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# COMPARISON OF HEMODYNAMIC EFFECTS OF EPIDURAL ROPIVACAINE-FENTANYL VERSUS BUPIVACAINE-FENTANYL IN INFRAUMBILICAL SURGERIES

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**ABSTRACT** **Background:** Postoperative hemodynamic stability is a key determinant of patient recovery following infraumbilical surgeries. Epidural analgesia using local anesthetics like ropivacaine and bupivacaine combined with fentanyl is commonly employed. This study compares the hemodynamic effects of epidural ropivacaine-fentanyl versus bupivacaine-fentanyl. **Methods:** 120 patients receiving elective infraumbilical surgery under combination spinal-epidural anesthesia participated in a prospective randomized double-blind research. Group A received 0.1% ropivacaine with 2 mcg/ml fentanyl while Group B received 0.1% bupivacaine with 2 mcg/ml fentanyl. Postoperative heart rate, systolic and diastolic blood pressure, respiratory rate, and oxygen saturation were recorded and analyzed. **Results:** Both groups were demographically comparable. The diastolic blood pressure was significantly higher in Group A (80.13 ± 3.88 mmHg) compared to Group B (78.4 ± 3.13 mmHg), p = 0.0082. Other parameters, including heart rate, respiratory rate, and oxygen saturation showed no significant differences. **Conclusion:** Ropivacaine-fentanyl provided more stable diastolic blood pressure postoperatively, indicating a potentially better hemodynamic profile compared to bupivacaine-fentanyl.

**KEYWORDS :** Ropivacaine, Bupivacaine, Hemodynamics, Infra-umbilical surgeries

## INTRODUCTION

Effective management of postoperative pain is crucial for enhancing patient recovery and minimizing morbidity following infraumbilical surgeries. Pain, as defined by the International Association for the Study of Pain (IASP), is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" [1]. It is a highly subjective phenomenon and remains a major clinical challenge in the postoperative period.

Postoperative pain triggers a series of physiological stress responses affecting various organ systems. Adequate pain control facilitates cardiovascular stability, early ambulation, prompt initiation of enteral feeding, reduced hospital stays, lower healthcare costs, and improved patient satisfaction. Among the several techniques for managing intraoperative and postoperative pain, the combined spinal-epidural anaesthesia (CSEA) has emerged as a preferred modality due to its rapid onset of action (via spinal block) and prolonged effect with adjustable dosing (via epidural route) [2].

Epidural anaesthesia, particularly when used postoperatively through an indwelling catheter, is an effective, safe, and widely adopted method for pain relief. It also offers advantages in terms of reduced systemic opioid requirements and better segmental control of analgesia [3,4,5].

Two commonly used amide-linked local anaesthetics in epidural anaesthesia are bupivacaine and ropivacaine. Bupivacaine has long been used in regional anaesthesia and is known for its potent sensory and motor blockade. However, its high lipid solubility also associates it with risks of cardiac and CNS toxicity, especially at higher plasma concentrations. In contrast, ropivacaine is a newer, long-acting local anaesthetic that exists as a pure S-enantiomer. It offers similar sensory blockade as bupivacaine but with reduced motor block and a superior safety profile due to decreased systemic toxicity [6]. Ropivacaine is associated with a lower risk of cardiotoxicity and neurotoxicity, making it an attractive alternative, particularly in patients with cardiovascular comorbidities [6,7].

Adjuvants such as fentanyl, when combined with local anaesthetics, further enhance analgesic efficacy, prolong the duration of action, and reduce the required dose of local anaesthetics [8,9]. Both ropivacaine and bupivacaine are routinely used with fentanyl for epidural analgesia; however, their comparative effects on postoperative hemodynamic stability have not been explored in detail.

Therefore, the purpose of this study was to evaluate the hemodynamic effects of 0.1% ropivacaine with fentanyl versus 0.1% bupivacaine with fentanyl given to patients undergoing infraumbilical operations via an epidural catheter. The primary objective was to assess differences in heart rate, systolic and diastolic blood pressure, and other parameters of cardiovascular stability following epidural top-up.

## MATERIALS AND METHODS

### Study Design And Setting

This study was conducted as a prospective, randomized, double-blind, parallel-group clinical trial in the Department of Anaesthesiology at the Hind Institute of Medical Sciences, Mau, Ataria, Sitapur, Uttar Pradesh, India, over a period of 18 months from January 2021 to July 2022, following approval from the Institutional Human Ethics Committee (Approval No. IHCE-HIMSA/MD/MS(20)/RD-14/01-21).

### Study Population

A total of 120 adult patients, aged 18–60 years, of either sex, with American Society of Anaesthesiologists (ASA) physical status I or II, scheduled for elective infraumbilical surgeries under combined spinal-epidural anaesthesia (CSEA), were enrolled after obtaining written informed consent.

### Inclusion Criteria

- Adults aged 18 to 60 years.
- ASA physical status I or II.
- Undergoing elective infraumbilical surgery (e.g., inguinal

hernia repair, lower limb orthopaedic procedures).
- Willingness to participate and provide informed consent.

**Exclusion Criteria**

**Patients Were Excluded If They Met Any Of The Following:**
- Refusal to participate or provide informed consent.
- Allergy to study medications (ropivacaine, bupivacaine, or fentanyl).
- Contraindications to neuraxial block (e.g., infection at puncture site, coagulopathy).
- Preexisting neurological deficit or spinal deformities.
- Uncontrolled systemic illnesses (e.g., hypertension, diabetes, ischemic heart disease).
- Pregnancy or lactation.
- Psychiatric illness affecting pain reporting.
- Body mass index (BMI) > 35 kg/m$^2$.
- Failed epidural catheterization or conversion to general anaesthesia.

**Randomization And Blinding**

Participants were randomized into two groups using a computer-generated random number table:
- **Group A**: Received epidural 0.1% ropivacaine with fentanyl 2 mcg/ml.
- **Group B**: Received epidural 0.1% bupivacaine with fentanyl 2 mcg/ml.

An independent anesthesiologist who was not involved in patient care or data collection developed the research solutions in order to preserve double blinding. Throughout the study, the patient and the researcher were blind to the group assignment.

**Sample Size Estimation**

Sample size was calculated using Power and Sample Size Calculation Software (Version 2.1.30, Dupont & Plummer, 2003). Based on prior clinical data and literature review, it was predicted that a 30-minute difference in duration of analgesia would be clinically meaningful, with an expected standard deviation of 60 minutes. To achieve a power of 90% and a type I error (α) of 0.05, the minimum required sample size was 85 participants. After adjusting for a 20% dropout rate, a final sample of 120 patients (60 per group) was chosen.

**Preoperative Preparation**

All patients underwent a pre-anaesthetic check-up the day prior to surgery, including physical examination, airway assessment, and review of laboratory investigations. Patients were kept nil per oral for 8 hours preoperatively. On the day of surgery, standard premedication was administered:
- Inj. Ranitidine 0.25 mg/kg IV
- Inj. Metoclopramide 0.15 mg/kg IV
- Inj. Midazolam 0.01 mg/kg IV
- Inj. Ceftriaxone 30–40 mg/kg IV after sensitivity testing
- Inj. Ondansetron 0.1–0.15 mg/kg IV for antiemetic prophylaxis

**Anaesthesia Technique**

Upon arrival in the operating room, standard monitors (non-invasive blood pressure, pulse oximeter, ECG) were attached. A wide-bore 18G IV cannula was inserted, and patients were preloaded with 15–20 ml/kg of crystalloid (normal saline) over 10 minutes.

**The combined spinal-epidural (CSE) technique was performed under strict aseptic precautions:**
- **Epidural Catheter Insertion:** Performed at L2–L3 or L3–L4 interspace using a 16G Tuohy needle. Epidural space was identified using the loss of resistance (LOR) technique. An 18G epidural catheter was advanced 5 cm cephalad and secured.
- A test dose of 3 ml 2% lignocaine with adrenaline (1:200,000) was administered to rule out intrathecal or intravascular placement.
- Spinal anaesthesia was performed via a separate space using a 25G Quincke spinal needle, injecting 3.5 ml of 0.5% hyperbaric bupivacaine.

**Postoperative Analgesia**

Upon emergence from spinal anaesthesia, postoperative pain was assessed using the Visual Analog Scale (VAS). When VAS ≥ 3, a single epidural top-up dose of 20 ml of the respective study drug was administered.

**Drug Preparation:**
- **Group A**: 10 ml of 0.2% ropivacaine + 0.8 ml fentanyl (2 mcg/ml) + 9.2 ml normal saline
- **Group B**: 4 ml of 0.5% bupivacaine + 0.8 ml fentanyl (2 mcg/ml) + 15.2 ml normal saline (Final volume = 20 ml in both groups)

**Hemodynamic Monitoring And Data Collection**

The following parameters were recorded at baseline and at 15, 30, 60, 90, and 120 minutes post-epidural top-up:
- Heart Rate (HR)
- Systolic Blood Pressure (SBP)
- Diastolic Blood Pressure (DBP)
- Respiratory Rate (RR)
- Peripheral Oxygen Saturation ($SpO_2$)

The onset of analgesia was defined as the time from drug administration to VAS score < 2.

The duration of analgesia was recorded as the time from drug administration to the next request for rescue analgesia (VAS ≥ 3).

**Adverse Events Monitoring**

**Patients Were Observed For Potential Side Effects:**
- Nausea, vomiting
- Bradycardia (HR < 60 bpm)
- Hypotension (MAP fall > 20% from baseline)
- Respiratory depression (RR < 8/min or $SpO_2$ < 92%)

All adverse events were treated as per standard clinical protocols and documented.

**Statistical Analysis**

**Data were analysed using IBM SPSS Statistics version 20.0.**
- Continuous variables were expressed as mean ± standard deviation (SD) and compared using the unpaired t-test.
- Categorical variables were expressed as percentages and analysed using the Chi-square test or Fisher's exact test.
- A p-value < 0.05 was considered statistically significant.

## RESULTS

A total of 133 patients were screened for eligibility. Thirteen patients were excluded due to non-compliance with inclusion criteria or failure of epidural catheter placement. Finally, 120 patients (60 in each group) completed the study and were included in the final analysis. Both groups were comparable with respect to demographic characteristics such as age, weight, height, and ASA physical status (p > 0.05).

**Hemodynamic Parameters**

**Diastolic Blood Pressure (DBP)**

The mean postoperative diastolic blood pressure was consistently higher in the Ropivacaine group (Group A) as compared to the Bupivacaine group (Group B) at all time points. The difference at baseline (time 0) was statistically significant (p = 0.0082), while subsequent measurements were not statistically different.

**Table 1: Comparison of Diastolic Blood Pressure Between Groups**

| Time (min) | Group A DBP (mmHg) | Group B DBP (mmHg) | Mean Diff | p-value | Significance |
|---|---|---|---|---|---|
| 0 | 80.1 | 78.4 | 1.7 | 0.0082 | Significant |
| 30 | 79.9 | 78.1 | 1.8 | >0.05 | Not Significant |
| 60 | 80.2 | 78.0 | 2.2 | >0.05 | Not Significant |
| 90 | 80.0 | 78.3 | 1.7 | >0.05 | Not Significant |
| 120 | 80.1 | 78.2 | 1.9 | >0.05 | Not Significant |

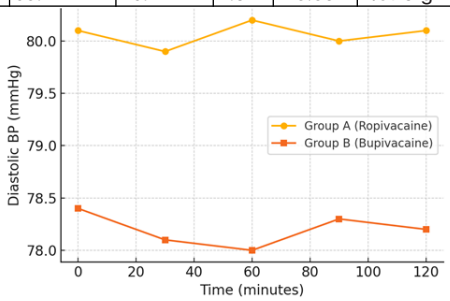


**Figure 1:** Illustrates the trend in diastolic BP between both groups, showing sustained higher values in Group A across all time intervals.

Figure 1 illustrates the mean systolic blood pressure (SBP) at 0, 30, 60, 90, and 120 minutes after epidural administration of study drugs. Group A (Ropivacaine + Fentanyl) consistently shows slightly higher SBP values than Group B (Bupivacaine + Fentanyl), although the difference is not statistically significant ($p > 0.05$). Both groups demonstrate stable SBP trends over time, indicating effective cardiovascular control in the postoperative period.

### Systolic Blood Pressure (SBP)

Both groups showed comparable systolic blood pressure values throughout the postoperative period. Although Group A maintained marginally higher SBP at each interval, the differences were not statistically significant ($p > 0.05$).

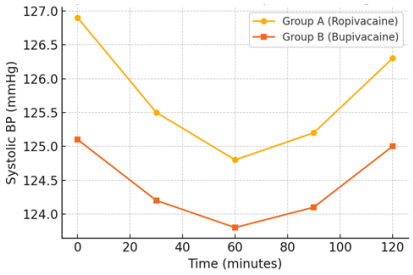


**Figure 2:** Depicting time-wise trend in SBP for both groups, showing a parallel pattern without clinical or statistical divergence.

### Heart Rate (HR)

Postoperative heart rate remained stable in both groups. The values were closely matched with no significant intergroup differences. No episodes of bradycardia (HR < 60 bpm) were noted.

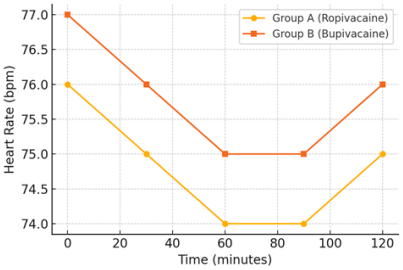


**Figure 3** shows the heart rate trend post-analgesia, with both groups maintaining heart rates between 74–77 bpm.

Figure 3 shows the mean heart rate (beats per minute) at 0, 30, 60, 90, and 120 minutes following epidural top-up. Both Group A and Group B maintain heart rates within a narrow range (74–77 bpm). No cases of bradycardia were observed. The trends are almost superimposed, indicating no significant difference in heart rate response between the two groups.

### Respiratory Rate And Oxygen Saturation

The mean respiratory rate and $SpO_2$ were maintained within normal physiological limits in both groups throughout the observation period. No statistically significant differences were found.

No major complications were observed. Minor side effects such as nausea or mild hypotension were noted but were evenly distributed across both groups and managed conservatively.

## DISCUSSION

Effective postoperative pain management is critical not only for patient comfort but also for minimizing surgical stress responses and preserving hemodynamic stability. In this prospective randomized study, we compared the hemodynamic effects of epidural 0.1% ropivacaine-fentanyl versus 0.1% bupivacaine-fentanyl in patients undergoing infraumbilical surgeries. The primary parameters evaluated were heart rate, systolic and diastolic blood pressure, respiratory rate, and oxygen saturation over a 120-minute postoperative period.

Our results showed that diastolic blood pressure (DBP) was significantly better maintained in the ropivacaine group (Group A) compared to the bupivacaine group (Group B), particularly at baseline ($p = 0.0082$), although the trend remained consistent throughout the observation period. Conversely, systolic blood pressure (SBP), heart rate (HR), respiratory rate (RR), and $SpO_2$ were comparable between both groups, with no significant differences.

These findings suggest that ropivacaine-fentanyl combination may offer superior hemodynamic stability, especially in terms of maintaining diastolic pressure, compared to bupivacaine-fentanyl when used in epidural analgesia.

Our results align with those of Bhupendra Tiwari et al. and Jagtap S et al., both of whom demonstrated that ropivacaine maintained more stable hemodynamic parameters in comparison to bupivacaine when administered epidurally [17,18]. In their studies, diastolic blood pressure and mean arterial pressure were found to be better preserved in the ropivacaine group, which echoes the findings of our trial.

On the other hand, studies by Beilin et al. and Bawdane et al. observed lower VAS pain scores in the bupivacaine group than the ropivacaine group; however, these differences were not statistically significant [10,16]. Importantly, their focus was on analgesic efficacy rather than hemodynamic outcomes, which may explain the discrepancy.

Further, Eddleston et al. and Finegold et al. reported that the duration of analgesia was marginally longer with ropivacaine compared to bupivacaine, although differences were not always statistically significant [11,12]. While our study was not designed to assess analgesia duration as a primary endpoint, it supports the notion that ropivacaine offers adequate postoperative pain control with a favourable safety margin.

The stability of diastolic blood pressure is especially important in patients with limited cardiovascular reserve, as fluctuations can adversely affect perfusion to vital organs. The

lower cardiotoxicity profile of ropivacaine, as noted in previous pharmacodynamic studies [6,7], further strengthens the case for its use in high-risk patients.

Our study, therefore, adds to a growing body of evidence favouring ropivacaine as a safer alternative to bupivacaine for epidural analgesia, particularly when hemodynamic precision is desired.

### Limitations

**While Our Study Was Adequately Powered And Methodologically Robust, It Had A Few Limitations:**

1. Short observation period (120 minutes) may not reflect late-phase hemodynamic changes or cumulative drug effects.
2. Motor block assessment and total 24-hour analgesic requirement were not evaluated.
3. The study was limited to ASA I–II patients; results may not directly generalize to higher-risk populations (e.g., ASA III–IV).

### Recommendations For Future Research

- Studies incorporating extended postoperative monitoring (up to 24 hours).
- Comparative studies including other adjuvants (e.g., clonidine, dexmedetomidine).
- Investigations in geriatric or cardiac-compromised patients.

## CONCLUSION

This prospective, randomized, double-blind study was conducted to evaluate and compare the hemodynamic effects of epidural 0.1% ropivacaine with fentanyl versus 0.1% bupivacaine with fentanyl in patients undergoing infraumbilical surgeries under combined spinal-epidural anaesthesia.

The study revealed that while most hemodynamic parameters—including systolic blood pressure, heart rate, respiratory rate, and oxygen saturation—remained statistically comparable between both groups, the diastolic blood pressure was significantly better preserved in the ropivacaine group. This finding suggests a more stable hemodynamic profile with ropivacaine, which could be clinically beneficial, especially in patients at risk for cardiovascular instability.

Both drug combinations were safe, effective, and well-tolerated, with no major adverse effects observed during the postoperative period. Given its favourable safety margin and more consistent maintenance of diastolic pressure, ropivacaine-fentanyl may be considered a superior alternative to bupivacaine-fentanyl for epidural analgesia in infraumbilical surgeries.

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