



## COMPLICATIONS OF ROPIVACAINE USED ALONE AND WITH FENTANYL CITRATE FOR EPIDURAL ANAESTHESIA : A DESCRIPTIVE STUDY.

### Anesthesiology

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### ABSTRACT

**BACKGROUND:** Ropivacaine is one of the commonly used medications in epidural anaesthesia. It is either used alone or in combination of opioids like fentanyl to increase its effect.

**METHODS:** The present study was conducted at a tertiary care centre in north India. The drug ropivacaine hydrochloride was used alone and also with varying combination of fentanyl for epidural anaesthesia for below umbilical surgeries. The side effects associated with the drug were closely monitored.

**RESULTS:** Shivering and pruritis were the common side effect seen.

**CONCLUSION:** The drug ropivacaine hydrochloride when used alone or in combination of fentanyl citrate is safe to use for epidural anaesthesia without much significant side effects

### KEYWORDS

ropivacaine, fentanyl, epidural, side effects

### INTRODUCTION:

Pain is an "unpleasant, sensory and emotional experience associated with actual or potential tissue damage." (40) Pain management is one of the important aspect of any lower abdominal or below umbilical surgeries. The epidural anaesthesia is commonly used technique for providing post operative pain relief in such kind of surgeries. Epidural anaesthesia can provide benefits of superior pain control, improved patient satisfaction, decreased stress response to surgery, reduced operative and postoperative blood loss, diminished postoperative nausea and vomiting, and decreased logistic requirements. (2)

Ropivacaine hydrochloride is unique in being the first local anesthetic marketed as a pure levorotatory stereoisomer, this characteristic gives it motor block- sparing properties (3), less cardiotoxicity and neurotoxicity as compared to bupivacaine (4,5) become preferred long-acting local anesthetic drug.

Local anesthetics are often used in combination with opioids for epidural anesthesia. Such drug combinations may produce analgesia by additive or even synergistic ('supra-additive') mechanisms and permit smaller doses of each drug with correspondingly fewer dose-related side-effects, to make epidural anesthesia last longer (3,6), to improve the quality of blockade, or to accelerate the onset of blockade. Hence the present study was conducted to evaluate the side effects profile with use of ropivacaine alone or in combination of fentanyl citrate (50 µg and 75 µg) for epidural anesthesia in patients undergoing below umbilical surgeries.

### METHODS:

The present study was conducted at tertiary care centre of north India after approval from institute ethics committee. The study was conducted in two parts. In a first, patients were evaluated for side effects profile of epidural anaesthesia with use of ropivacaine hydrochloride alone or in combination with varying doses of fentanyl citrate which will be described in the present paper. The part two of the study comparing the efficacy of ropivacaine hydrochloride alone and with varying combination of fentanyl citrate (50 µg and 75µg) has been considered for publication in JMSCR

Total of 90 patients of ASA grade I & II, between 20-60 years of age of either sex, for elective below umbilical surgeries were involved in the study. There were 30 patient in each group to receive either 18.5 ml of 0.75% Ropivacaine hydrochloride with 1.5 ml of normal saline (Group R; n=30), or 18.5 ml of 0.75% Ropivacaine hydrochloride with 50 µg of Fentanyl Citrate (1 ml) and 0.5 ml of normal saline (Group RF1; n=30) or 18.5 ml 0.75% Ropivacaine hydrochloride with

75 µg of Fentanyl Citrate (1.5 ml) (Group RF2, n=30).

Anaesthetic procedure was well explained to all the patients and well informed written consent was obtained. Patients who were hypersensitive to fentanyl citrate or ropivacaine hydrochloride, having spinal deformity or infection at the site of epidural puncture, having chronic backache, cardiovascular diseases, hepatic disease, bleeding diathesis, renal impairment, and neurological disorders were excluded from the study.

All the patients were to be kept nil orally for at least 6 hours before procedure. Intradermal sensitivity test with 0.75% ropivacaine hydrochloride was done in every patient. Inj. Glycopyrrolate 0.2 mg IM was given 30 minutes prior to operative procedures and 500ml of lactated Ringer's solution was infused before induction of epidural anesthesia.

On arrival into operation theatre, patients were placed in sitting position. All monitors were applied to monitor vital signs. Under all aseptic precautions, the L<sub>3</sub>-L<sub>4</sub> interspace was infiltrated with 0.75% ropivacaine hydrochloride using 24G hypodermic needle. Toughy 17-gauge needle was advanced, through which epidural catheter 19G was guided in the epidural space which was identified by the loss of resistance technique using a midline approach. Finally catheter was fixed & patient made supine.

Each patient received a test dose of 3 ml of 0.75% ropivacaine hydrochloride solution to detect an unintentional intrathecal or intravascular placement of catheter. Intrathecal injection will manifest by signs of spinal block within few minutes (like decreased sensation in the buttock's, paresis of legs and absence of knee jerk). Haemodynamic and respiratory monitoring was done for all enrolled patients at regular interval and side effects related to drug was monitored.

Pruritus, nausea, vomiting shivering, pain, bradycardia, urinary retention, muscular rigidity and any other side effects and the need of any additional medication was recorded. Hypotension was considered if there was a decrease in systolic arterial pressure of at least 30% of baseline, and was treated with IV ephedrine hydrochloride (6 mg every 5 minutes until systolic arterial pressure reached 100 mm Hg). Bradycardia, was considered if heart rate below 60 per minute, and was treated with inj. atropine sulphate accordingly. Respiratory depression was considered if a respiratory rate less than 10 breaths per minutes or SpO<sub>2</sub> less than 90%, and was treated by oxygen supplementation through face mask.

**RESULTS:**

In the present study, the mean  $\pm$  SD of age (yr) were  $47 \pm 9.69$ ,  $50 \pm 8.32$ , and  $47 \pm 10.75$  in groups R, RF1 and RF2 respectively. The mean  $\pm$  SD of duration of surgery (min) were  $93.87 \pm 25.08$ ,  $88.83 \pm 14.72$ , and  $90.17 \pm 20.02$  in groups R, RF1 and RF2 respectively. These variables were statistically analyzed, and found to be comparable. In the present study in group R; 14 were male & 16 were female, in group RF1; 16 were male and 14 were female, and in group RF2; 12 were male and 18 were female.

**Vital Parameters (Haemodynamics)**

Preoperative Mean  $\pm$ SD of pulse rate/min in the present study before epidural administration of drugs in group R was  $91.23 \pm 5.27$ , group RF1 was  $86.27 \pm 6$  and group RF2 was  $86.27 \pm 6$ . On intragroup statistical analysis, statistically significant fall in pulse rate from pre-operative value was observed ( $p$  value $<0.05$ ) after epidural injection of study drug.

Pre-operative Mean  $\pm$ SD of SBP in the present study for group R was  $129.33 \pm 5.57$ , for group RF1 was  $127.67 \pm 6.08$  and for group RF2 was  $130.47 \pm 7.08$ . On intragroup statistical analysis, statistically significant fall in SBP from baseline value was observed ( $p$  value $<0.05$ ) after epidural injection of study drug.

Preoperative Mean  $\pm$ SD of DBP in the present study was  $83 \pm 3.67$  for group R,  $82.27 \pm 6.82$  for group RF1 and  $80.53 \pm 6.24$  for group RF2. On intragroup statistical analysis, statistically significant fall in DBP from baseline value was observed ( $p$  value $<0.05$ ) after epidural injection of study drug.

Thus, in the present study on intragroup statistical analysis, a significant fall in pulse rate, systolic and diastolic blood pressure from preoperative value in all the three groups after epidural injection of study drug has been observed, but none of the patients in any group had bradycardia, and only two patients had hypotension in group RF2. (Bradycardia HR $<60$ , Hypotension  $>30\%$  fall in BP from base line) Table 1.

In the present study, preoperative respiratory rate of group R was  $16.3 \pm 0.46$ , of group RF1 was  $16.4 \pm 0.5$  and of group RF2 was  $16.57 \pm 0.63$ . On intragroup comparison of respiratory rate changes were found to be statistically nonsignificant ( $p$  value $>0.05$ ). Thus we found from the present study, epidural fentanyl citrate did not affect the respiratory rate. Other complications noted in the study are presented in table 1.

**Table 1. Incidence of complications in all the three groups**

| Complications                      | Group R   | Group RF1 | Group RF2 |
|------------------------------------|-----------|-----------|-----------|
| Nausea and vomiting                | -         | -         | -         |
| Hypotension                        | -         | -         | 2(6.67%)  |
| Bradycardia                        | -         | -         | -         |
| Shivering                          | 4(13.33%) | 6(20%)    | 3(10%)    |
| Respiratory depression             | -         | -         | -         |
| Pruritus                           | -         | 3(10%)    | 4(13.33%) |
| Urinary retention                  | -         | -         | -         |
| Muscular rigidity                  | -         | -         | -         |
| Backache                           | -         | -         | -         |
| Urinary retention                  | -         | -         | -         |
| Insufficient Anaesthesia/Analgesia | -         | -         | -         |

**DISCUSSION:**

Shivering, hypotension and pruritis were among the common side effects seen in patients in the present study. Scott D A et al(7) also observed that the incidence of hypotension was higher in epidural ropivacaine hydrochloride with fentanyl citrate group than epidural ropivacaine hydrochloride alone. Cooper D W et al(8) reported more incidence of hypotension in epidural bupivacaine fentanyl citrate group than epidural bupivacaine or fentanyl citrate alone. Curatolo M et al(9) reported hypotension with epidural bupivacaine and fentanyl citrate combination. Larson M D et al(10) reported decrease in heart rate and blood pressure by fentanyl citrate when used either epidurally or intravenous route.

Fall in blood pressure may be due to epidural ropivacaine hydrochloride and fentanyl citrate occurred probably due to interruption of sympathetic outflow by both the local anesthetic agent and the opioid via opioid receptor in the spinal cord with augmented

parasympathetic tone or it may be due to increasing extension of segmental sympathetic blockage.

In the present study, respiratory rate changes were found to be statistically nonsignificant ( $p$  value $>0.05$ ). Similarly Macias A et al(11) reported no significant change in respiratory rate between ropivacaine hydrochloride alone, ropivacaine hydrochloride fentanyl citrate and bupivacaine fentanyl citrate group. Scott D A et al(7) also observed that the respiratory rate over time was similar among groups.

Shivering was observed in 04 patients (13.33%) of group R, 03 patient (10%) in group RF2, and 04 patients (13.33%) in group RF2. It was found to be statistically insignificant ( $p$  value $>0.05$ ). Similar findings were observed by Cherng C H et al(12) that the incidences of shivering were same in epidural ropivacaine hydrochloride 1% with or without epidural fentanyl citrate (100 $\mu$ g). Bachmann-Mennenga B et al(13) also observed that incidence of shivering didn't differ between epidural 0.75% ropivacaine hydrochloride with or without epidural fentanyl citrate (20  $\mu$ g).

Pruritus was found in 03 patients (10%) in group RF1, and in 04 patients (13.33%) in group RF2, while no case was observed in group R, but it was mild and did not require any treatment. Pruritus may be due to systemic absorption of the drug and subsequent histamine release. Sinatra R S et al(14) and Halonen D M et al(15) similarly reported mild pruritus in the fentanyl citrate group. Cherng C H et al(12) also reported mild pruritus in fentanyl citrate group either given epidurally or by I.V. route. Scott D A et al(7) observed that pruritus was significantly more common in the patients receiving the larger doses of epidural fentanyl citrate. Nausea, vomiting, respiratory depression and urinary retention were not observed in any patients.

**CONCLUSION**

Fentanyl citrate as an adjuvants to ropivacaine citrate does not have any adverse effects except for hypotension and pruritus in few cases.

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