

Efficacy Of Ropivacaine - Fentanyl In Comparison To Bupivacaine - Fentanyl In Epidural Anaesthesia

S Gautam, S Singh, R Verma, S Kumar, V K Srivastava, R Kumar, R Wahal

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Abstract

Background- Epidural anesthesia is a safe and inexpensive technique with the advantage of providing surgical anesthesia and prolonging post-operative pain relief. Epidural anesthesia is frequently given to patients undergoing lower abdominal and lower limb surgeries. Aims: In this prospective, randomized, double blind study, we compared the analgesic effectiveness, haemodynamic changes and side effects of epidural anesthesia with drug combination- bupivacaine-fentanyl and ropivacaine-fentanyl for lower abdominal and lower limb surgeries. Material & Methods- The group-A received 20 ml Bupivacaine 0.5% + 100 µg fentanyl (50 patients) and group-B received 20 ml ropivacaine 0.75% + 100 µg fentanyl (50 patients). The patients were monitored during surgery. After epidural drugs injection, data recording were performed during the first hour at 5, 10, 15, 30, 45 and 60 min, there after every hour up to four hours. The statistical analysis was done by using SPSS version 15.0 Statistical Analysis Software. Results and conclusion-There was no significant difference in group- A and group-B in terms of quality of block which was assessed by taking into account the rating of comfort by the patients while hypotension were more in group A.

INTRODUCTION

The benefit of good quality epidural anesthesia include improved respiratory functions, decreased post-operative cardiac complications, earlier mobilization and less chances of deep vein thrombosis with shorter hospital stay. The advantage of epidural over spinal anesthesia is the ability to maintain continuous anesthesia after placement of an epidural catheter thus making it suitable for procedure of long duration. This feature also enables the use of this technique into the postoperative period for analgesia using lower concentration of local anesthesia drugs or in combination with different agents.

Ropivacaine is a new long acting amino amide local anesthetic which combines the anesthetic potency and long duration of action of bupivacaine with toxicity profile intermediate between bupivacaine and lidocaine [1,2] The ropivacaine with its efficacy, lower propensity for motor block and reduced potential for Central Nervous System(CNS) and cardiac toxicity appear to be important option for regional anesthesia and for management of postoperative pain and labour [3, 4]

AIMS

In this prospective, randomized, double blind study, we

compared the analgesic effectiveness of drug combination- bupivacaine- fentanyl(Group-A) and ropivacaine fentanyl.(Group-B) for lower abdominal and lower limb surgeries in epidural anaesthesia. The secondary outcomes measured were the .side effects and haemodynamic changes.

MATERIALS & METHODS

After obtaining approval from hospital ethical committee and informed consent from the patients. This prospective, double blind and randomized controlled study was conducted in 100 patients aged 30-60 years belonging to American Society of Anaesthesiologist (ASA) physical status I or II with $\pm 20\%$ ideal body weight and height undergoing lower abdominal and limb surgeries in epidural anesthesia were included for this study. The study period was for one year from June 2009 to July 2010. The patients were divided in to two groups Group A and Group B. Group –A(N=50) received 20ml bupivacaine 0.5% + 100µg fentanyl and Group B-(N=50) also received 20 ml ropivacaine 0.75%+100µg fentanyl. All patients of study received ringer lactate (10ml/kg bodyweight) infusion over 15 minutes to preload the intravascular compartment. Patient with history of drugs allergy to study medication, on analgesia and steroid for past one month, peripheral neuropathy, without consent and other contraindication

(liver, dysfunction, renal disease, coagulation disorder and local pathology) were excluded from study.

A midline epidural Catheter was introduced & placed at L3/4 with patient in the sitting position (18 gauge epidural needle.) using the loss of resistance technique. A test dose of 3 ml lidocaine 1.5% with epinephrine 1:200,000 was administered, through the epidural needle and 3 minutes were allowed to elapse for detection of signs of an intravascular or subarachnoid injection. If the signs were negative, 20ml drug in combination were given intermittently through the catheter in each groups over three minutes. The patients were monitored for heart rate, ECG, blood pressure and oxygen saturation. After epidural drugs injection, data recording were performed during the first hour at 5, 10, 15, 30, 45 and 60 minutes, there after every hour up to four hours. The duration of analgesia was measured as the time interval between epidural injection and regression of sensory block below L1 and it was monitored by pin prick method every 10 minutes after 1 hour. The time for next analgesic (Top up) requirement for pain was also noted. The intensity of pain was assessed using a 10-point visual analogue scale (VAS) where 0 indicated no pain while 10 indicated unbearable distress [5]. Quality of block was assessed by taking into account the rating of comfort (TABLE 3) by the patients and the additional medications received.

- Excellent-no pain/discomfort.
- Very good- only mild discomfort not requiring treatment.
- Good- pain/discomfort requiring further local anesthetics.
- Fair-in addition to further administration to local anesthetic, intravenous agents had to be given.
- Poor- general anaesthetic had to be induced.

Statistical Analysis: The statistical analysis was done using SPSS(Statistical Package for Social Sciences)Version 15.0 Statistical Analysis Software. The result were analyzed as number, Mean+_ standard deviations, chi-squares test and student 't' test A 'P' value <0.05 was taken as significant.

Table 3
Rating of comfort

	Group A	Group B	P value
Excellent	35(70%)	33(66%)	>0.05
Very good	9(18%)	10(20%)	>0.05
Good	4(8%)	4(8%)	>0.05
Fair	1(2%)	1(2%)	>0.05
Po Or	1(2%)	1(2%)	>0.05

RESULTS

The demographic variables such as age, body weight, height, BMI and ASA physical status were comparable in the both groups. There was no statistically significant difference in base line characteristic in two groups before administration of anesthesia (table 1). Similarly, the baseline hemodynamic variables (heart rate, systolic blood pressure, diastolic blood pressure and oxygen saturation) were matched in both groups and there was present statistically significant difference in mean blood pressure. ($p < 0.05$).

Table 1
Baseline characteristics of the two groups

	Group A (Bupivacaine 0.5% + 100 µg fentanyl)	Group B (Ropivacaine 0.75% + 100 µg fentanyl)	Statistical significance
	Mean± S.D	Mean± S.D	'p'
Age (years)	48.80±9.18	48.86±8.51	.973
Weight(Kg)	56.38±7.07	56.68±8.51	.895
Height(cm)	155.06±7.18	156.96±8.51	.215
BMI(kg/m ²)	23.58±3.57	23.20±8.51	.626
ASA Grade I/2	23/27	28/22	.317

At the time of block, the rise in heart rate was seen in both the groups and the mean heart rate in group B was found to be significantly higher as compared to group A. On comparison of systolic blood pressure, it was seen that in group B the systolic blood pressure (SBP) was seen to be steady and regular whereas in group A there was a sharp decline in blood pressure.

Group A had more hypotension as compared to group B patients while nausea and vomiting and heart rate were comparable in both groups. (Table 2).

Table 2
Comparison of complications in the two groups

Complication	Group A (Bupivacaine 0.5% + 100 µg fentanyl)	Group B (Ropivacaine 0.75% + 100 µg fentanyl)	Statistical Significance P value
Hypotension	39(78%)	18(36%)	<0.001
Bradycardia (min)	22(44%)	16(32%)	0.216
Vomiting and Nausea	11(22%)	15(30%)	0.362

DISCUSSION

Abdominal surgeries are frequently performed using central neuraxial block. The aim of anesthesia and analgesia are to provide intense, block and somatic response to pain, to reduce costs, to allow early ambulation and earlier hospital discharge.

Although central neuraxial block provide an excellent regional anesthesia, they have their own side effect due to sympathetic blockade such as hypotension in 30-40 %, bradycardia 13% , nausea & vomiting 18%, and dysrhythmia 7% etc [6]. Excessive hypotension may produce severe cerebral and myocardial ischemia. To maintain uniformity, both the groups were administered same volume of epidural test dose (3 ml) and medications (20 ml). In this study, both ropivacaine 0.75% and bupivacaine 0.5% produced effective and well tolerated epidural anaesthesia in patient undergoing abdominal and lower limb surgeries.

Katz JA et al [7] conducted a double blind comparison of 0.5% bupivacaine and 0.75% ropivacaine administered epidurally in humans. No significant differences were found between the two anesthetic groups except for time to two segment regression. This was comparable to present study..

The pain relief was assessed by using standardized visual analogue scale (VAS). Here patient was asked to evaluate pain on VAS (VAS 0 = no pain; VAS 100 = worst possible pain). The wide variation in the pain scores were seen throughout the study period. Quality of block was assessed by rating of comfort by patients and this was statistically not significant.

The duration of motor blockade was found to be significantly higher in bupivacaine group as compared to ropivacaine group. Griffith et al [8] conducted a double blind comparative study of epidural 0.5% ropivacaine with 0.5% bupivacaine for caesarean section. They found that there was no significant difference in the time of onset or intensity of motor block between the groups but the duration of motor block was significantly shorter in the ropivacaine group. Kerkamp et al [9] compared 0.75% ropivacaine with epinephrine and 0.75% bupivacaine with epinephrine in urban epidural anesthesia. The duration of analgesia at the T10 level was 190+12 minutes in the ropivacaine group and 234+20 minutes in the bupivacaine group. Duration of sensory block is similar to that of bupivacaine 0.75% with epinephrine however the motor block is less profound and of shorter duration in ropivacaine group 0.75%. Both these studies are comparable to the present study.

Preoperatively, both the groups were matched for heart rate. At the time of shifting there was statistically no significant difference among the groups ($p > .005$), however, it was seen that hypotension was more significantly present in group A in compare to Group B.. In one study Kampe S et al [10] compared the epidural block with ropivacaine 0.75% and bupivacaine in healthy pregnant women, scheduled for elective caesarean section in terms of maternal cardiovascular parameters, comfort and neonatal well being and observed that ropivacaine 0.75% resulted in greater decrease of maternal heart rate but this effect did not influence neonatal well being. Both the drugs produced equally satisfactory epidural block.

Kerkamp et al [11] compared cardiovascular effects of epidural 0.75% bupivacaine and 0.70% ropivacaine with adrenaline. The maximum mean arterial blood pressure decreased significantly from baseline values after 10 minutes but decrease after 20/minutes was more pronounced with bupivacaine (21%) than with ropivacaine (9.6%).

The side effects like bradycardia, nausea and vomiting were seen to be present in both the groups but statistically not significant.

Conclusion: To be concluded, -Both ropivacaine-fentanyl and bupivacaine-fentanyl provides equal quality of epidural block for lower abdominal and lower limb surgeries but use of ropivacaine-fentanyl was associated with more haemodynamic stability and early recovery of motor power.

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Author Information

Shefali Gautam, MD

Department of Anaesthesiology, King George's Medical University
Lucknow , India
vinish Singh@gmail.com

Sarita Singh, MD

Department of Anaesthesiology, King George's Medical University
Lucknow , India

Reetu Verma, MD

Department of Anaesthesiology, King George's Medical University
Lucknow , India

Sanjeev Kumar, MS

Department of General Surgery, King George's Medical University
Lucknow , India

Vinod Kumar Srivastava, MD

Department of Anaesthesiology, King George's Medical University
Lucknow , India

Rashmi Kumar, MD

Department of Anaesthesiology, King George's Medical University
Lucknow , India

Reeta Wahal, MD

Department of Anaesthesiology, King George's Medical University
Lucknow , India