lower abdominal and lower extremity surgeries receiving either epidural 0.5 % ropivacaine or 0.5 % bupivacaine with fentanyl were similar in both groups with p value of more than 0.05. These findings were comparable to that of studies comparing Ropivacaine and Bupivacaine in epidural anesthesia done by Shah Ushma et al and D. P. Mc GLADE et al, which concluded that there were no significant changes in mean pulse rate and mean arterial pressure between two groups in the present study.[1,2]

CONCLUSION:

In present study comparing 0.5% Ropivacaine versus 0.5 % Bupivacaine with Fentanyl for epidural anesthesia in patients undergoing lower abdominal and lower extremity surgeries results have shown that time taken for onset of sensory and motor block and total duration of motor block was shorter in Ropvacaine compared to Bupivacaine, other parameters like time taken for maximum sensory block , time for two dermatome regression, time for regression up to T12 and hemodynamic changes were similar in both groups.

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