

**TO STUDY ANALGESIC EFFICACY OF INTRAVENOUS LIDOCAINE-FENTANYL AND EPIDURAL BUPIVACAINE-FENTANYL AFTER MAJOR ABDOMINAL SURGERIES: A RANDOMIZED CONTROLLED TRIAL**

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ABSTRACT **Introduction:** Effective pain management post-abdominal surgery is essential to prevent complications, promote recovery, and improve patient outcomes. Traditional methods, including epidural local anesthetics (LAs) and intravenous opioids, are effective but have limitations. While epidural bupivacaine-fentanyl provides superior analgesia, it may cause hypotension and bradycardia. Intravenous opioids, though effective, pose risks like respiratory depression and opioid addiction. **Aim:** This study aims to compare the analgesic efficacy of intravenous lidocaine-fentanyl versus epidural bupivacaine-fentanyl in patients undergoing major abdominal surgery. The primary objective is to evaluate postoperative pain relief using the Numerical Rating Scale (NRS) between the two groups. **Materials And Methods:** Sixty patients scheduled for elective abdominal surgeries were randomly assigned to receive either intravenous lidocaine-fentanyl (Group IV) or epidural bupivacaine-fentanyl (Group EPI). Participants were between 18-60 years old, classified as ASA I-III. Postoperative pain was assessed at various intervals using the NRS. Statistical significance was determined at $p < 0.05$ using SPSS version 25.0. **Results:** Preliminary findings suggest that the epidural group experienced more effective pain relief with reduced rescue analgesia requirements compared to the intravenous group. Mean NRS scores were lower in the epidural group at multiple time points, though not all differences were statistically significant. Fewer opioid-related side effects, such as nausea and pruritus, were observed in the epidural group. **Conclusion:** While both regimens were effective, epidural bupivacaine-fentanyl provided better pain relief with reduced rescue analgesia, though not statistically significant. Both methods demonstrated similar safety profile and viable options for postoperative pain management.

KEYWORDS : Postoperative analgesia, Abdominal surgery, Epidural vs intravenous analgesia, Opioid-sparing analgesics.

INTRODUCTION

A significant portion of both planned and emergency surgeries involves abdominal procedures, each catering to diverse patient populations with distinct pain management needs.¹ Effective analgesic techniques must consider patient-specific factors and the type of surgical procedure, as increased pain scores during the postoperative period are linked to complications, slower recovery, and reduced quality of life. Despite the development of several multimodal analgesia regimen, about 41% of patients in the immediate postoperative period and 30% of patients on the first post operative period experience moderate to severe pain.² Inadequate pain control after surgery can also lead to prolonged opioid use, increasing the risk of opioid addiction and chronic post-surgical pain.³ Postoperative pain management options, such as epidural local anesthetics (LAs) and intravenous opioids, each come with limitations. Epidural LAs are often preferred for providing superior analgesia but carry risks such as hypotension and bradycardia, making them less suitable for surgeries with significant blood loss.^{4,5} Moreover, complications such as dislodgement or occlusion affect up to 37% of epidurals, potentially leading to inadequate pain relief and other clinical issues.

Intravenous opioids, though effective for managing postoperative pain, are frequently associated with adverse effects like itching, sedation, ileus, PONV, and respiratory depression, with some studies suggesting a link between opioid use and cancer recurrence.^{6,7} This necessitates careful consideration when selecting an analgesic strategy. The anti-inflammatory and opioid-sparing effects of intravenous lidocaine have shown promise in expediting gastrointestinal recovery, particularly after colorectal surgery, as highlighted in the "ALLEGRO trial (ISRCTN52352431)," which aims to assess its effectiveness in improving gastrointestinal recovery post-surgery.^{8,9} Intravenous lidocaine in infusion form is emerging as a viable alternative with documented efficacy in providing pain relief while minimizing opioid-related complications.¹⁰ However, protocols for lidocaine administration remain debated, with dosing strategies needing to account for factors like patient weight, hepatic blood flow changes, and potential interactions with other medications, particularly those affecting CYP1A2 and CYP3A4 metabolic pathways.^{11,12} This highlights the need for further research, especially in the Indian context, where a comparative analysis of epidural bupivacaine-fentanyl and intravenous lignocaine-fentanyl for

postoperative pain management is still largely unexplored.¹³

AIMS AND OBJECTIVES

The study aims to compare the analgesic efficacy of intravenous lidocaine-fentanyl and epidural bupivacaine-fentanyl following major abdominal surgeries. The primary objective is to evaluate and compare the post-operative pain scores using the Numerical Rating Scale (NRS) between the two groups. Additionally, the study seeks to assess and compare other potential complications that may arise in each group during the post-operative period.

MATERIAL AND METHODS

This prospective, randomized clinical study, was conducted during the period 2022-2024, following approval from the Board of Studies and the Ethical Committee. The sample size was calculated using G-power software, based on the prevalence of abdominal surgeries from January to December 2023. A total of 60 patients, undergoing major open abdominal surgeries under general anesthesia, aged 18-60 years and weighing more than 40 kg with ASA grade I, II, or III, were selected and randomly divided into two groups of 30 each: Group IV, receiving intravenous lignocaine and fentanyl, and Group EPI, receiving epidural bupivacaine and fentanyl. Randomization was performed using computer-generated numbers, and while blinding was not possible due to the inability to place sham epidural catheters in the IV group, postoperative analgesia was monitored by a third party to ensure unbiased results.

The average duration of surgeries in our study ranges from 2 to 3 hours, depending on complexity of the procedure.

Exclusion criteria included refusal to provide consent, renal or hepatic disease, pregnancy, pre-existing cardiac disease, mental illness, current opioid use, history of epilepsy, allergy to local anesthetic agents, and the need for postoperative ventilatory support.

Prior to the surgery, a detailed medical history, physical examination, and routine investigations were performed on all patients. General anesthesia was induced using propofol at a dose of 2-2.5 mg/kg, fentanyl at 2 µg/kg, and vecuronium at 0.1 mg/kg. Anesthesia was maintained with desflurane, and end-tidal CO₂ levels were kept between 35-45 mmHg. A balanced salt solution was infused at a rate of

6 mL/kg/h throughout the surgery. Neuromuscular blockade was reversed using neostigmine (0.06 mg/kg) and glycopyrrolate (0.01 mg/kg), and patients were extubated once they met the institutional criteria for postoperative stability. Intraoperative analgesia was maintained with a fentanyl bolus of 0.4 mcg/kg.

In the postoperative analgesic regimen, patients in Group IV received intravenous bolus of lignocaine (1.5 mg/kg) 10 minutes before induction of general anesthesia, followed by continuous intraoperative lignocaine infusion at 1 mg/kg/h. Fentanyl was administered as a bolus (0.5 µg/kg) before the surgical incision and then as a continuous infusion at 0.25 µg/kg/h postoperatively. In the postoperative period, patients received continuous infusions of lignocaine 0.5 mg /kg/h and fentanyl 0.25 µg/ kg/h, the maximum duration for intravenous lignocaine infusion in this study was 24 hours.

In Group EPI, an epidural catheter was placed before induction of general anesthesia, and a test dose of 2% lignocaine with adrenaline (1:200,000) was used to confirm the correct placement of the catheter. Epidural analgesia was initiated with bupivacaine 0.25% and fentanyl (2 µg/mL), followed by a continuous intraoperative infusion of 5 mL/h. Postoperatively, the continuous epidural infusion was maintained with bupivacaine 0.125 % fentanyl 1 µg/mL at 3-5 mL/h.

RESULT

A randomized prospective study was conducted involving 60 patients, aged 18 to 60 years, classified as ASA Grade I, II, or III, and scheduled for elective open abdominal surgeries under general anesthesia. The patients were randomly assigned into two groups: Group IV received intravenous lignocaine combined with fentanyl, and Group EPI received epidural bupivacaine combined with fentanyl.

The patient demographics and types of surgeries between the intravenous lignocaine-fentanyl (Group IV) and epidural Bupivacaine-fentanyl (Group EPI) groups are comparable across age, gender, and surgical procedures. The distribution of patients is similar in both groups, with no significant differences in demographic factors or types of surgeries, as indicated by the p-values. This suggests that the two groups are well-matched, allowing for a fair comparison of the analgesic effects between the two methods. (Table 1) The study aimed to compare the analgesic efficacy and safety of these regimens for postoperative pain management. Pain was assessed using the numerical rating score (NRS) at regular intervals, with the mean NRS scores, rescue analgesia requirements, and incidence of side effects being recorded and compared. Preliminary findings suggest that the epidural group may experience more effective pain relief and lower rescue analgesia needs. (Table 2)

Table 1: Comparison Of Patient Demographics And Surgery Between Intravenous Lignocaine-fentanyl (IV) And Epidural Bupivacaine-fentanyl (EPI) Analgesia Groups

Parameter	EPI	IV	Total	p-value
21 To 30 years	4 (13.3%)	5 (16.7%)	9 (15%)	0.126
31 to 40 years	4 (13.3%)	7 (23.3%)	11 (18.3%)	
41 to 50 years	9 (30%)	8 (26.7%)	17 (28.3%)	
>51 years	13 (43.4%)	10 (33.3%)	23 (38.4%)	
Male	12 (40.0%)	10 (33.3%)	22 (36.7%)	0.789
Female	18 (60.0%)	20 (66.7%)	38 (63.3%)	
Exploratory Laparotomy (n)	4	5	9	
Whipple's procedure (n)	2	1	3	
Staging laparotomy (n)	5	6	6	
Nephrectomy (n)	2	3	3	
Gastrectomy (n)	5	3	5	
Splenectomy (n)	2	1	3	
Radical hysterectomy (n)	3	1	1	
Retroperitoneal mass excision (n)	1	0	1	
Colectomy (n)	5	6	11	
Radical cholecystectomy (n)	0	2	2	

Table 2: Describing The Study Groups As Per NRS AT Different Time Intervals

	GROUP	Mean	Std. Deviation	p-value
NRS PRE	EPI	6.97	1.497	0.862
	IV	6.90	1.470	
NRS OHRS	EPI	6.27	1.507	0.778
	IV	6.37	1.217	
NRS 1HR	EPI	5.87	1.106	0.660
	IV	5.73	1.230	
NRS 2HRS	EPI	5.53	1.279	0.090
	IV	5.00	1.114	
NRS 4 HRS	EPI	5.17	1.621	0.932
	IV	5.20	1.375	
NRS 8 HRS	EPI	4.10	1.373	0.662
	IV	4.23	.935	
NRS 16 HRS	EPI	3.87	1.279	0.907
	IV	3.90	.885	
NRS 24 HRS	EPI	3.77	1.251	0.534
	IV	3.57	1.223	

In both the EPI and IV groups, the need for rescue fentanyl was minimal, with the majority of patients achieving adequate analgesia without additional opioid requirements. This suggests both analgesic approaches provide effective postoperative pain control with a low incidence of supplementary fentanyl administration. (Table 3)

Table 3: Comparison Of Rescue Fentanyl Consumption Between EPI And IV Analgesia Groups

FENTANYL CONSUMPTION	EPI	IV	Total
25 MCG Fentanyl	2 (6.7%)	1 (3.3%)	3 (5.0%)
50 MCG Fentanyl	0 (0.0%)	1 (3.3%)	1 (1.7%)

Overall, complications were minimal in both the EPI and IV groups. (Table 4) Bradycardia was rare, occurring equally in both groups. Hypotension was slightly more frequent in the EPI group, while light headedness and visual disturbances were only observed in the IV group. Postoperative nausea and vomiting (PONV) was reported in the EPI group but not in the IV group. Despite these findings, the majority of patients in both groups experienced no complications, indicating that both analgesic techniques are generally safe with a low incidence of adverse effects.

Table 4: Comparing The Study Groups As Per Complications

COMPLICATIONS	EPI	IV	Total
BRADYCARDIA	1 (3.3%)	1 (3.3%)	2 (3.3%)
HYPOTENSION	3 (1%)	1 (3.3%)	4 (13.3%)
LIGHT HEADEDNESS 4HRS	0 (0.0%)	2 (3.3%)	(3.3%)
NA	24 (80.0%)	24 (80.0%)	48 (80.0%)
PONV	2 (6.6%)	0 (6.7%)	2 (3.3%)
VISUAL DISTURBANCE	0 (0.0%)	2 (3.3%)	2 (3.3%)
Total	30 (100.0%)	30 (100.0%)	60 (100.0%)

DISCUSSION

This randomized trial demonstrates that intravenous lignocaine-fentanyl infusion is as effective as epidural bupivacaine-fentanyl for managing post-operative pain within the first 24 hours following major abdominal surgery. Both pain scores and rescue analgesia requirements were comparable between the two groups, with similar rates of adverse events, making intravenous lignocaine-fentanyl a safe and effective alternative to the traditional epidural approach.

Previous studies have shown comparable efficacy between epidural and intravenous analgesia in various surgical settings. Nandi et al.¹⁴ and Swenson et al.¹⁵ found no significant difference in pain scores or rescue analgesic requirements between epidural and intravenous regimens. Our study supports these findings, highlighting the potential of intravenous lignocaine-fentanyl as an alternative, particularly in cases where epidural administration is contraindicated.

Importantly, our study utilized lower doses of lignocaine compared to typical regimens, facilitated by the addition of fentanyl, which allowed for effective analgesia while minimizing potential side effects. The use of a multimodal analgesic approach maximized pain relief and minimized the risk of lignocaine toxicity.¹⁴

Hemodynamic variations were observed, with increased hypotension in the epidural group, primarily attributed to local anaesthetic infusion. Despite these differences, intraoperative fentanyl consumption was similar between groups, underscoring the equianalgesic potential of both techniques. These findings emphasize the need for careful monitoring when using epidural analgesia in surgical settings.

Intravenous lignocaine-fentanyl offers distinct advantages, particularly in patients on anticoagulation therapy where epidural catheter insertion poses risks, including nerve damage and hematoma. Additionally, systemic lignocaine has been associated with benefits similar to epidural local anaesthetics, such as reduced incidence of DVT and postoperative ileus.^{16,17}

However, lignocaine toxicity remains a concern. While rare, the risk of toxicity limits its broad applicability, highlighting the need for careful dosing and monitoring. Our study indicates that intravenous lignocaine can be effective, but further research is necessary to optimize its use and explore its full potential in post-operative pain management.

Limitations of this study include the absence of a pre-calculated sample size due to the lack of similar comparative data. Although our results are promising, adequately powered studies are required to validate these findings and explore the broader implications of intravenous lignocaine-fentanyl for post-operative care.

CONCLUSION

This study compared intravenous lignocaine-fentanyl with epidural bupivacaine-fentanyl in managing postoperative pain in elective open abdominal surgeries. While both regimens were effective, the epidural group required less rescue analgesia and showed better pain relief, though not statistically significant. Both groups had similar safety profiles, with comparable side effects, including nausea and vomiting. Both methods are viable options for pain management.

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