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Comparison of clinical efficacy of bupivacaine-fentanyl with ropivacaine-fentanyl in patients undergoing abdominal and pelvic procedures

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Abstract
Background: The pain after major abdominal surgeries, if treated inadequately, may lead to increased postoperative morbidity and delayed recovery. Epidural analgesia is one of the most effective regimens for postoperative analgesia. The present study was undertaken to evaluate and compare the clinical efficacy of bupivacaine-fentanyl with ropivacaine-fentanyl in patients undergoing abdominal and pelvic procedures.
Method: Total 80 adult patients of age between 18 to 55 years were enrolled and divided into two groups of 40 patients in each. Group BF received 0.5% bupivacaine for epidural block with Fentanyl 25 micro gm and Group RF received 0.75% ropivacaine for epidural block with Fentanyl 25 micro gm.
Results: Two groups were statistically similar for demographic profile and duration of surgery, ($p>0.05$). In both the groups, majority of patients were undergoing abdominal surgery (BF-55% vs. RF-60%) compared to pelvic surgery (BF-45% vs. RF-40%), ($p = 0.821$). There was no significant difference between two groups with respect to haemodynamic parameters (HR, SBP, DBP, MAP and SpO_2) and respiratory rate at different perioperative intervals. Higher time to request first rescue analgesic in patients received ropivacaine-fentanyl (RF group), which was statistically significant. Also the duration of analgesia was longer in RF group (176.73 ± 11.13) than BF group (170.98 ± 8.60), ($p = 0.012$). Incidence of nausea, vomiting, hypotension and bradycardia were comparable between two groups.
Conclusion: The epidural infusion of 20 ml of 0.75% ropivacaine with fentanyl 25µg provides adequate anesthesia for lower abdominal and pelvic surgeries, also it provides longer intraoperative and postoperative analgesia with hemodynamic stability compared with bupivacaine 0.5% with fentanyl.

Keywords: epidural analgesia, bupivacaine, fentanyl, ropivacaine, haemodynamic, hypotension, bradycardia

Introduction
Epidural anesthesia and analgesia have the potential to reduce or eliminate the perioperative physiologic stress responses to surgery and thereby decrease surgical complications and improve outcomes. Also it significantly minimizes blood loss during lower abdominal/pelvis and hip surgery [1-3]. Many other beneficial aspects of epidural anesthesia have also been reported which include more stable cardiovascular hemodynamics, better peripheral vascular circulation, and better post-operative pain control [2].
Successful selection of a drug for epidural anesthesia requires an understanding of the local anesthetic potency and duration as well as estimation of postoperative analgesia requirements [4]. Although bupivacaine remains the most widely used long-acting local anesthetic, its commercial preparation is available as a racemic mixture (50:50) of its two enantiomers, levobupivacaine, S (−) isomer and dextrobupivacaine, R (+) isomer. Severe central nervous system (CNS) and cardiovascular adverse reactions have been linked to the R (+) isomer of bupivacaine. Ropivacaine is increasing being used as an epidural agent as it has less impact on neurotoxicity, motor block and cardiotoxicity but equipotent analgesia compared with bupivacaine in similar doses, although this is controversial [5]. However, bupivacaine toxicity is especially a concern when larger doses are used. Ropivacaine has a potentially improved safety profile when compared to bupivacaine by use of solutions with a higher concentration. To overcome these low concentration of an epidural local anaesthetic agent alone or more commonly in combination with epidural opioids, provides adequate analgesia, also minimizes individual doses of each drug and their adverse effects than when used alone [6].

Moreover, the use of lipophilic opioid (fentanyl) is preferred to hydrophilic as it provides rapid onset of action, rapid clearance, and prevents delayed respiratory depression [7]. Epidural fentanyl also provides prolong postoperative pain relief with advantage of lack of nausea, vomiting, pruritus, sedation and urinary retention effects in earlier studies [8]. Previously, the efficacies of epidural analgesia for labor with bupivacaine and ropivacaine have been reviewed and the outcomes were found similar for both the drugs except for a statistically untested (because of higher heterogeneity) evidence of higher incidence of motor blocks in bupivacaine-treated women, while study on patients undergoing abdominal and pelvic procedures in adults is lacking. Hence the present study was undertaken to compare the clinical efficacy of epidural analgesia with bupivacaine-fentanyl and ropivacaine-fentanyl in terms of quality and duration of post-operative analgesia, hemodynamic stability and adverse effects, if any, in patients undergoing abdominal and pelvic procedures.

Materials and Methods

After obtaining Institutional Ethical Committee approval and written informed consent from all the patients, this randomized prospective comparative study conducted in Department of Anesthesiology, at 7 Air Force Hospital, Kanpur, UP, India during a period of 12 months from November 2017 to November 2018. Total 80 adult patients of either sex, ASA grade I and II, aged 18-55 years, scheduled for elective lower abdominal and pelvic procedures under epidural anaesthesia were enrolled in the study. Patients non-willing to participate in the study, patients with significant co-morbidities such as cardiovascular, renal, hepatic, pulmonary, neuromuscular and bleeding disorders, ASA grade III or above, history of allergy or sensitivity to drugs under study were excluded from the study.

All the selected patients were randomized into two groups using computer generated random numbers as - Group BF (Bupivacaine Fentanyl Group) received 20ml of 0.5% bupivacaine for epidural anaesthesia and 0.125% bupivacaine with Fentanyl 25µg diluted and made up to 8 ml with Normal Saline for post-operative analgesia. Group RF (Ropivacaine Fentanyl Group) received 20 ml of 0.75% ropivacaine for epidural anaesthesia and 0.125% ropivacaine with Fentanyl 25 µg diluted and made up to 8 ml with Normal Saline for post-operative analgesia. Anthropometric data of the patients were noted and all the patients in both groups were pre-medicated with Tab. Alprazolam 0.25 mg and Tab. Ranitidine 150 mg in the night prior to surgery. Patient was asked to remain nil per oral for solid food 10 hours before surgery and nil per oral for clear liquid for 2 hours before surgery.

On the day of surgery, the patients were wheeled into the operation theatre and put on mandatory noninvasive monitors. Baseline parameters NIBP (SBP, DBP, MAP), pulse oximetry, pulse rate, ECG were recorded. After IV access established Ringer Lactate 10 ml/kg was infused. The epidural space was identified at L2-L3 or L3-L4 by midline approach using loss of resistance technique, 16/18 G epidural catheter was inserted into the epidural space. Group BF was received 20 ml 0.5% bupivacaine and Group RF received 20 ml 0.75% ropivacaine. Mandatory intra-operative monitoring was done for all the patients. At the time of closure of surgical wound, patients in group BF was received 8 ml of 0.125% bupivacaine with fentanyl 25 micro gm and group RF received 8 ml of 0.125% ropivacaine with fentanyl 25 micro gm.

Pain was assessed by using standard 10 point Numeric Rating Scale (NRS) in which a score of "0" indicated "no pain" and a score of "10" "worst pain imaginable". The rescue analgesic was defined as the repeat bolus of 08 ml 0.125% bupivacaine with fentanyl 25 micro gm, irrespective of the group. The time at which the rescue analgesia administered were recorded. Rescue analgesic was given as and when demanded by patient/Numeric Rating Scale (NRS) score above 5. The vitals (HR, NIBP, RR and SPO_2) were recorded at baseline, 5 minutes, 15 minutes, 30 minutes, 1 hour and post operatively at 15 minutes, 30 minutes and hourly for 04 hours and the last recording at the time of rescue analgesic administration. Times for recordings were T0-Before administration of drug, T1-5 mins, T2-15 mins, T3-30 mins, T4-1 hr, T5-2hr, T6-3hr, T7-4hr after administration of drug and T8-Time of administration of rescue analgesia. Adverse effects like nausea, vomiting, shivering and hypotension were also recorded and managed symptomatically. Hypotension was defined as decrease in MAP below 20% of baseline or SBP <90 mm Hg and was recorded and treated with Inj. Mephentermine 3 mg/ml incremental.

Data analysis

Data so obtained will be compiled and analyzed statistically using Statistical Package for Social Sciences, version 15.0 or above. Independent samples 't'-test, paired 't'-test, chi-square test, Mann-Whitney U test and Wilcoxon signed rank test shall be used for the purpose of analysis of data. The confidence level of the study shall be kept at 95%.

Observations and Results

A total of 80 patients were enrolled in the study and divided in to two groups of 40 patients in each. Both the groups were comparable and found no significant difference in regard to demographic profile and duration of surgery as shown in table 1.

Table 1: Demographic profile of patients and duration of surgery

Variables		Group BF	Group RF	P value
Age (year)		35.65 ± 11.13	37.45 ± 10.90	0.467
Height (m)		1.59 ± 0.08	1.60 ± 0.06	0.796
Weight (kg)		64.15 ± 5.95	64.63 ± 5.72	0.717
BMI (kg/m^2)		25.24 ± 3.48	25.13 ± 1.72	0.856
Sex	Male	31 (77.5%)	28 (70%)	0.306
	Female	9 (22.5%)	12 (30%)	
ASA grade	I	25 (62.5%)	26 (65.0%)	0.500
	II	15 (37.5%)	14 (35.0%)	
Duration of surgery (In min)		80.73 ± 10.84	81.23 ± 12.08	0.846

In both the groups, majority of patients were undergoing abdominal surgery compared to pelvic surgery as depicted in figure 1. On comparing the data statistically, the difference was not significant (p = 0.821).

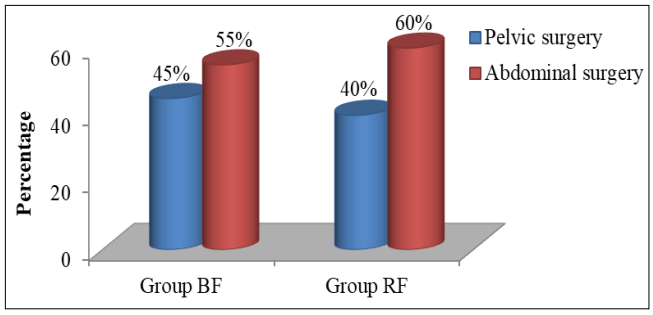

Fig 1: Surgical distribution of patients

At baseline, the hemodynamics was within normal range for either group. Mean heart rate (HR) ranged from 79.75 ± 4.41 bpm to 89.38 ± 5.22 bpm in two groups at different perioperative time intervals. Mean systolic blood pressure (SBP) and diastolic blood pressure (DBP) showed an initial decline followed by a restorative trend in two groups. In both the groups, oxygen saturation (SpO_2) was maintained well above 97% during different observation periods. There was no significant difference between two groups with respect to haemodynamic parameters (HR, SBP, DBP, MAP and SpO_2) at different perioperative intervals, (Figure 2).

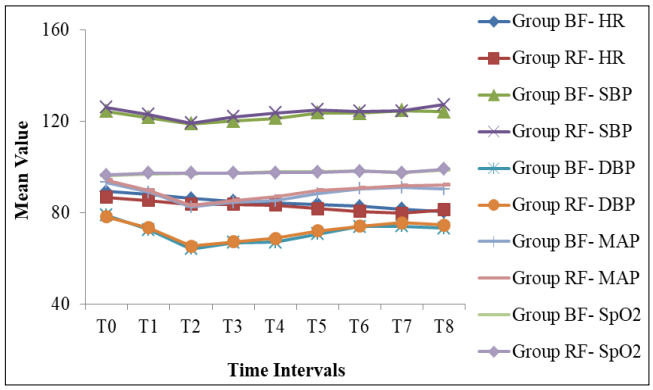

Fig 2: Comparison of haemodynamic parameters between two groups

There was no statistically significant change in mean respiratory rate, recorded in either group at T0 – T8 intervals, (p>0.05) as shown in figure 3.

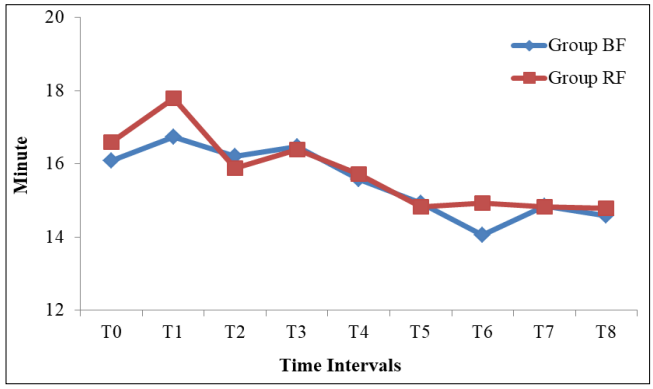

Fig 3: Respiration rate (Per minute)

Statistically there was significant prolongation of duration of analgesia in RF group (176.73 ± 11.13) as compared to BF group (170.98 ± 8.60), (p = 0.012). Higher time to request first rescue analgesic in patients received ropivacaine-fentanyl group (RF), which was statistically significant. Incidence of nausea, vomiting, hypotension and bradycardia were comparable between both the groups and these were statistically insignificant, (Table 2).

Table 2: Incidence of adverse effects

Adverse effects	Group BF	Group RF	p-value
Nausea	3 (7.5%)	2 (5.0%)	>0.05
Vomiting	2 (5.0%)	1 (2.5%)	>0.05
Bradycardia	2 (5.0%)	1 (2.5%)	>0.05
Hypotension	5 (12.5%)	1 (2.5%)	0.20

Discussion

Planning for proper postoperative pain management is an essential component of good anaesthetic practice since the consequences of untreated pain can be devastating. Among the most commonly used pain-relieving techniques, epidural local anesthetic or local anesthetic/opioid combinations are the most effective in providing pain relief after major surgical procedures [9, 10]. However the local anesthetics along with lipophilic opioid analgesics have become a popular choice. In the present study demographic features, mean duration of surgery and the ASA physical status were comparable between the groups which is comparable with the study done by Prajwal *et al.* [11] and Kumar *et al.* [12]. The demographic profile and type of surgeries were kept identical in both groups to avoid variations in intraoperative and postoperative outcome of patients.

Baseline hemodynamic parameters were comparable between two groups. Also we found that following epidural block; changes in, SBP, DBP, MAP, HR and RR was statistically similar in both the groups. Following administration of BF and RF combination drug to either there was one isolated significant change in heart rate at T6 recording (03 hours after the administration of drug combination), rest all haemodynamic parameters were comparable. The differences in the SBP, DBP, MAP, HR and SpO2 between the two groups were statistically insignificant at all intervals measured. These findings are correlated with the previous studies [13-15]. In both the groups, oxygen saturation (SpO_2) was maintained well above 97% during different observation periods. In Patil *et al.* [16] study the mean oxygen saturation in the post-operative period was 99% in both the groups.

Epidural injection of ropivacaine with fentanyl decreased postoperative pain with stable vital signs as compared to bupivacaine or ropivacaine alone in a study by Kanai A, *et al.* possibly because of the maintenance of sensory blockade by ropivacaine and enhancement of this sensory blockade by fentanyl [17]. In the present study there was significant prolongation of duration of analgesia in RF group compared to BF group (p-value 0.012) which is in accordance with the study done by Lakshmi K *et al.* [4], Kumar L *et al.* [13], Yadava and Jaiswal [18]. Epidural administered opioids produce segmental analgesia and improve the quality and duration of sensory block produced by local anesthetics, which may explain the better pain relief compared with intravenous analgesia. However, the present study showed better postoperative analgesia with respect to the quality and duration of sensory blockade with epidural ropivacaine with fentanyl. Some studies have found similar efficacy for post-operative analgesia between bupivacaine and ropivacaine. No significant differences were found in the block parameters using 0.75% ropivacaine and 0.5% bupivacaine

epidurally in a study by Chandran S *et al.* but ropivacaine was associated with relatively longer duration of postoperative analgesia [19]. The dissimilar results could be because the study populations in both studies were different and intraoperative use of intravenous opioids in our study might have influenced the postoperative pain scores.

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 [16]. We did not have any of the above complications related to the procedure. Incidence of nausea and vomiting were not significant in both the groups in this study. 5 (12.5%) patients had hypotension and 2 (5%) had bradycardia in BF group. Single case of bradycardia and hypotension in RF group and no other side effects were noted in the study. On the basis of published data reported by Priestly *et al.* [20] showing adequate pain relief and minimal side effects with epidural fentanyl 2 mcg/ml along with a local anesthetic agent in patients undergoing coronary artery bypass surgery, we chose the present dose. A higher dose of fentanyl was associated with an increase in dose-dependent complications such as hypotension, pruritus, respiratory depression, and sedation. Layek *et al.* [21]. observed equal incidence of postoperative nausea and vomiting between the both RF and BF groups while Jagtap *et al.* [14] observed more stable haemodynamics in ropivacaine group, hypotension was observed in 3.3% patients in the RF group and 10% patients in BF group. They also found patient in RF group had nausea/vomiting as similar to present study. Seetharam *et al.* [22] had shown that incidence of hypotension was 8% in group RF, with no episodes of bradycardia in this group, showing that combination of ropivacaine with fentanyl provides good cardiovascular stability than bupivacaine with fentanyl.

Conclusion

The present study reveals that the epidural infusion of 20 ml of 0.75% ropivacaine with fentanyl 25 µg provides adequate anesthesia for lower abdominal and pelvic surgeries. It is also concluded that ropivacaine 0.75% with fentanyl administered as an epidural infusion provides longer intraoperative and postoperative analgesia with hemodynamic stability in abdominal surgery compared with bupivacaine 0.5% with fentanyl. With the quality and duration of motor block achieved with ropivacaine, it can be justified to use it for lower abdominal and pelvic surgeries or surgeries which are short duration ambulatory surgeries and not requiring intense motor blockade.

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