Comparison of continuous epidural infusion of 0.125% ropivacaine with 1 μg/ml fentanyl versus 0.125% bupivacaine with 1 μg/ml fentanyl for postoperative analgesia in major abdominal surgery

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Abstract

Background and 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 total of 60 patients scheduled for major abdominal surgery were randomized into two study Groups B and R with thirty 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 μg/ml fentanyl (Group B) or of 0.25% ropivacaine with 1 μg/ml fentanyl (Group R) at the rate 6 ml/h intraoperatively. Postoperatively, they received 0.125% bupivacaine with 1 μg/ml fentanyl (Group B) or 0.125% ropivacaine with 1 μg/ml fentanyl (Group R) at the rate 6 ml/h.

Results: Hemodynamic parameters, visual analog scale (VAS), level of sensory block, and degree of motor block (based on Bromage scale) were monitored for 24 h postoperatively.

Conclusion: Both ropivacaine and bupivacaine in the concentration of 0.125% with fentanyl 1 μg/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 most common type of acute pain that the anesthesiologists deal with, is postoperative pain with resultant neuroendocrine stress response causing protein catabolism, hyperglycemia, poor wound healing, decreased respiratory function, and increase in myocardial oxygen demand.\(^1\)

Pain relief can be provided by systemic opioids and nonopioid analgesics, regional neuraxial and peripheral analgesic techniques, and epidural route being safer resulting in shorter Intensive Care Unit stays.\(^2\) Addition of opioids to local anesthetics has several benefits such as improved dynamic pain relief, limited regression of sensory blockade, and decreased dose of local anesthetic.\(^3\)

Use of lipophilic opioid (fentanyl) is preferred to hydrophilic as it provides rapid onset of action, rapid clearance, and prevents delayed respiratory depression.\(^4\)

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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.\[^{31}\]

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.

### Material and Methods

After Institutional Ethics Committee approval, a randomized, prospective, double-blind study was carried out in sixty 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. 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 thirty 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 = 30) received 0.125% bupivacaine with 1 ug/ml fentanyl and Group R (n = 30) 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 SpO\(_2\) 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% adrenalinized 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% O\(_2\) 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 O\(_2\), N\(_2\)O, 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, SpO\(_2\), and EtCO\(_2\) 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

#### Demographic data

Intraoperative pulse rate, diastolic and systolic blood pressure were similar in the two groups.
In the postoperative period, mean pulse rate, diastolic and systolic blood pressure were comparable in both the groups. However, four (13.3%) patients in the bupivacaine group and only one (3.3%) patient in the ropivacaine group developed hypotension [Figure 1]. 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].

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 ($P = 0.004$ at 12 h).

In our study, adverse events (hypotension, motor block, respiratory depression, need for rescue analgesia, and others) were reported in 26.7% of cases of Group R as compared to 50.0% of cases of Group B ($P = 0.063$). 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 7 (23.3%) patients in Group B. Only 2 (6.7%) patients in the R Group had motor block ($P = 0.071$). The summary of various parameters is given in Table 1.

**Discussion**

Epidural analgesia provides preemptive analgesia thus prevents central sensitization, avoids polypharmacy, facilitates physiotherapy, and allows early mobilization.\[6\] Local anesthetics along with lipophilic opioid analgesics have become a popular choice. In the recent years, there has been an increasing amount of research over newer local anesthetic ropivacaine which is considered to be less toxic and safer than bupivacaine with similar pharmacodynamic properties.\[7,8\] Ropivacaine is a long-acting, enantiomerically pure (S-enantiomer) amide local anesthetic with a high $p$K$_a$ (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 less propensity to cause motor blockade at low concentrations.\[5\] 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.\[5,7\]

Before the actual project, a pilot study was done to determine the optimum concentration of local anesthetic to be administered in our patient population. Considering the efficacy and relative lack of side effects, 0.125% drug (bupivacaine and ropivacaine) was considered optimum and hence selected for the study.

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.\[9\] Wheatley et al. analyzed four studies and reported that the group that received a combination of local anesthetic and lipophilic opioid as a continuous epidural infusion had much
Table 1: Summary of various parameters studied immediately after surgery and 24 h postoperatively

| Parameters                          | Group R     | Group B     |
|------------------------------------|-------------|-------------|
| Pulse rate (bpm)                   |             |             |
| Baseline                           | 86.3±13.5   | 88.1±16.5   |
| End of surgery                     | 66.7±3.1    | 86.0±0.00.0 |
| 0 min postoperative                | 86.0±15.8   | 97.1±12.9   |
| 24 h postoperative                 | 74.9±7.9    | 80.6±13.3   |
| Systolic BP (mm Hg)                |             |             |
| Baseline                           | 122.4±19.6  | 127.3±16.8  |
| End of surgery                     | 102.0±3.5   | 110.0±0.00.0|
| 0 min postoperative                | 119.4±17.0  | 125.7±15.8  |
| 24 h postoperative                 | 116.1±16.1  | 113.5±15.6  |
| Diastolic BP (mm Hg)               |             |             |
| Baseline                           | 79.3±9.5    | 81.8±9.1    |
| End of surgery                     | 70.0±0.00.0 | 80.0±0.00.0 |
| 0 min postoperative                | 77.0±9.0    | 81.1±9.8    |
| 24 h postoperative                 | 73.2±7.4    | 74.9±10.0   |
| Mean saturation (%)                |             |             |
| 0 min postoperative                | 99.0±0.00.0 | 99.0±0.00.0 |
| 24 h postoperative                 | 98.4±3.5    | 98.4±0.00.2 |
| VAS score                          |             |             |
| 0 min postoperative                | 3.0±2.2     | 3.0±1.6     |
| 24 h postoperative                 | 1.8±1.3     | 2.2±1.0     |
| Mean quantity of drug (mg)         | 197.3±42.9  | 179.5±39.9  |
| Mean Bromage                       |             |             |
| 0 min postoperative                | 0.1±0.4     | 0.1±0.4     |
| 24 h postoperative                 | 0.1±0.4     | 0.1±0.3     |
| Postoperative sensory level above T10 (% of patients) |             |             |
| 0 min postoperative                | 43.3        | 52          |
| 24 h postoperative                 | 37.9        | 73.3        |
| Adverse events (% of patients)     | 26.7        | 50          |

BP = Blood pressure, VAS = Visual analog scale

better dynamic relief as compared to groups that received either drug alone.[10]

We decided to add opioids as it reduces the requirement of local anesthetic and the subsequent complications and enhances the analgesia.[11] A lipophilic opioid such as fentanyl is preferred as it gets rapidly absorbed in the spinal cord and nearby vessels. Therefore, there is rapid decrease in the cerebrospinal fluid concentration and reduced cephalad spread.[12] Thus, there is decreased risk of delayed respiratory depression.

Hemodynamic parameters remained stable in both the groups in the postoperative period. However, four patients in the bupivacaine group developed hypotension, of which two patients required temporary withholding of infusion. Only one patient in the ropivacaine group developed hypotension (systolic blood pressure <90 mm Hg).[13] This hypotension was mild and responded to intravenous fluid. Thus, when used in the said concentrations, both the drugs were found to be safe and had a similar effect on the patient’s heart rate and blood pressure.

This trend of hemodynamic parameters was similar to that observed by Akifumi et al., Pouzeratte et al., and Finucane et al.[14-16]

The mean oxygen saturation in the postoperative period was 99% in both the groups. One patient in the ropivacaine group developed saturation <90% 16 h after surgery. He had to be intubated and ventilated mechanically. A lipophilic opioid such as fentanyl is less likely to cause respiratory depression. It is more common with hydrophilic opioids such as morphine, which are capable of cephalad migration. Subarachnoid or intravenous migration of the epidural catheter can also result in respiratory depression. Furthermore, with continuous infusion, there is increase in protein binding (α1-acid glycoprotein) and decreased clearance of the drug.[17,18] In addition, the poor general condition and extensive surgery can also contribute to respiratory insufficiency.

In our study, the mean quantity of drug required in the postoperative period in ropivacaine group was more than in bupivacaine group as against Korula et al.[19] However, the difference between them was not statistically significant (P = 0.102). Higher doses of ropivacaine as compared to bupivacaine are generally required to elicit equivalent analgesic effects.[20] Bupivacaine is said to be 40% more potent than ropivacaine.[3,9]

Mean VAS score during the postoperative period at 0 min was similar in the two Groups. It decreased steadily with the progression of infusion. This is similar to the findings reported in earlier studies.[11,21-22]

The essence of good postoperative analgesia using a local anesthetic lies in pain relief without loss of motor power. This is important to allow physiotherapy, facilitate early mobilization, and prevent deep vein thrombosis.

The degree of motor block was calculated according to Bromage scale. Out of thirty patients in each group, 2 (6.6%) patients in the ropivacaine group and 7 (23.3%) patients in the bupivacaine group developed motor block. In the ropivacaine group, one patient had Bromage score of 2 at 0 min, probably as a result of continued effect of 0.25% ropivacaine received intraoperatively that led to the partial motor block in the lower limb. The infusion was stopped temporarily, and motor power was allowed to revert according to the protocol. The score improved to Bromage 1 by 30 min and 0 by 90 min. In the second patient, the score had reached a value of more than 2 by 16 h. The infusion was stopped. He also developed respiratory depression at this time.
and was intubated and mechanically ventilated. This could probably be due to fentanyl in the infusion over 20 h causing respiratory depression in an elderly patient.[10,17]

There is a greater degree of separation between motor and sensory blockade with ropivacaine. This can be due to it being less lipophilic than bupivacaine and is less likely to block large myelinated nerve fibers.[31] However, the motor block so developed is usually not incapacitating and does not hamper the patient’s mobilization in bed or physiotherapy. Brodner et al. reported bromage of >0 only in the bupivacaine group.[11] Furthermore, ability to mobilize was better in the ropivacaine group. Jørgensen et al. observed that 7% of patients in ropivacaine group and 15% in bupivacaine group had motor blockade.[21] Berti et al. and Paddalwar et al. also had similar findings.[13,23]

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 = 0.003) 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 Casati et al., Pouzeratte et al., Jørgensen et al., and Surabathuni et al. reported that the need for rescue analgesia was more in the ropivacaine group than the bupivacaine group.[15,21,24,25] However, in our study four patients (13.3%) in each group required rescue analgesia.

The complications or the side effects of continuous epidural infusion of the local anesthetics and the opioids could be due to the technical complications involved in the insertion of the epidural catheter such as trauma, bloody tap, or injury to the nerve root. The side effects could also occur due to the effect of the drugs causing autonomic blockade and hemodynamic disturbance or effect of intravascular absorption of the drug reaching toxic levels. We did not have any of the above complications related to the procedure.

In our study, the most common side effect was motor block (7 in Group B as against 2 in Group R) followed by hypotension (4 in Group B vs. 1 in Group R) and use of rescue analgesia (4 in each group). No other complications such as nausea, urinary retention, and convulsions were found in our study.

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Conflicts of interest
There are no conflicts of interest.

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**CONFERENCE CALENDAR January-March 2018**

| Name of conference | Dates          | Venue                                           | Name of organising Secretary with contact details |
|--------------------|----------------|-------------------------------------------------|--------------------------------------------------|
| 28th Annual National Conference of the Research Society of Anaesthesiology Clinical Pharmacology | 6th - 8th April 2018 | BM Birla Science & Technology Centre, Jaipur, India | Dr SP Sharma, Org Chairman, Email: spsharma2018@gmail.com |
| North Zone ISACON and ISACON Delhi 2018 | 13th - 15th April 2018 | NASC Complex, Dev prakash shastri marg, PUSA, New Delhi - 110012 | Prof & Head Dr Ashok Saxena, Department of Anaesthesiology, Critical Care & Pain Medicine, OT Block, Near Main ICU, University College of Medical Sciences, And GTB Hospital, Dilsad Garden, Delhi-110095. Mob: +919868399703, 9810431367 Email id: isacondelhi2018@gmail.com Website : www.isadelhi.net |
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