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COMPARISON OF ROPIVACAINE WITH FENTANYL VS BUPIVACAINE WITH FENTANYL FOR POSTOPERATIVE EPIDURAL ANALGESIA IN INFRAUMBILICAL SURGERY: A PROSPECTIVE RANDOMIZED STUDY

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ABSTRACT **Background:** Epidural neuraxial analgesia is frequently used for postoperative pain relief. This study was aimed to compare postoperative epidural analgesia using 0.1% ropivacaine with 2mcg/ml fentanyl and 0.1% Bupivacaine with 2mcg/ml fentanyl in infraumbilical surgery. **Material & Method:** In this double-blinded randomized study, 120 patients, of age 18-60 years, planed for elective infra umbilical surgery under combined spinal-epidural anesthesia, were randomly allocated to receive either 10ml of 0.2% ropivacaine + 0.8ml fentanyl +9.2 ml of NS (Group A) or 4ml of 0.5% bupivacaine +0.8 ml fentanyl + 15.2 ml of NS (Group B) for postoperative analgesia with a lumber epidural catheter. Postoperatively, the onset and duration of epidural analgesia and stress response (HR, NIBP, RR, SPO2) were recorded. **Results:** Demographic data were comparable in both the groups. Also, no differences were noted in hemodynamic variabilities except mean postoperative diastolic blood pressure of group B was significantly lower in compared to ropivacaine group, { group A (80.13), group B (78.4) and p-value = 0.0082} but it never fell <20% of baseline. Mean onset time of epidural analgesia was significantly higher in ropivacaine group (12.2 ± 2.50 minutes) compared to bupivacaine group (11.2 ± 2.40 minutes), (p-value = 0.0273). The duration of analgesia was 4.44±1.85 hours (Group A) and 3.83±1.55 hours (Group B) which was comparable. **Conclusion:** Ropivacaine with fentanyl proved to have marginally greater analgesic efficacy and hemodynamic stability. For this reason, Ropivacaine is found to be a better alternative for both intraoperative and postoperative local anaesthetic and analgesia.

KEYWORDS : epidural analgesia, postoperative analgesia, ropivacaine, bupivacaine, fentanyl.

INTRODUCTION

Management of acute pain, resulting form tissue injury associated with surgery, is still one of the major medical challenge in postoperative period. Pain is a subjective & vastly personal phenomenon exclusive to the individual. The definition of pain is "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage" [1].

Efficacious management of postoperative pain relief after abdominal surgery leads to cardiovascular stability, early mobilization, early start with enteral feeding, lessen the hospital stay, reduces hospital costs with a better life and great patient satisfaction. There are various techniques of anaesthesia but combined spinal-epidural anaesthesia (CSEA) technique has been accepted as an ideal technique because it combines rapid profound analgesia of spinal with flexibility and longer duration of epidural techniques. It also reduces or eliminates the disadvantages of both spinal and epidural anesthesia while preserving their advantages [2].

Epidural anesthesia is a technique that may be used as a primary surgical anesthetic or as a resource for postoperative pain management. It is safe and relatively easy to learn and perform. Both, ropivacaine and bupivacaine are being commonly used for epidural analgesia either individually or in combination with opioids [3-4]. Continuous epidural analgesia via an indwelling epidural catheter is an effective and safe mode of delivering post-operative pain relief. It has been found that post-operative epidural anaesthesia is superior than systemic opioids for pain relief [5].

Epidural Bupivacaine has a well-defined role in regional anesthesia and analgesia for several years. Ropivacaine is a newer long-acting amide-linked local anesthetic agent. It is a pure S enantiomer with greater differentiation between sensory and motor blocks and with better margin of safety due to reduced toxic potential.(6) Ropivacaine is associated with a lesser amount of risk for cardiac and central nervous system toxicity. A slightly larger dose of Ropivacaine is required when compared to Bupivacaine but the addition of an adjuvant like clonidine, fentanyl, epinephrine, tramadol etc, helps in reducing the total dose required for local anaesthesia and adjuvant also enhances the efficacy, thereby increasing the duration of action and the intensity of blockade. (7-9)

This study was conducted to compare the postoperative analgesic efficacy and adverse events of epidural 0.1% Ropivacaine – 2mcg/ml fentanyl and 0.1% Bupivacaine-2mcg/ml Fentanyl. This study would be a prospective randomised double blind study.

MATERIAL AND METHODS

After the approval of the institutional ethics committee (IHCE-HIMSA/MD/MS(20)/RD-14/01-21), this prospective randomized study was conducted in the Department of Anaesthesiology, HIMS, Sitapur, Uttar Pradesh, from January 2021 to July 2022.

INCLUSION CRITERIA : Total 120 patients of either sex, aged 18-60 years, scheduled for elective infra-umbilical surgery belonging to American Society of Anesthesiologists (ASA) physical status Classes I and II.

EXCLUSION CRITERIA: Patients were excluded if they denied to give consent for the study, had a history of allergy to the study drug, any contraindication to central neuraxial blockade i.e. infection at the injection site, history of clotting or bleeding disorder, preexisting neurological deficit and haemodynamic unstable. Also, patients were excluded if they have h/o any major systemic illness (uncontrolled Diabetes, hypertension, IHD), pregnant patient, history of psychiatric illness, and all those with BMI>35kg/m^2.

After getting written and informed consent, patients were randomly divided into two groups, using computer-generated random number table, (Group A and Group B) of 60 patients each. In Group A: Patients received 0.1% ropivacaine (10 ml of 0.2% ropivacaine) with 2mcg/ml of fentanyl (0.8 ml of fentanyl) & 9.2 ml of normal saline making a total volume of 20 ml and in Group B: Patients received 0.1% bupivacaine (4 ml of 0.5% bupivacaine) with 2mcg/ml of fentanyl (0.8

ml of fentanyl) & 15.2 ml of NS making a total volume of 20 ml. For ensuring the double blinding drugs were prepared by anaesthesiologist who was not performing subarachnoid block and not participating in data collection.

A day before surgery pre anaesthetic check-ups with detailed physical and systemic examinations was done. All relevant investigation was reviewed.

On the day of surgery, premedication was done with an injection of Ondansetron 0.10 to 0.15mg/kg IV, an injection of ranitidine 4-8 mg/kg IV, and an injection Ceftriaxone 30-40 mg/kg IV after performing sensitivity test in the preop room. The patients were moved to the operation room, connected to a multiparameter monitor. After securing 18G intravenous line, patients were preloaded with 15 ml/kg crystalloid before the start of combined spinal epidural (CSE) anesthesia over 10 min. Under all aseptic conditions, an epidural catheter was inserted in a sitting position in L2-L3 or L3-L4 vertebral space with a 16G touhy epidural needle. Epidural space was recognized by the loss of resistance (LOR) technique. 18G Epidural catheter was inserted 5 cm in the cephalad direction, after negative aspiration for CSF and blood, a test dose of 3ml of 2% lignocaine with adrenaline (1:200000) was injected. The patient was monitored for 3 minutes for any complications to test dose, then the catheter was anchored on the back of the patient. Subarachnoid block was given in a space lower than the epidural catheter insertion space with a 25 gauge quincke spinal needle with 3.5cc of 0.5% hyperbaric bupivacaine and the case was conducted. After completion of the case, the patient was shifted to the postoperative ward and VAS scoring was assessed. Epidural top-up with drugs understudy was done if Visual Analog Scale (VAS) >3.0

All patients were explained about the grading of pain using a Visual Analog Scale (VAS) pain score (0 cm signifying no pain and 10 cm signifying worst pain). Patients complaining of pain with VAS>3 were given single dose of 20 ml of the drug under study according to randomization. VAS was assessed every 15 minutes for the first hour and then every 30 minutes for the next 3 hours. Stress responses like heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate, and oxygen saturation were monitored. The onset of analgesia was the time taken for the relief of pain with a VAS score to become <2. Duration of postoperative analgesia was measured from the time taken of epidural drug injection to the next complaint of pain or VAS >3.

Any adverse effects such as nausea, vomiting, bradycardia (HR<60), and hypotension (defined as a fall in mean arterial pressure > 20% of baseline) were recorded and treated accordingly.

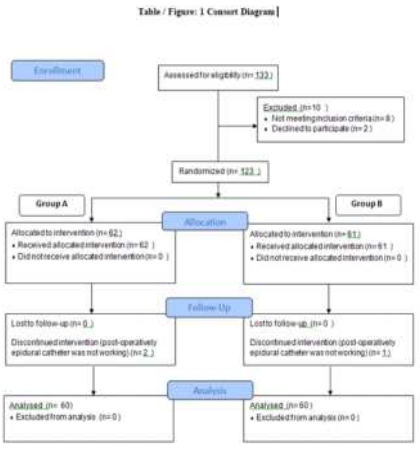
Sample size calculation: Power and sample size computation software used to estimate the sample size i.e version 2.1.30, DuPont & Plummer, February 2003. An educated prediction was made that a 30-minute difference in the mean duration of analgesia between two groups would be statistically significant based on clinical experience and literature review. The anticipated standard deviation within the group was 60. Using this data and assuming a study power of 0.9 and a probability of type I error of 0.05, a sample size of 85 patients was found to be required for obtaining a statistically significant mean difference in the mean duration of analgesia in the two groups. Taking into consideration a dropout rate of 20%, 60 patients were enrolled in each group. Therefore, a total of 120 patients (n = 120) were included in the study, with 60 patients in each of the two groups, assuming equal distribution of patients in both groups.

STATISTICAL ANALYSIS: MS Excel sheet 10 was used for data entry and IBM SPSS 20.0 software was used for data analysis. Discrete (categorical) data were summarized as proportions and percentages and quantitative data were summarized as means ± SDs. Unpaired t-test and Chi-square test were used to compare the two groups for quantitative data variables and qualitative data variables, respectively. P value less than 0.05 was considered statistically significant.

RESULTS:

Total 133 patients of age 18-60 years were screened for eligibility for this study. Total 123 patients, fulfilling the inclusion criteria, were randomised in two groups. During intervention total 3 patients (2 in group A and 1 in Group B) were excluded from study due to failure of epidural catheter in post-operative period. So at the end of study data of total 120 (60 in each group) patients were available for final statistical analysis. [Table/Fig-1]

TABLE/FIGURE: 1 CONSORT DIAGRAM



Patients in both groups were comparable to each other in terms of demographic characteristics. (Table/figure 2). The mean age (years) in group A, and B was 43.60 ± 12.53 and 44.8 ± 10.34 years respectively with no significant difference, (p-value= 0.5683). Also, both groups were comparable to each other in terms of weight and height with no statistically significant difference, (p= >0.05).

TABLE/FIGURE: 2 PATIENTS DEMOGRAPHY PROFILE

	Group A [n = 60]	Group B [n = 60]	p-value
Age in years (Mean±SD)	43.60 ± 12.53	44.8 ± 10.34	0.5683
Weight in kilograms (Mean±SD)	55.06 ± 9.9	51.44 ± 6.07	0.2370
Height in cm (Mean±SD)	158.06 ± 3.48	156.14 ± 4.29	0.1890

Postoperatively after epidural top-up with study drugs, the mean time of onset of analgesia was higher in group A (12.2 ± 2.50 minutes) in compared to group B (11.2 ± 2.4 minutes). The difference in the mean time of onset of analgesia was statistically significant (p-value = 0.0273). (table/Figure 3).

The mean time for giving 1st rescue analgesia for those who required rescue analgesia i.e duration of postoperative analgesia was higher in group A (4.44 ± 1.85 hours) in comparison to group B (3.83± 1.55 hours). The p-value between the two was >0.05, which shows that difference in duration of postoperative analgesia was insignificant in between the groups. (Table/Figure 3)

TABLE/FIGURE: 3 ONSET AND DURATION OF POSTOPERATIVE ANALGESIA

	Group A [n = 60] (Mean±SD)	Group B [n = 60] (Mean±SD)	p-value
Onset of analgesia (Minute)	12.2 ± 2.50	11.2 ± 2.4	0.0273
Duration of postoperative analgesia (Hours)	4.44 ± 1.85	3.83 ± 1.55	0.0526

Although patients in both groups reported Visual Analog Scale (VAS) pain score at rest less than 2.5cm. The mean pain score in group A was 1.8 with a standard deviation of 0.27. In group B the mean pain score was 2.2 with a standard deviation of 0.53. The p-value between both groups was 0.014 which is statistically considerable. (Table/Figure 4)

TABLE/FIGURE: 4 MEAN VAS SCORE

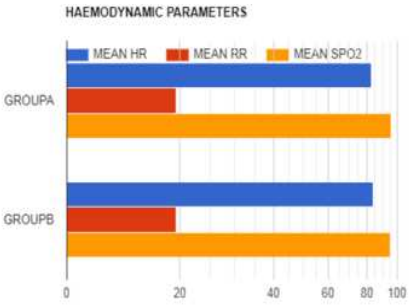
	Group A [n = 60]	Group B [n = 60]	p-value
Mean VAS (± SD)	1.8 ± 0.27	2.2 ± 0.53	0.014

The heart rate, respiratory rate, and oxygen saturation were measured at various intervals after epidural top-up and were comparable among groups with statistically insignificant difference (p= >0.05). (Table/Figure 5)

The mean postoperative systolic blood pressure in both group were comparable to each other, (in group A and group B, it was 126.93±7.7 and 125.13±3.22 respectively, p-value= 0.099). While in term of diastolic blood pressure, In group A the mean post-operative diastolic

BP was 80.13 mm of Hg with a standard deviation of 3.88 which was higher in comparison to group B (78.4 ±3.13 mmHg). The p-value = 0.0082 which was highly significant. (Table/Figure 6)

TABLE/FIGURE: 5 HAEMODYNAMIC PARAMETERS(HEART RATE, RESPIRATORY RATE AND SPO2



TABLE/FIGURE: 6 MEAN SYSTOLIC AND DIASTOLIC BLOOD PRESSURE

	Group A [n = 60] mmHg	Group B [n = 60] mmHg	p-value
Mean SBP (Mean±SD)	126.93 ± 7.7	125.13 ± 3.22	0.099
Mean DBP (Mean±SD)	80.13 ± 3.88	78.4 ± 3.13	0.0082

DISCUSSION

Good delivery of anaesthesia is of the greatest importance to avoid complications and consequent fear in both patients and surgeons. Postoperative analgesia is one of the most important component of balanced anaesthesia. A good post-operative analgesia is aimed to provide patients comfort with minimal side effect, blunting the autonomic response to pain, and helping in early ambulation and restoration of normal function.

In this study, the demographic profile in terms of age, body weight, and height in both groups were comparable and statistically insignificant.
In our study, the mean time of onset of analgesia in Group B (11.2 ± 2.4 min.) was significantly (p=0.0273) rapid as compared to Group A (12.2 ± 2.5 min.) These outcomes are inconsistent with the studies conducted by Beilin et al. (10), Eddleston et al. (11), and Finegold et al. (12). Although the results of Beilin et al study were not significant.

Group A also showed comparatively good results over Group B in the prolongation of postoperative analgesia. The duration of postoperative analgesia recorded in Group A (4.44 ± 1.85 hours) was longer when compared with group B (3.83 ± 1.55 hours) but this difference was statistically insignificant (p=0.0526). These results are in concordance with the study of Eddleston et al (11) and Finegold et al. (12). This difference between the two groups could be due to the potency ratio (1:1.5) (13). When small concentrations are used, these two local anesthetics seemed equipotent. (14)

In this study, the mean VAS for group B (2.2±0.53) was higher than group A (1.8±0.27) and the differences were statistically significant (p=0.014). the result of this study is in accordance with the study of Anita Kulkarni et al.(15) in which postoperative VAS scores at rest were between 2 and 4 in Group BF patients compared with Group RF patients who had VAS scores <3 at rest. On the contrary Beilin et al.(10) and Bawdane et al. (16) observed lower VAS in bupivacaine group than in ropivacaine group but the results were not statistically significant.

Concerning haemodynamic parameters, few studies observed that Ropivacaine group had stable hemodynamics compared to Bupivacaine group with p-value of <0.05 which was statistically significant like Bhupendra Tiwari et al(17) study and Jagatap S et al (18) study. But in this study regarding haemodynamic variables, heart rate, respiratory rate and oxygen saturation remained stable throughout the intra-operative and post-operative period in both groups and data were comparable in each group which was statistically insignificant, except for the mean post-operative diastolic BP that was 80.13 mm of Hg in ropivacaine group while the group B had the mean postoperative diastolic BP as 78.4 mm of Hg which was highly significant (p-value = 0.0082) but it never fell <20% of the baseline value.

CONCLUSION:

This study conclude that 0.1% ropivacaine and 0.1% bupivacaine with fentanyl in equal doses were comparable regarding the duration of analgesia, and adverse effects. In terms of onset of analgesia and VAS score, 0.1% ropivacaine showed better results in comparison to 0.1% bupivacaine. Also, ropivacaine with fentanyl maintains stable heamodynamic postoperatively compared with bupivacaine with fentanyl. The authors concluded that 0.1% ropivacaine with fentanyl proved to have marginally greater analgesic efficacy and hemodynamic stability than 0.1% bupivacaine with fentanyl. For this reason, Ropivacaine is found to be a better alternative for both intra-operative & postoperative local anaesthesia and analgesia.

LIMITATION:

New parameters like motor blockage assessment, 24 hour Visual Analog Scale (VAS) pain score and need of total analgesic drugs required in 24 hours are needed to boost the reliability of study.

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