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Original Research Article

A PROSPECTIVE RANDOMIZED DOUBLE-BLIND STUDY COMPARING EPIDURAL NALBUPHINE WITH 0.125% BUPIVACAINE VERSUS PLAIN 0.125% BUPIVACAINE FOR POSTOPERATIVE ANALGESIA IN UPPER ABDOMINAL SURGERY

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ABSTRACT

Background: Postoperative pain after upper abdominal surgery often leads to respiratory complications and delayed recovery. Thoracic epidural with 0.125% bupivacaine is effective but limited by short duration. This study aimed to determine whether adding nalbuphine (0.2 mg/kg) enhances onset, duration, quality of analgesia, and safety compared to plain 0.125% bupivacaine. **Materials and Methods:** This prospective, randomised, double-blind study included 60 ASA I–III patients undergoing upper abdominal surgery, allocated into two groups (n=30 each). Group A received epidural nalbuphine (10 mg) with 0.125% bupivacaine, while Group B received 0.125% bupivacaine with saline. Onset and duration of analgesia, VAS scores, sedation, hemodynamic parameters, rescue analgesia, and side effects were evaluated ($p < 0.05$ considered significant). **Results:** Groups were comparable in demographics, surgery types, and baselines (all $p>0.05$). Group A showed faster onset of sensory blockade (7.07 ± 1.08 vs 17.83 ± 2.98 min; $p<0.001$) and longer analgesia (8.40 ± 0.62 vs 3.67 ± 0.53 h; $p<0.001$). VAS scores were significantly lower in Group A from 15 min to 4 h ($p\leq0.020$). Sedation was higher in Group A early postoperatively ($p<0.001$) but mild/transient. No rescue analgesia in Group A (vs 2 in Group B). Hemodynamics remained stable with no intergroup differences or clinical instability. No side effects occurred in either group. **Conclusion:** Epidural nalbuphine (0.2 mg/kg) with 0.125% bupivacaine provides faster onset, prolonged duration, superior early pain control, and excellent safety, making it an effective adjuvant for postoperative analgesia in upper abdominal surgery.

INTRODUCTION

Postoperative pain following upper abdominal surgery remains a major clinical challenge, often leading to prolonged hospital stays, delayed recovery, and increased risk of complications such as pulmonary dysfunction.[1] Effective management of this pain is crucial for improving patient outcomes and supporting early mobilisation.[2] Thoracic epidural analgesia has emerged as a preferred method for postoperative pain control in such procedures, offering targeted relief while minimising systemic opioid use.[3] This technique involves the administration of local anaesthetics into the epidural space at the thoracic level, thereby blocking nociceptive signals from the surgical site.[4] Bupivacaine, a long-acting amide local anaesthetic, is commonly used at concentrations such as 0.125% for its balance between analgesic efficacy and reduced motor blockade.[5] However, when used alone, plain bupivacaine may provide insufficient duration of analgesia, necessitating frequent dosing or higher concentrations that could precipitate hemodynamic instability or other adverse effects.[6]

To improve epidural analgesia, adjuvants are frequently added to local anaesthetics to prolong pain relief and improve quality without escalating doses.[7] Among these, opioids have been widely studied, but concerns over side effects like respiratory depression, nausea, and pruritus limit their appeal.[8] Nalbuphine, a synthetic opioid with kappa-agonist and mu-antagonist properties, presents a promising alternative by providing effective analgesia through

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kappa receptor activation while reducing mu-mediated complications.[9] Its mixed profile allows for effective visceral pain control, which is particularly relevant in upper abdominal surgeries involving peritoneal irritation.[10] Recent investigations have demonstrated that adding nalbuphine to bupivacaine in neuraxial blocks extends postoperative analgesia compared to bupivacaine alone.[11] In abdominal procedures, nalbuphine adjuvants have shown faster onset and longer duration of sensory blockade without affecting hemodynamic stability.[12] Previous studies highlight reduced requirements for rescue analgesics and a lower incidence of side effects such as sedation or vomiting when nalbuphine is incorporated.[13]

Even with optimal dosing and comparative efficacy, thoracic epidurals specifically for upper abdominal surgery require further investigations.[14] Variations in patient response, including sedation levels and pain assessment via tools like the Visual Analogue Scale (VAS), need careful evaluation to refine protocols.[15] Hemodynamic monitoring is essential, as epidural techniques can affect blood pressure and heart rate (HR), which may be further increased by the use of adjuvants.[16] This study compares thoracic epidural analgesia using nalbuphine with 0.125% bupivacaine versus 0.125% bupivacaine alone for postoperative pain control after upper abdominal surgery. Parameters evaluated include onset and duration of analgesia, pain scores (VAS), sedation, hemodynamic stability, need for rescue analgesia, and incidence of side effects.

MATERIALS AND METHODS

This prospective, double-blind, randomised controlled trial was conducted in the Department of Anaesthesiology, Government Theni Medical College and Hospital, Theni. Ethical clearance was obtained from the Institutional Ethics Committee prior to the study, and written informed consent was obtained from all parents.

Inclusion Criteria

Patients of both sexes, aged between 18 and 55 years, with ASA physical status I, II, and III, who were posted for elective and emergency upper abdominal surgery.

Exclusion Criteria

Pregnant patients, known alcoholics or drug abusers, patients with an allergy to drugs involved in the study, bradycardia, any type of atrioventricular block or heart failure, significant neurological, hepatic, renal or pulmonary diseases. Patients with ASA grade IV and V, infection at the site of injection, contraindications such as thrombocytopenia or coagulopathy, uncooperative patients, and patients with failed epidural.

Methods

This study included 60 patients posted for elective and emergency upper abdominal surgeries at Government Theni Medical College, who were randomly allocated by systematic random sampling into two groups of 30 each. The study drug for Group A consisted of 1 ml of nalbuphine (10 mg) with 2.5 ml of 0.5% bupivacaine diluted with normal saline to a total volume of 10 ml, while Group B received 1 ml of normal saline with 2.5 ml of 0.5% bupivacaine diluted to 10 ml. During the preoperative visit, a detailed history and general and systemic examinations were performed, and demographic variables such as age, sex, height, and weight were recorded; the 10-cm Visual Analogue Scale (VAS) was explained to all patients. After securing an 18-gauge intravenous cannula, patients were preloaded with Ringer's lactate 15 ml/kg and premedicated with intramuscular midazolam 0.1–0.5 mg/kg 45–60 minutes before surgery. Standard monitoring with pulse rate, mean arterial pressure (MAP), SpO_2 , and ECG was instituted. Prior to induction of general or regional anaesthesia, an epidural catheter was placed at the T9–T11 level using a 17–18 gauge Tuohy needle and advanced 4–5 cm into the epidural space to lie at T7–T9; correct placement was confirmed with a 3 ml test dose of lignocaine with adrenaline (1:200,000). Intraoperative fluid therapy was guided by haemodynamic parameters and blood loss, and patients were monitored postoperatively in the recovery unit. Sedation was assessed using Wilson's sedation score, pain using VAS at 2-hour intervals, and duration of analgesia was defined as the time to VAS $\geq$5 or patient complaint of moderate to severe pain. SpO_2 was monitored continuously, and pulse rate, blood pressure, MAP, and respiratory rate were recorded every 5 minutes. The requirement for rescue analgesia and adverse effects such as nausea, vomiting, pruritus, respiratory depression, urinary retention, and level of sedation were also documented.

Statistical Analysis

Data were analysed using statistical software. Continuous variables were expressed as mean ± SD, and categorical variables as frequencies and percentages. Intergroup comparison of continuous variables was performed using the Student's t-test, while categorical variables were analysed using the Chi-square test. Changes in HR and MAP over time were analysed using factorial repeated-measures ANOVA, with post-hoc pairwise comparisons applied where appropriate. A p value < 0.05 was considered statistically significant.

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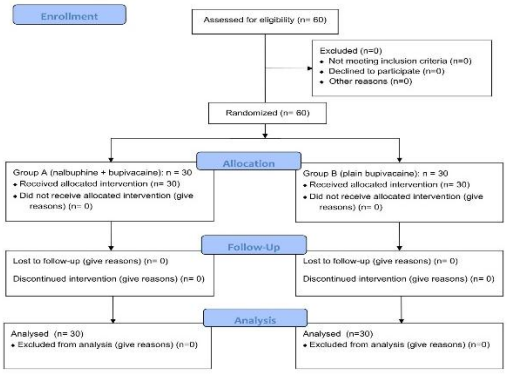

Figure 1: CONSORT flow diagram

RESULTS

The mean age in Groups A and B is (42.43 ± 10.85 vs 47.33 ± 8.08 years) (p = 0.052). Age distribution, gender distribution (63.3% vs 70% males; p = 0.584), mean weight (55.80 ± 9.90 kg vs 56.00 ± 10.22 kg; p = 0.939), and mean height (158.73 ± 5.33 cm vs 159.10 ± 4.82 cm; p = 0.781) showed no statistically significant difference between the groups. [Table 1]

Table 1: Baseline demographic characteristics of the study groups (n = 60)

Parameter		Group A (n=30)	Group B (n=30)	p value
Mean Age (years)		42.43 ± 10.85	47.33 ± 8.08	0.052
Age distribution	<25 years	3 (10%)	1 (3.3%)	–
	26–40 years	9 (30%)	4 (13.3%)	
	41–55 years	18 (60%)	25 (83.3%)	
Gender	Male	19 (63.3%)	21 (70%)	0.584
	Female	11 (36.7%)	9 (30%)	
Mean Weight (kg)		55.80 ± 9.90	56.00 ± 10.22	0.939
Mean Height (cm)		158.73 ± 5.33	159.10 ± 4.82	0.781

The distribution of elective and emergency surgeries was similar in both groups (p = 0.774). The type of surgery performed was also comparable between groups (p = 0.953). [Table 2]

Table 2: Distribution of subjects according to surgical indication and type of surgery (n = 60)

	Parameter	Group A n (%)	Group B n (%)	p value
Indication of surgery	Elective	22 (73.3%)	21 (70%)	0.774
	Emergency	8 (26.7%)	9 (30%)	
Type of surgery	Supraumbilical hernia	6 (20%)	5 (16.7%)	0.953
	Gastrointestinal surgery	7 (23.3%)	9 (30%)	
	Hepatobiliary surgery	8 (26.7%)	6 (20%)	
	Emergency laparotomy	8 (26.7%)	9 (30%)	
	Renal surgery	1 (3.3%)	1 (3.3%)	

Group A showed a significantly earlier onset of sensory blockade (7.07 ± 1.08 min) compared to Group B (17.83 ± 2.98 min), with a mean difference of −10.77 minutes (p < 0.001). The duration of analgesia was significantly longer in Group A (8.40 ± 0.62 hours) than in Group B (3.67 ± 0.53 hours), with a mean difference of 4.73 hours (p < 0.001). [Table 3]

Table 3: Comparison of onset of sensory blockade and duration of analgesia (n = 60)

Parameter	Group A (n=30)	Group B (n=30)	Mean difference	p value
Onset of sensory blockade (min)	7.07 ± 1.08	17.83 ± 2.98	−10.77	<0.001
Duration of analgesia (hours)	8.40 ± 0.62	3.67 ± 0.53	4.73	<0.001

Baseline HR and MAP were comparable between Group A and Group B (p > 0.05). At 15 minutes, 30 minutes, 60 minutes, and 2 hours, both parameters showed similar changes in both groups with no significant intergroup differences throughout the study period (p > 0.05). [Table 4]

Table 4: Group-wise comparison of mean heart rate and arterial pressure at various time intervals (n = 60)

Parameter	Time Interval	Group A (Mean ± SD)	Group B (Mean ± SD)	p value
HR (beats/min)	Baseline	99.67 ± 15.20	95.70 ± 14.35	> 0.05
	15 min	87.53 ± 10.67	90.47 ± 13.15	
	30 min	86.17 ± 10.50	82.83 ± 11.49	
	60 min	85.57 ± 9.80	79.43 ± 10.29	
	2 hours	86.00 ± 9.39	80.37 ± 9.08	
MAP (mmHg)	Baseline	95.20 ± 7.06	96.83 ± 10.30	> 0.05
	15 min	82.40 ± 6.94	84.90 ± 9.13	
	30 min	80.20 ± 6.42	79.27 ± 8.37	
	60 min	83.17 ± 6.53	80.47 ± 6.72	
	2 hours	89.10 ± 6.08	88.17 ± 5.62	

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Significantly higher sedation levels were observed in Group A from 15 minutes to 2 hours ($p < 0.001$). Baseline VAS scores were similar ($p = 0.47$), but Group A showed significantly lower pain scores from 15 minutes to 4 hours ($p \leq 0.020$) (Table 5). Rescue analgesia was required in two patients in Group B and none in Group A. No side effects were reported in either group.

Table 5: Comparison of sedation scores, pain scores (VAS), rescue analgesia, and side effects between study groups (n = 60)

Parameters	Time interval	Sedation score	Group A (n)	Group B (n)	p value
Sedation Scores (Wilson's Sedation Scale)	Baseline (n=60)	1	30	30	NA
		2	0	0	
	15 min (n=60)	1	0	30	<0.001
		2	22	0	
		3	8	0	
	30 min (n=60)	1	0	30	<0.001
		2	15	0	
		3	15	0	
	60 min (n=60)	1	0	30	<0.001
		2	13	0	
		3	17	0	
	2 hours (n=60)	1	0	30	<0.001
		2	8	0	
		3	21	0	
		4	1	0	
	4 hours (n=30)	2	8	0	NA
		3	20	0	
		4	2	0	
	6 hours (n=30)	2	20	0	NA
		3	10	0	
	8 hours (n=30)	1	17	0	NA
		2	13	0	
	10 hours (n=17)	1	17	0	NA
VAS Scores	**Time interval**	**VAS score**	**Group A (n)**	**Group B (n)**	**p value**
	Baseline (n=60)	6	4	1	0.47
		7	8	10	
		8	9	8	
		9	8	11	
		10	1	0	
	15 min (n=60)	1	15	7	0.020
		2	12	10	
		3	3	10	
		4	0	3	
	30 min (n=60)	1	15	7	0.003
		2	15	12	
		3	0	10	
		4	0	1	
	60 min (n=60)	1	15	7	0.005
		2	15	13	
		3	0	9	
		4	0	1	
	2 hours (n=60)	1	14	4	<0.001
		2	16	12	
		3	0	10	
		4	0	3	
		6	0	1	
	4 hours (n=60)	1	12	0	<0.001
		2	17	0	
		3	1	0	
		5	0	4	
		6	0	11	
		7	0	9	
		8	0	6	
	6 hours (n=30)	1	6	0	NA
		2	18	0	
		3	3	0	
		4	3	0	
	8 hours (n=30)	2	3	0	NA
		3	4	0	
		4	4	0	
		5	4	0	
		6	9	0	
		7	5	0	
		8	1	0	

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	10 hours (n=14)	5	2	0	NA
		6	4	0	
		7	3	0	
		8	5	0	

NA – Not applicable (statistical comparison not possible due to absence of observations in one group).

DISCUSSION

Postoperative pain following upper abdominal surgery is a major contributor to respiratory complications, delayed mobilisation, and prolonged hospital stay, making effective analgesia essential for enhanced recovery. This study evaluated the effect of adding epidural nalbuphine (0.2 mg/kg) to 0.125% bupivacaine on the onset, duration, and quality of postoperative analgesia, along with sedation, hemodynamic stability, rescue analgesic requirement, and adverse effects in patients undergoing upper abdominal surgery. The nalbuphine combination produced a faster onset and prolonged duration of analgesia, lower early postoperative pain scores, and reduced need for rescue analgesia, while maintaining stable hemodynamics with only mild, transient sedation and no major side effects.

In our study, the baseline demographic variables, including age distribution, gender distribution, weight, and height, were comparable between the two groups, with no statistically significant differences observed. Similarly, in the randomized study by Patel et al. the mean age of patients was 49.47 ± 11.68 years vs 44.2 ± 16.1 years ($p = 0.1521$) and mean weight was 59.9 ± 8.75 kg versus 57.6 ± 7.77 kg ($p = 0.2861$), with a similar gender distribution between groups (male: 16 [53%] vs 20 [67%], female: 14 [47%] vs 10 [33%], $p = 0.4292$), indicating no significant demographic differences between groups.[17] Thus, baseline demographic variables were comparable, ensuring comparability between the two groups.

In our study, the distribution of elective and emergency surgeries was similar in both groups, and the types of surgeries performed were uniformly distributed with no statistically significant difference. Group A showed a significantly earlier onset of sensory blockade and a significantly longer duration of analgesia compared to Group B. Baseline HR and MAP were comparable between groups ($p > 0.05$), and hemodynamic parameters remained stable at 15, 30, 60 minutes, and 2 hours with no significant intergroup differences. Similarly, Mahilamani and Pradeep reported comparable distribution of elective (73.3% vs 70%) and emergency surgeries (26.7% vs 30%) between groups ($p = 0.774$), with uniformly distributed surgical types including supraumbilical hernia, gastrointestinal, hepatobiliary, emergency laparotomy, and renal surgeries ($p = 0.953$). They also observed a significantly faster onset of sensory blockade in the nalbuphine group (7.07 ± 1.08 min vs 17.83 ± 2.98 min; $p < 0.001$) and prolonged duration of analgesia (8.40 ± 0.62 vs 3.67 ± 0.53 hours; $p < 0.001$). Baseline HR was comparable (99.67 ± 15.19 vs 95.70 ± 14.34 bpm), with time-related reductions at 15, 30, 60 minutes, and 2 hours, and significant MAP reductions from baseline at 15 (11.93), 30 (17.56), 60 (16.36), and 120 minutes (8.66) ($p < 0.001$), though without clinically significant instability.[18] These findings are consistent with our study, suggesting that the addition of nalbuphine to epidural bupivacaine results in faster onset and prolonged postoperative analgesia without clinically significant hemodynamic instability. The stable HR and MAP observed in both studies further support epidural nalbuphine as a safe and effective analgesic adjuvant.

Sedation was comparable at baseline but significantly higher in Group A early postoperatively. Baseline pain scores were similar; however, Group A had significantly lower early postoperative pain scores. Rescue analgesia was required only in Group B, and no side effects occurred. Similarly, Mahilamani and Pradeep reported faster onset (7.07 ± 1.08 vs 17.83 ± 2.98 min; $p < 0.001$) and longer duration of analgesia (8.40 ± 0.62 vs 3.67 ± 0.53 hrs; $p < 0.001$) with epidural nalbuphine, with stable hemodynamics and no major complications, findings consistent with our results.18 Similarly, Devi et al reported earlier onset (16.52 ± 2.25 vs 22.04 ± 2.64 min; $p = 0.0001$) and longer duration of analgesia (10.04 ± 2.25 vs 4.85 ± 0.69 hrs; $p = 0.0001$) with buprenorphine. VAS scores were significantly lower at 1, 2, 4, and 8 hours ($p = 0.0001$), and no patient required rescue analgesia compared to five in the bupivacaine group. Nausea (28%) and pruritus (32%) were higher in the opioid group, but no respiratory depression or motor blockade occurred.[19] Although buprenorphine and nalbuphine are different drugs, both are semisynthetic opioids acting on spinal receptors as epidural adjuvants, producing comparable improvements in onset, duration, and quality of analgesia. These findings support that adding nalbuphine to epidural bupivacaine improves analgesic onset and duration while maintaining hemodynamic stability and safety in upper abdominal surgeries.

Limitations

The sample size was relatively small, which may limit the generalizability of the findings. The study was conducted at a single centre, and variations in surgical techniques or patient populations may influence outcomes. Long-term follow-up beyond the immediate postoperative period was not performed, so delayed complications or prolonged analgesic effects could not be assessed. Biochemical markers of stress response were not evaluated. Larger multicentric studies with extended follow-up are recommended to further validate the efficacy and

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safety of epidural nalbuphine in upper abdominal surgeries.

CONCLUSION

The addition of epidural nalbuphine (0.2 mg/kg) to 0.125% bupivacaine in thoracic epidural analgesia provides a faster onset and significantly prolonged duration of postoperative analgesia, along with improved early pain control and reduced requirement for rescue analgesia. Although mild sedation was observed in the nalbuphine group, it remained clinically acceptable. Hemodynamic changes noted over time were consistent with the pharmacological effects of the drugs but were not associated with clinically significant instability. No major adverse effects or complications were observed in either group. These findings support epidural nalbuphine as a safe and effective adjuvant for postoperative analgesia in upper abdominal surgeries.

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