e-ISSN: 0975-5160, p-ISSN: 2820-2651

Available online on www.ijtpr.com

International Journal of Toxicological and Pharmacological Research 2023; 13(4); 160-166

Original Research Article

Assessment of the Continuous Epidural Infusion of 0.125% Ropivacaine with 1μg/Ml Fentanyl versus 0.125% Bupivacaine with 1μg/Ml Fentanyl for Postoperative Analgesia in Major Abdominal Surgery: A Retrospective Study

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Received: 11-01-2023 / Revised: 20-02-2023 / Accepted: 25-03-2023
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Conflict of interest: Nil

Abstract

Aim: The present study was carried out to compare the efficacy of continuous epidural infusion of two amide local anesthetics, ropivacaine and bupivacaine with fentanyl for postoperative analgesia in major abdominal surgeries.

Material and Methods: A randomized, prospective, study was carried out in Department of Anesthesiology, Lord Buddha Koshi Medical College and Hospital, Saharsa, Bihar, India for one year .A total of 80 patients scheduled for major abdominal surgery were randomized into two Groups B and R with forty patients in each group. All patients were administered general anesthesia after placing epidural catheter. Patients received continuous epidural infusion of either 0.25% bupivacaine with 1 ug/ml fentanyl (Group B) or of 0.25% ropivacaine with 1 ug/ml fentanyl (Group R) at the rate 6 ml/h intraoperatively. Postoperatively, they received 0.125% bupivacaine with 1 ug/ml fentanyl (Group B) or 0.125% ropivacaine with 1 ug/ml fentanyl (Group R) at the rate 6 ml/h.

Results: Till the end of 120 min, the sensory blockade was comparable in both the groups. After 150 min, however, the number of patients with level above T10 were significantly more in Group B as compared to Group R till the end of 24 h ($P = 0.001$ at 12 h).

Conclusion: Both ropivacaine and bupivacaine in the concentration of 0.125% with fentanyl 1 ug/ml are equally safe, with minimal motor block and are effective in providing postoperative analgesia.

Keywords: Bromage score, bupivacaine, epidural infusion, postoperative analgesia, ropivacaine, visual analog scale.

Introduction

The epidural administration of local anaesthetic with opioids and patient-controlled analgesia (PCA) by intravenous (IV) opioid administration is commonly used for postoperative pain management. [1-3]

The main factor which has limited the use of epidural analgesia has been the difficulty in making a reasonable risk/benefit analysis about the technique, which has resulted in clinicians constantly asking whether epidurals are effective for postoperative pain relief and whether the technique is safe. [4]

Use of lipophilic opioid (fentanyl) is preferred to hydrophilic as it provides rapid onset of action, rapid clearance, and prevents delayed respiratory depression. [5]

Both bupivacaine and ropivacaine cause similar degree of sensory blockade. However, ropivacaine is reported to have a slower onset, lower intensity, and shorter duration of motor block with lesser propensity to produce the cardiac and central nervous system (CNS) toxicity as compared to bupivacaine. [6]

In this study, we have compared continuous epidural infusion of 0.125% ropivacaine with 1 ug/ml fentanyl and 0.125% bupivacaine with 1 ug/ml fentanyl for postoperative analgesia.

This study was designed to compare the efficacy of epidural infusion of bupivacaine and fentanyl with IV PCA morphine in patients undergoing gynaecological laparotomy. The objectives of the study were to compare these two techniques with respect to the quality of postoperative analgesia, the incidence of side effects and the patients' overall satisfaction.

Material & Methods

A randomized, prospective, study was carried out in Department of Anesthesiology, Lord Buddha Koshi Medical College and Hospital, Saharsa, Bihar, India for one year. eighty ASA (American Society of Anesthesiologists) I and II consenting adult patients of either sex between the ages of 18–65 years undergoing major abdominal surgery.

Methodology

Patients with ASA III and IV, those with infection at the site of epidural injection, coagulopathy or bleeding disorders, severely hypovolemic patients, those with raised intracranial pressure, sepsis, preexisting neurological deficit, demyelinating disorder, or severe spinal deformities were excluded from this study.

Sample size of forty in each group was calculated based on available reference studies, within 95% confidence limit and 80% of power. Patients were randomized by computer-generated randomization charts into two study groups, Group B (n = 40) received 0.125% bupivacaine with 1 ug/ml fentanyl and Group R (n = 40) received 0.125% ropivacaine with 1 ug/ml fentanyl postoperatively. Both groups were comparable with respect to their demographic data.

Baseline blood pressure, pulse rate, and SpO2 were recorded. Adequate preloading (500 ml) was done with 18‑gauge intravenous cannula. Patients received injection glycopyrrolate (0.004 mg/kg) and injection ranitidine (1 mg/kg) intravenously as premedication. Thereafter, an epidural catheter was inserted at the lumbar level (L1–L2 or L2–L3). The space was checked by loss of resistance technique and confirmed by the meniscus sign.

Epidural test dose was given with 3 ml 2% adrenalized lignocaine. The absence of tingling numbness in the lower limbs and tachycardia was confirmed after 5–7 cm of catheter was placed in the epidural space. After fixation of catheter, patients were made supine and free injection of saline through the catheter was checked. Patients were premedicated with injection fentanyl 2 ug/kg and injection midazolam 0.02 mg/kg. Patients were preoxygenated with 100% O2 for 3 min. General anesthesia was given with injection propofol 2 mg/kg mixed with injection xylocard 20 mg intravenously.

Suitable relaxant was given to facilitate tracheal intubation after confirming ventilation. Anesthesia was maintained with O2, N2O, and propofol or isoflurane. Muscle paralysis was maintained with injection vecuronium bromide intravenously. Group B patients received 0.25% bupivacaine with 1 ug/ml fentanyl 8 ml bolus after induction of general

anesthesia. After 1 h of bolus, the patient received continuous epidural infusion of 0.25% bupivacaine with 1 ug/ml fentanyl at the rate 6 ml/h intraoperatively. The rate of infusion was adjusted as per the hemodynamic parameters of the patient. Group R patients received ropivacaine instead of bupivacaine. The pulse rate,blood pressure, central venous pressure, SpO2, and EtCO2 were monitored intraoperatively. Infusion was stopped at closure which was approximately 30–45 min before reversal. All patients were reversed with 0.008 mg/kg glycopyrrolate and 0.06 mg/kg neostigmine.

Postoperatively, patients were shifted to recovery room. Patient's hemodynamic stability was confirmed, and visual analog scale (VAS) score and Bromage score were noted before initiation of respective epidural local anesthetic infusion. Group B received continuous epidural infusion of 0.125% bupivacaine with 1 ug/ml fentanyl at the rate 6 ml/h. Group R received 0.125% ropivacaine instead of bupivacaine.

The rate of infusion was increased or decreased as per the hemodynamic parameters and VAS score of the patient. Hemodynamic parameters, visual analog scale (0‑10), level of sensory block (assessed by pinprick), and level of motor block (based on Bromage scale: 0 ‑ able to move hip, knee, ankle, and toes [0% block], 1-just able to flex knee but still full flexion of ankles possible [33%] [partial], 2-unable to flex knees but flexion of ankles possible [66%] [acceptable], and 3-unable to move knees and ankle [100%] [complete block]) were monitored for 24 h postoperatively and need for rescue analgesia, side effects, and interventions if any were noted. Whenever the VAS score was more than 3, the rate of infusion was stepped up in a graded manner by 2 ml/h up to 10 ml/h. If not relieved after 10 ml/h, rescue analgesia was given in the form of injection tramadol 50 mg intravenously. No other form of sedative or analgesia was permitted except rescue analgesia. In case of occurrence of motor block the infusion was stopped temporarily till the Bromage score was 0.

The findings were analyzed statistically using Chi‑square test and Student's *t*‑tests using SPSS version 12 (SPSS, Inc., Chicago, IL). The $P < 0.05$ was considered statistically significant.

Results

Intraoperative pulse rate, diastolic and systolic blood pressure was similar in the two groups.

In the postoperative period, mean pulse rate, diastolic and systolic blood pressure was comparable in both the groups. However, six (15%) patients in the bupivacaine group and only two (5%) patient in the ropivacaine group developed hypotension [Figure 1].

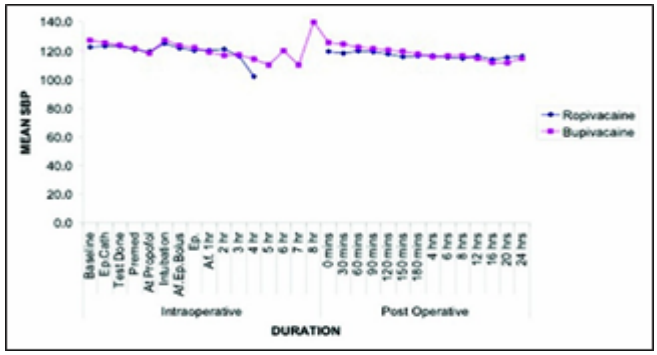

Figure 1: Changes in intra- and post-operative mean systolic pressure in Group B and Group R

There was no significant change observed in mean saturation between the two groups and the same trend continued till the end of 24 h though one patient in the R Group developed saturation <90%. Mean VAS scores, mean Bromage score, and mean quantity of drug required were comparable in the two groups [Figures 2 and 3].

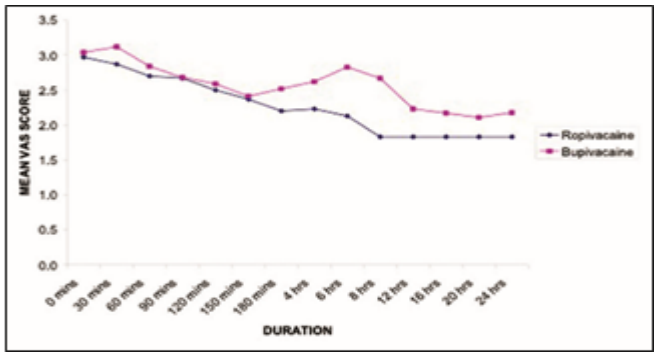

Figure 2: Changes in the mean postoperative visual analog scale scores of Group B and Group R

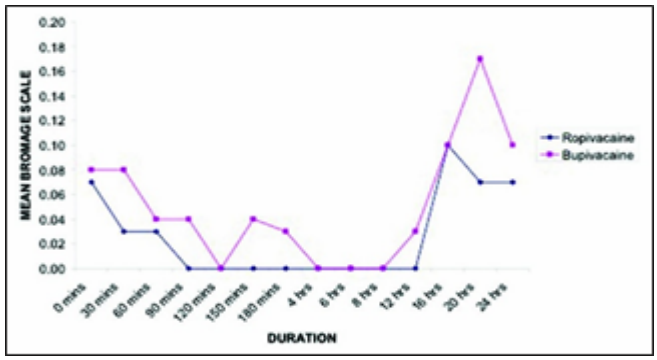

Figure 3: Changes in the postoperative Bromage scores of Group B and Group R

Till the end of 120 min, the sensory blockade was comparable in both the groups. After 150 min, however, the number of patients with level above T10 were significantly more in Group B as compared to Group R till the end of 24 h ($P = 0.001$ at 12 h).

In our study, adverse events (hypotension, motor block, respiratory depression, need for rescue analgesia, and others) were reported in 24% of cases of Group R as compared to 50.7% of cases of Group B ($P = 0.072$). None of the side effects were severe or life-threatening and were easily treated. The most common adverse event was the institution of motor block in the postoperative period, which accounted for 25% patients in Group B. Only 7.8% patients in the R Group had motor block ($P = 0.064$). The summary of various parameters is given in Table 1.

Table 1: Summary of various parameters studied immediately after surgery and 24 h postoperatively

Parameters	Group R	Group B
Pulse rate (bpm)		
Baseline	80.2±11.2	83.7±12.8
End of surgery	55.91±3.6	84.7±00.1
0 min postoperative	81.6±11.6	95.9±10.3
24 h postoperative Systolic BP (mm Hg)	70.2±7.5	77.8±12.7
Baseline	120.2±18.56	122.3±15.8
End of surgery	105.9±3.2	109.3±00.0

0 min postoperative	114.8±15.7	121.3±14.7
24 h postoperative Diastolic BP (mm Hg)	120.3±18.2	111.1±12.8
Baseline	72.4±7.5	80.4±8.4
End of surgery	70.3±1.7	78.3±00.0
0 min postoperative	74.6±9.7	83.8±9.5
24 h postoperative Mean saturation (%)	70.71±7.8	78.3±9.7
0 min postoperative	98.3±00.0	97.8±00.2
24 h postoperative VAS score	92.7±4.6	94.7±00.3
0 min postoperative	4.7±2.7	3.2±1.8
24 h postoperative	2.7±1.5	3.1±1.6
Mean quantity of drug (mg) Mean Bromage	188.3±40.5	168.1±36.3
0 min postoperative	0.2±0.5	0.2±0.4
24 h postoperative Postoperative sensory level above T10 (% of patients)	0.1±0.7	0.1±0.5
0 min postoperative	44.7	50.2
24 h postoperative	35.7	74.7
Adverse events (% of patients)	24.8	52

Discussion

Moderate to severe postoperative pain commonly occurs following laparotomy and inadequate analgesia may aggravate postoperative morbidity. Conventional intermittent IM opioid injection fails to provide satisfactory analgesia in the majority of cases. [7-9] Analgesic techniques like epidural analgesia and PCA are more effective than IM opioid and are commonly employed. [10-11]

The efficacy and safety of epidural opioids have been extensively studied in adult patients with randomized clinical trials. The safety of epidural opioids has also been demonstrated in infants and neonates when vital signs are continuously monitored in the postoperative period. [12] Several authors have questioned the validity of these data because they came from retrospective studies. To further complicate the issue, the authors of a recent study have questioned the clinical advantages of adding fentanyl to the local anesthetic in infants.

Accompanying the sensory and motor block of epidural Las are the sympatholytic effects due to blockade of the sympathetic chain; this results in hypotension. If the block height reaches the cardiac outflow between T1 and T5, there may be a marked hypotensive and bradycardia response, particularly in the presence of hypovolemia. The degree of hypotension depends on the actual dose, lower concentrations of LA causing less effect on blood pressure. Unopposed parasympathetically mediated bronchoconstriction has also been proposed as the cause of a case of severe bronchospasm during epidural anaesthesia. [13] Combining the results of three studies involving nearly 9000 patients, the incidence of hypotension during epidural infusion of LA is 0.7±3% depending on the concentration used (0.0625±0.25% bupivacaine) and the criteria for hypotension. [14-15] Use of a PCEA gave a 6.8% incidence of hypotension. [16]

Ropivacaine is a long‑acting, enantiomerically pure (S‑enantiomer) amide local anesthetic with a high pKa (ionization constant), and low lipid solubility which blocks nerve fibers involved in pain transmission (A delta and C fibers) more than those controlling motor function (A‑beta fibers). Thus, it is similar to bupivacaine with regard to pain relief but has fewer propensities to cause motor blockade at low concentrations.

Furthermore, the duration of motor block is shorter with ropivacaine. The drug is less cardiotoxic than equal concentrations of bupivacaine and has a much higher threshold for CNS toxicity than bupivacaine. [6,17,18]

Virmani *et al*. concluded that continuous infusion as compared to intermittent boluses provided better pain relief at rest, on movement and provided sustained degree of analgesia. [19]

Excessive lower limb motor blockade with controlled infusion of epidural LAs is uncommon, occurring in only in 3.0% of cases using low concentrations of bupivacaine. [20] If motor blockade does occur, it may result in the development of pressure areas on the heels and deep venous thrombosis. [21-22]

Proportion of cases with a sensory level of T6–T10 was significantly more in bupivacaine group as compared to ropivacaine group till the end of 24 h (P = 0.001) though their VAS scores were comparable. Surgical pain is related to traction and dissection which amounts to visceral pain. However, what we assessed by pinprick was somatic pain and not visceral pain.

Studies by Pouzeratte *et al*., Jorgensen *et al*.reported that the need for rescue analgesia was more in the ropivacaine group than the bupivacaine group. [23-25] However, in our study four patients (13.3%) in each group required rescue analgesia.

Conclusion

Both ropivacaine and bupivacaine in the concentration of 0.125% with fentanyl 1 ug/ml are equally safe, with minimal motor block and are effective in providing postoperative analgesia.

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