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Efficacy and Safety of Fentanyl as An Adjuvant To 0.75% Isobaric Ropivacaine in Epidural Anaesthesia for Infraumbilical Surgeries

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Abstract:

Background: *Epidural anaesthesia with ropivacaine is commonly employed for infraumbilical surgeries. The addition of fentanyl as an adjuvant aims to enhance analgesic efficacy, but a comprehensive assessment of its effects on sensory and motor blockade, hemodynamic stability, and safety is warranted.*

Objectives: *This randomized controlled trial aimed to compare the efficacy and safety of 0.75% isobaric ropivacaine alone versus 0.75% isobaric ropivacaine with fentanyl in epidural anaesthesia for infraumbilical surgeries.*

Methods: *Sixty adult patients undergoing elective infraumbilical surgeries were randomly assigned to receive either 0.75% isobaric ropivacaine (Group R) or 0.75% isobaric ropivacaine with 50 mcg fentanyl (Group RF) epidurally. Sensory and motor blockade characteristics, including onset, duration, and two-segment regression, were recorded. Hemodynamic parameters (systolic, diastolic, and mean arterial pressures, and heart rate) were monitored at regular intervals. Perioperative sedation and postoperative analgesic effect were assessed. Perioperative and postoperative complications were documented.*

Results: *Baseline demographic and clinical characteristics were comparable between the two groups. Group RF exhibited a significantly shorter time to two-segment regression of sensory level (59.2 ± 5.1 min vs. 67.3 ± 7.4 min, p=0.02) and a shorter time to reach the highest sensory blockade (19.1 ± 1.8 min vs. 22.1 ± 1.3 min, p=0.01). The duration of sensory and motor block was similar between both groups (p>0.05). Hemodynamic parameters in Group RF showed an initial transient decrease in blood pressure, followed by stabilization, and an initial increase in heart rate, followed by a decrease at later time points. The incidence of bradycardia and hypotension was low and comparable between the groups (p>0.05).*

Conclusions: *The addition of 50 mcg fentanyl to 0.75% isobaric ropivacaine in epidural anaesthesia for infraumbilical surgeries significantly accelerates the onset and progression of sensory blockade without prolonging its duration. Fentanyl induces transient hemodynamic changes that are clinically manageable. The combination is safe and effective for providing surgical anaesthesia.*

Keywords: *Epidural anaesthesia, ropivacaine, fentanyl, infraumbilical surgery, sensory blockade, hemodynamic parameters, randomized controlled trial.*

INTRODUCTION:

Central neuraxial blockade in the form of epidural anaesthesia is widely regarded as the gold standard technique for providing comprehensive and dynamic anaesthesia. Its advantages include suppression of the surgical stress response through sympatholysis, maintenance of stable haemodynamics with a reduction in cardiac morbidity, and a decreased incidence of pulmonary complications due to facilitation of active physiotherapy and early mobilization. Additionally, epidural anaesthesia has been shown to

reduce intraoperative blood loss and thromboembolic events, while avoiding the potential disadvantages of general anaesthesia, such as airway manipulation and polypharmacy [1.]

For infraumbilical procedures, spinal anaesthesia offers a rapid, reliable, and cost-effective means of achieving surgical anaesthesia. The therapeutic use of spinal anaesthesia dates back to 1898, when Karl August Bier first applied the technique [2.] Among the most frequently used local anaesthetics for central neuraxial blockade are ropivacaine, levobupivacaine, and bupivacaine. One of the key determinants of the extent and quality of anaesthesia produced is the baricity of the local anaesthetic, defined as the ratio of its density to that of cerebrospinal fluid [3.]

Epidural anaesthesia is particularly valued for its ability to provide both intraoperative anaesthesia and extended postoperative analgesia in lower abdominal and limb surgeries. Its benefits include a documented reduction in perioperative cardiac morbidity by 30%, pulmonary infections by 40%, pulmonary embolism by 50%, postoperative ileus by approximately 2 days, acute renal failure by 30%, and intraoperative blood loss by 30%, alongside a shortened hospital stay[4]. Ropivacaine, while effective, requires higher doses to achieve anaesthetic effects comparable to bupivacaine. The use of adjuvants can reduce the required dose, thereby minimizing dose-related side effects. Opioids remain the most widely used adjuvants in this context [5,6].

Fentanyl, a potent μ-opioid receptor agonist, exerts its analgesic action when administered epidurally by either crossing the dura to bind to spinal opioid receptors, being absorbed systemically to act at supraspinal sites, or through a combination of both mechanisms[7,8]. Considering these properties, the present study was designed to evaluate the efficacy and safety of fentanyl (50 μg) as an adjuvant to 0.75% isobaric ropivacaine in epidural anaesthesia for infraumbilical surgeries. Specifically, the study aimed to compare plain ropivacaine versus ropivacaine with fentanyl in terms of onset, duration, intensity, and recovery of sensory and motor block, as well as to assess intraoperative haemodynamic parameters, two-segment regression time, postoperative analgesic duration, perioperative sedation, and the incidence of intra- and postoperative complications.

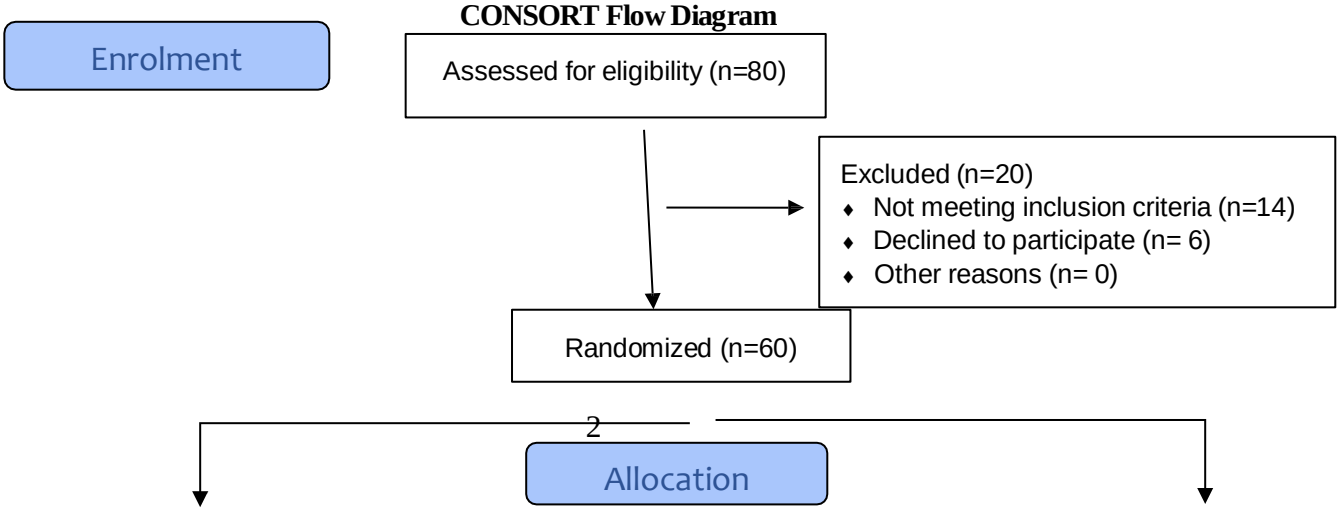
MATERIAL AND METHODS

This prospective, hospital-based, randomized controlled trial was conducted in the Department of Anaesthesiology, JSS Medical College and Hospital, Mysuru, India. A total of 60 adult patients, aged 20–50 years, scheduled for elective infraumbilical surgeries under epidural anaesthesia were recruited between the study period. The study was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants. **Inclusion criteria**: ASA Physical Status I or II, Age between 20 and 50 years and Elective infraumbilical surgery requiring epidural anaesthesia. Patients with Known hypersensitivity to study drugs, Emergency surgeries, Peripheral neuropathy and Coagulopathies were excluded from the study.

The sample size was calculated based on the difference in mean duration of sensory block between plain ropivacaine and ropivacaine with fentanyl as reported by Bhatia et al. (277.4 ± 27.0 min vs. 325.1 ± 36.8 min). Using a 95% confidence level, 80% power, and the formula:

Sample size (N) = $2SD^2(Z_{\alpha/2} + Z_{\beta})^2 / d^2$

Using these values at 95% Confidence limit and 80% power sample size of 27 was obtained in each group by using the below mentioned formula and Med calc sample size software. With 10% allowable error sample size of 27 + 2.7 ≈ 30 cases were included in each group.



Participants were randomized in a 1:1 ratio into two groups using a computer-generated sequence. Group R received plain isobaric ropivacaine (0.75%, 15 ml) with 1 ml normal saline; Group RF received isobaric ropivacaine (0.75%, 15 ml) with fentanyl 50 µg (1 ml). Drug preparation and administration were performed under aseptic precautions via the L2–L3 epidural space using an 18G Tuohy's needle and the hanging-drop technique.

Baseline vitals (heart rate, blood pressure, respiratory rate, SpO_2, ECG) were recorded. An intravenous line was secured, and lactated Ringer's or normal saline was infused at 10 ml/kg/h. All patients received intravenous ondansetron 4 mg as premedication. Accidental dural puncture or intravascular aspiration led to immediate exclusion.

Sensory block was assessed using cold swab and pin-prick tests every 2 min until T10 level was achieved, noting: Onset time, Time to complete block, Time to two-segment regression and Duration until return of sensation at S1

Motor block was evaluated via the Modified Bromage Scale, noting: Onset time, Time to complete block and Duration until full recovery (Bromage 6)

Hemodynamic parameters were recorded immediately post-injection, at 2-min intervals for 10 min, every 5 min until 30 min, every 15 min until 120 min, then every 30 min until 150 Postoperative pain was assessed using a visual analogue scale (VAS). Analgesia duration was defined as the time from drug administration to first rescue analgesic (intravenous diclofenac 75 mg for VAS ≥ 4).

Statistical Analysis: Data were entered into Microsoft Excel and analysed with SPSS v22. Categorical data were expressed as frequencies and percentages, and continuous data as mean ± SD. Chi-square or Fisher's exact test was used for categorical comparisons, and independent t-test or Mann–Whitney U test for continuous variables, as appropriate. A p-value < 0.05 was considered statistically significant.

RESULTS:

Table 1: General characteristics across the study participants (N=60)

Characteristics		Plain ropivacaine Frequency (%)	Isobaric ropivacaine with fentanyl Frequency (%)	P value
Age group	18-40 years	13 (43.3)	12 (40.0)	0.790
	41-60 years	17 (56.7)	18 (60.0)	
Sex	Male	16 (53.3)	15 (50.0)	0.630
	Female	14 (46.7)	15 (50.0)	
ASA status	One	22 (73.3)	23 (76.7)	0.910
	Two	8 (26.7)	7 (23.3)	
Duration of surgery (in minutes)	Mean ± SD	77.3 ± 26.3	73.5 ± 22.7	0.440#
BMI	Mean ± SD	27.3 ± 2.1	26.2 ± 1.7	0.680#

Pearson Chi-square Test, #Independent t test

The study included 60 participants, evenly distributed between the plain ropivacaine and isobaric ropivacaine with fentanyl groups. Age distribution was similar, with 43.3% of participants aged 18–40 years in the plain ropivacaine group and 40.0% in the fentanyl group (P = 0.79). The proportion of male and female participants was comparable between the groups (P = 0.63). Most participants had an ASA status of one (73.3% in the plain ropivacaine group vs. 76.7% in the fentanyl group, P = 0.91). The mean duration of surgery was slightly longer in the plain ropivacaine group (77.3 ± 26.3 min vs. 73.5 ± 22.7 min, P = 0.44), and BMI values were similar between the groups (P = 0.68). Overall, the baseline

characteristics were well-matched between the two groups proving that randomization had done properly [Table 1].

Table 2: Comparison of outcomes across the study participants (N=60)

Characteristic	Plain ropivacaine Mean [SD]	Isobaric ropivacaine with fentanyl Mean [SD]	P value
Duration of sensory blockade (minutes)	194.3 ± 27.6	190.4 ± 29.7	0.09
Duration of motor blockade (minutes)	116.5 ± 27.1	113.1 ± 17.5	0.120
Time to two-segment regression of sensory level (minutes)	67.3 ± 7.4	59.2 ± 5.1	0.02*
Time onset of sensory blockade (minutes)	15.6 ± 1.4	14.4 ± 1.8	0.650
Time onset of motor block (minutes)	24.3 ± 1.6	22.7 ± 1.7	0.410
Time for highest sensory blockade (minutes)	22.1 ± 1.3	19.1 ± 1.8	0.01*

Independent t test

The study compared the effects of plain ropivacaine and isobaric ropivacaine with fentanyl on various anesthetic outcomes. The duration of sensory and motor blockade was slightly longer with plain ropivacaine (194.3 ± 27.6 min vs. 190.4 ± 29.7 min, P = 0.09; and 116.5 ± 27.1 min vs. 113.1 ± 17.5 min, P = 0.12, respectively). The time to two-segment regression of sensory level was significantly longer in the plain ropivacaine group (67.3 ± 7.4 min vs. 59.2 ± 5.1 min, P = 0.02). Similarly, the time required to reach the highest sensory blockade was longer with plain ropivacaine (22.1 ± 1.3 min vs. 19.1 ± 1.8 min, P = 0.01). However, the onset times for sensory and motor blockade were comparable between the two groups (P = 0.65 and P = 0.41, respectively). These results suggest that while the addition of fentanyl to isobaric ropivacaine may shorten several anesthetic durations [Table 2].

Table 3. Comparison of adverse outcomes across the Study Groups (N = 60)

	Characteristics	Plain ropivacaine Frequency (%)	Isobaric ropivacaine with fentanyl Frequency (%)	P value
Bradycardia	Yes	1 (3.3%)	3 (10.0%)	0.610
	No	29 (96.7%)	27 (90.0%)	
Hypotension	Yes	2 (6.7%)	5 (16.7%)	0.460
	No	28 (93.3%)	25 (83.3%)	

Pearson Chi-square Test

The incidence of adverse outcomes, including bradycardia and hypotension, was low in both study groups. Bradycardia occurred in 3 patients (10.0%) in the isobaric ropivacaine with fentanyl group compared to 1 patient (3.3%) in the plain ropivacaine group (P = 0.61). Hypotension was observed in 5 patients (16.7%) in the fentanyl group and 2 patients (6.7%) in the plain ropivacaine group (P = 0.46). Although the fentanyl group had slightly higher rates of both adverse effects, the differences were not statistically significant [Table 3].

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Table 4: Change in Vital Parameters across the groups, n=60

Time	SBP			DBP			MAP			Heart rate		
	Plain ropivacaine	Isobaric ropivacaine with fentanyl	p-value	Plain ropivacaine	Isobaric ropivacaine with fentanyl	p-value	Plain ropivacaine	Isobaric ropivacaine with fentanyl	p-value	Plain ropivacaine	Isobaric ropivacaine with fentanyl	p-value
5 Min	122 ± 8.5	120 ± 7.5	0.278	78 ± 5.2	77 ± 4.8	0.338	92 ± 5.5	91 ± 4.9	0.387	75.1 ± 13.4	76.7 ± 14.2	0.415
10 Min	118 ± 7.2	114 ± 6.8	<0.001*	74 ± 5.0	72 ± 4.5	0.001*	89 ± 5.0	86 ± 4.8	0.003*	78.5 ± 11.9	78.2 ± 13.9	0.562
15 Min	130 ± 6.9	116 ± 5.8	<0.001*	80 ± 4.8	75 ± 4.3	<0.001*	97 ± 5.2	89 ± 4.3	<0.001*	80.4 ± 12.6	83.3 ± 12.6	<0.001*
20 Min	128 ± 7.5	115 ± 6.3	<0.001*	79 ± 5.1	74 ± 4.2	<0.001*	95 ± 4.8	88 ± 4.4	<0.001*	79.1 ± 11.7	82.7 ± 13.9	<0.001*
40 Min	126 ± 8.0	113 ± 7.0	<0.001*	76 ± 4.7	73 ± 4.6	<0.001*	94 ± 5.0	87 ± 4.5	<0.001*	78.3 ± 10.7	80.7 ± 11.3	<0.001*
60 Min	132 ± 7.8	118 ± 6.7	<0.001*	82 ± 5.3	76 ± 4.8	<0.001*	99 ± 5.6	90 ± 5.0	<0.001*	77.1 ± 12.1	78.2 ± 11.2	0.134
120 Min	124 ± 7.4	119 ± 7.2	0.002*	77 ± 5.0	75 ± 4.9	0.024*	93 ± 5.1	91 ± 5.2	0.04*	75.6 ± 12.1	75.0 ± 11.1	0.451
150 Min	122 ± 8.0	121 ± 7.5	0.315	76 ± 5.1	75 ± 5.0	0.425	92 ± 5.4	91 ± 5.3	0.310	73.4 ± 10.9	72.1 ± 10.6	0.314
180 Min	118 ±17.7	124 ±14.9	0.023*	76 ± 9.5)	76 ± 12.1	0.412	93 ± 5.1	92 ± 4.2	0.410	72.5 ± 10.8	69.1 ± 11.1	0.045*
210 Min	112 ±18.2	118 ±13.0	0.011*	72 ± 9.8)	72 ± 12.0	0.313	92 ± 4.6	93 ± 3.9	0.330	71.5 ± 10.7	65.8 ± 10.6	0.001*
240 Min	110 ±17.1	112 ±13.8	0.091	70 ±10.1	70.8 ±9.8	0.213	90 ± 4.4	91 ± 4.3	0.210	70.5 ± 10.2	63.6 ± 10.7	0.001*

Independent t test

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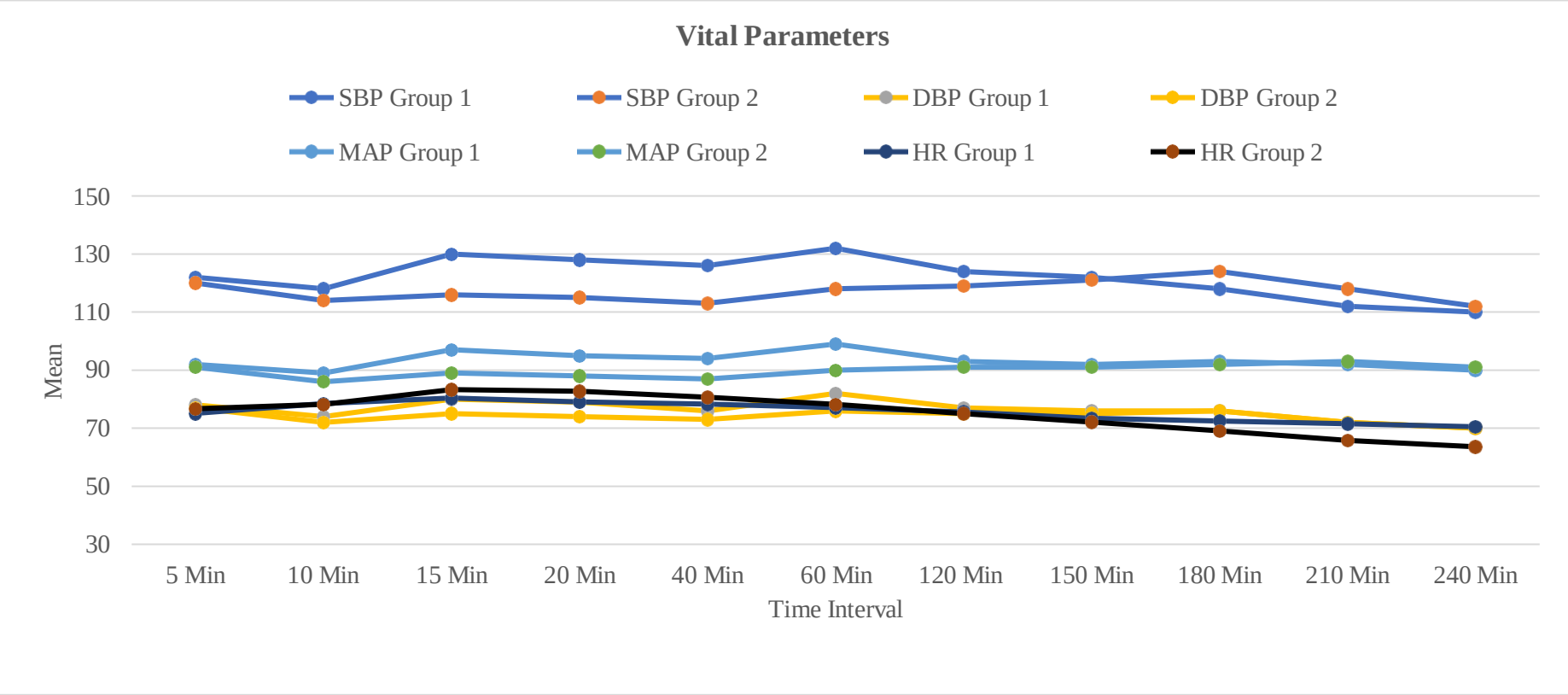

Figure 1: Line diagram showing Change in Vital Parameters across the groups

The systolic blood pressure (SBP) showed notable variations between the plain ropivacaine and isobaric ropivacaine with fentanyl groups over time. At 5 minutes, SBP values were comparable (P = 0.278), but from 10 minutes to 2 hours, the fentanyl group consistently demonstrated significantly lower SBP (P < 0.001 to P = 0.002). By 2.5 hours, differences were no longer significant (P = 0.315). Interestingly, at 3 and 3.5 hours, the fentanyl group recorded significantly higher SBP compared to the plain ropivacaine group (P = 0.023 and P = 0.011, respectively), with the difference diminishing by 4 hours (P = 0.091). Diastolic blood pressure (DBP) followed a similar trend, with no significant difference at baseline (P = 0.338), but significantly lower values in the fentanyl group from 10 minutes to 2 hours (P < 0.001 to P = 0.024). The mean arterial pressure (MAP) changes mirrored SBP and DBP trends, showing no significant difference at 5 minutes (P = 0.387) but significantly lower values in the fentanyl group from 10 minutes to 2 hours (P < 0.001 to P = 0.04), stabilizing thereafter.

Heart rate (HR) trends revealed distinct early and late effects. At 5 and 10 minutes, HR differences were insignificant (P = 0.415 and P = 0.562), but from 15 to 40 minutes, the fentanyl group exhibited significantly higher HR (P < 0.001). By 60 minutes through 2.5 hours, HR differences were not statistically significant (P > 0.1). However, from 3 hours onwards, HR was significantly lower in the fentanyl group, with the most pronounced decline noted at 3.5 and 4 hours (P = 0.001). Overall, isobaric ropivacaine with fentanyl was associated with an early reduction in SBP, DBP, and MAP, accompanied by a transient increase in HR, followed by late-phase stabilization or reversal of trends, particularly with SBP and HR [Table 4].

DISCUSSION: The present findings demonstrate that fentanyl, when added to isobaric ropivacaine in epidural anaesthesia, significantly shortens the time to two-segment regression and the time to achieve maximal sensory blockade, consistent with prior evidence of opioid–local anaesthetic synergy [9,10]. Fentanyl's μ-opioid receptor agonism enhances sensory blockade by acting at the dorsal horn of the spinal cord, a mechanism well-documented in neuraxial analgesia literature[11,12]. Rathmell et al. similarly observed that adding opioids to local anaesthetics accelerates sensory onset through synergistic modulation of nociceptive transmission [13].

Our observation that sensory and motor block durations were only minimally reduced in the fentanyl group contrasts with the prolonged analgesia often expected from opioids, but aligns with evidence suggesting that fentanyl's primary effect is on onset and intensity rather than duration[14]. A plausible explanation is that fentanyl reduces the local anaesthetic requirement, producing adequate block quality without prolonging its duration.

Hemodynamic effects in this study are also in line with the pharmacological profile of fentanyl. The initial reductions in SBP, DBP, and MAP are attributable to fentanyl's sympatholytic action and vasodilatory effect[15]. Subsequent stabilization or relative increases in blood pressure may reflect compensatory activation of the renin–angiotensin–aldosterone system or catecholamine release. Bradycardia and hypotension occurred slightly more often in the fentanyl group, consistent with prior reports [16,17], and are recognized in meta-analyses evaluating neuraxial opioids18 and safety reviews of epidural agents [19].

The biphasic HR response—early increase followed by later reduction—mirrors patterns seen in other studies of neuraxial fentanyl [20]. The initial tachycardia could result from procedural anxiety or transient sympathetic activation, while the subsequent bradycardia likely reflects central vagal stimulation.

From a pharmacodynamic perspective, fentanyl enhances ropivacaine's efficacy by inhibiting release of excitatory neurotransmitters such as substance P and glutamate in the substantia gelatinosa. Ropivacaine, by blocking sodium channels, prevents nerve impulse propagation. Their combined action yields faster and more profound sensory blockade [21]. The rapid regression observed may be linked to reduced ropivacaine dosing when combined with fentanyl, leaving less residual anaesthetic to sustain the block [22,23]. Overall, this study supports fentanyl as a safe and effective adjuvant to isobaric ropivacaine for epidural anaesthesia in infraumbilical surgeries. It offers faster peak block and earlier regression without increasing adverse events, while inducing only transient and clinically manageable haemodynamic changes.

The main limitations of this study are its single-centre design, which may restrict generalisability, and a modest sample size that, while statistically adequate, could be expanded for greater power. Additionally, the absence of long-term postoperative outcome evaluation limits conclusions on sustained analgesic benefits.

CONCLUSION: This randomized controlled study demonstrates that fentanyl, when added as an adjuvant to isobaric ropivacaine in epidural anaesthesia for infraumbilical surgeries, enhances the onset and intensity of sensory blockade, improves intraoperative hemodynamic stability with appropriate monitoring, and optimizes postoperative analgesia. Clinical application of this combination can shorten recovery time, improve patient satisfaction, and reduce the need for additional analgesic interventions. Recommendations from these findings include incorporating fentanyl as a standard adjuvant in infraumbilical epidural anaesthesia, optimizing its dosing based on patient factors, implementing patient-controlled epidural analgesia (PCEA) for tailored postoperative care, investigating its long-term effects on pain control and satisfaction, and exploring its synergistic potential with other adjuvants such as clonidine or dexmedetomidine to refine epidural protocols.

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