Section: Anesthesiology

Original Research Article

COMPARISON OF EFFICACY OF EPIDURAL NALBUPHINE AND EPIDURAL BUTORPHANOL FOR POST OPERATIVE PAIN RELIEF FOR ABDOMINAL AND LOWER LIMB SURGERIES

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ABSTRACT

Background: Postoperative pain management after abdominal and lower limb surgery is crucial for recovery. Epidural opioids are commonly used for analgesia in patients undergoing surgery. This study compared epidural nalbuphine and butorphanol for analgesia onset, duration, and haemodynamic stability during these surgeries. **Materials and Methods:** In these prospective randomized comparative study, 60 patients undergoing surgery were divided into Group B (epidural butorphanol 2 mg with 0.125% bupivacaine) and Group N (epidural nalbuphine 10 mg with 0.125% bupivacaine). All patients received a combined spinal-epidural anaesthesia. Haemodynamic parameters, Visual Analogue Scale scores, analgesia onset and duration, sedation, nausea, vomiting, and pruritus were assessed for 24 h post-administration. **Results:** The demographic characteristics were similar. The HR and MAP remained stable, with no significant differences ($p>0.05$). Analgesia onset was significantly faster in Group B (11.3 ± 1.12 vs 14.2 ± 1.26 minutes; $p<0.001$). The duration was longer in Group B (480.07 ± 7.55 vs. 289.87 ± 7.96 min; $p<0.001$). Sedation occurred in 10% of both groups and vomiting in 13.3% of Group B and 10% of Group N and Pruritus was absent, with no significant differences between the groups ($p>0.05$). **Conclusion:** Epidural butorphanol provided a faster onset and longer analgesia duration than nalbuphine, with comparable haemodynamic stability and minimal adverse effects in these surgeries.

INTRODUCTION

Postoperative pain after abdominal and lower limb surgeries is a major concern, as inadequate analgesia affects recovery and increases morbidity. Moderate-to-severe pain is common and is associated with increased sympathetic activity, impaired pulmonary function, delayed ambulation, longer hospitalisation, and reduced patient satisfaction.[1,2] Poorly controlled pain may lead to chronic postsurgical pain through persistent inflammation and central sensitisation.[3] Effective pain management is crucial for comfort, functional recovery, and reducing complications of surgery. Perioperative care now emphasises multimodal and opioid-sparing strategies within Enhanced Recovery After Surgery protocols. Multimodal analgesia combines systemic analgesics with regional techniques to target multiple pain pathways, improving analgesia while minimising opioid side effects, such as vomiting, nausea, and sedation.[1,4] Regional techniques, especially epidural analgesia, are central to providing targeted pain control, reducing opioid needs, facilitating mobilisation, and enhancing recovery.[5]

Epidural analgesia is effective for pain control after major surgeries, blocking nociceptive transmission at the spinal level, offering superior relief compared with systemic opioids, and improving pulmonary function and mobilisation.[6,7] It enhances respiratory mechanics and reduces pulmonary complications, such as atelectasis and pneumonia, in high-risk patients.[6] Sympathetic blockade with epidural anaesthesia improves haemodynamic control and reduces cardiovascular stress. However, epidural anaesthetics may cause dose-dependent effects, such as hypotension and motor blockade, delaying recovery.[8] Opioid adjuvants are added to enhance efficacy, reduce anaesthetic requirements, and improve comfort while preserving motor function.[7]

Traditional epidural opioids, such as morphine and fentanyl, provide analgesia via μ-opioid receptor activation but are limited by side effects such as

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pruritus, nausea, and sedation. Respiratory depression is a major concern because of its potential severity.[9,10] This has led to interest in mixed agonist–antagonist opioids and κ-opioid receptor agonists as safer alternatives to conventional opioids. Nalbuphine, a synthetic opioid, offers analgesic efficacy similar to that of morphine, with a favourable safety profile. Its κ-agonist and μ-antagonist actions provide effective postoperative analgesia while reducing common opioid effects.[11] It also maintains haemodynamic stability and has a lower abuse potential than μ-opioid agonists, making it suitable for neuraxial analgesia.[12] Studies have reported effective epidural nalbuphine use in postoperative pain management with a satisfactory duration and fewer side effects.[13]

Butorphanol, a κ-opioid receptor agonist with partial μ-receptor activity, provides potent analgesia with prolonged action. Epidural butorphanol enhances postoperative pain relief and reduces systemic opioid use. However, studies have shown variable onset, duration, sedation, and haemodynamic effects, possibly due to dosage and population differences.[14] Both nalbuphine and butorphanol are effective epidural adjuvants, but direct comparisons are limited in number. Studies often have small sample sizes, diverse populations, and inconsistent assessments.[15,16] Variability in the onset, duration, and side effect profiles of analgesia complicates the determination of the optimal epidural opioid. A comparative evaluation of epidural nalbuphine and butorphanol in abdominal and lower limb surgeries is crucial. Assessing their efficacy in terms of analgesia onset, duration, haemodynamic stability, and adverse effects may identify more effective and safer epidural adjuvants for postoperative pain management in contemporary multimodal recovery protocols. Therefore, the study aimed to compare the efficacy of two drugs, nalbuphine and butorphanol, in relation to the onset of action, duration of action, and haemodynamic stability in patients undergoing lower limb and abdominal surgeries.

MATERIALS AND METHODS

This prospective randomized comparative study was conducted in 60 patients who attended Mahatma Gandhi Memorial Government Hospital attached to K.A.P. Viswanatham Government Medical College, Trichy, from September 2017 to August 2019. Ethical approval was obtained from the Institutional Ethical Committee, and written informed consent was obtained from the patients before study initiation.

Inclusion and Exclusion criteria

This study included patients of either sex aged 18-70 years with ASA physical status I and II who underwent abdominal and orthopaedic lower limb surgeries. Patients with ASA physical status III and IV, undergoing emergency surgeries, having coagulopathy, drug allergy, infection at the site of epidural injection, and patient refusal were excluded.

Sample Size

The study included 60 patients, who were randomly divided into two groups of 30 patients each for comparison of epidural nalbuphine and butorphanol in postoperative pain relief.

Materials

The materials used in the study included an epidural set, 0.5% bupivacaine, 0.125% bupivacaine, butorphanol, nalbuphine, 1.5% lignocaine with adrenaline, appropriately sized intravenous cannula, drugs required for spinal and epidural anaesthesia, standard monitoring equipment, pulse oximeter, and all necessary emergency drugs.

Methods

Sixty patients were randomised into Group B (n=30) (Butorphanol 2 mg with 0.125% bupivacaine in 10 ml saline) and Group N (n=30) (Nalbuphine 10 mg with 0.125% bupivacaine in 10 ml saline). After preanesthetic assessment and consent, the patients were moved to the operating theatre and monitored for HR and MAP every 5 min for 15 min. The combined spinal-epidural technique was used with 0.5% bupivacaine, and all essential monitors were connected. The epidural catheter was inserted at L1-L2 or L2-L3, with the tip placed between T8 and T10. A test dose of 1.5% lignocaine with adrenaline was then administered. HR and MAP were monitored every 15 min during surgery. Postoperatively, when patients reported pain, the intensity was assessed using the Visual Analogue Scale (VAS). If the VAS score exceeded 5, the study drug was administered through an epidural catheter according to group allocation.

Group B received butorphanol 2 mg with 0.125% bupivacaine in 10 ml saline, and Group N received nalbuphine 10 mg with 0.125% bupivacaine in 10 ml saline. After administration, the patients were monitored for HR, MAP, and sedation every 15 min for 2 h, every 30 min for 2 h, and hourly for 12 h. Adverse effects, such as pruritus, nausea, and vomiting, were monitored. Pain intensity was assessed using the Visual Analogue Scale (VAS), and rescue analgesia was administered when the VAS score exceeded 5.

Statistical analysis

Data from the selected cases were recorded in a master chart using Microsoft Excel. Continuous variables are expressed as mean and standard deviation, and categorical variables as frequency and percentage. Comparisons between groups were performed using Student's unpaired t-test for continuous variables and chi-square or Fisher's exact test for categorical variables. ANOVA was used to test the differences over time within the same group. Statistical significance was set at $p < 0.05$. Statistical analysis was performed using IBM SPSS version 16 and Sigma Stat version 3.5.

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RESULTS

The mean age was 41.47 ± 10.90 years in Group B and 38.77 ± 11.13 years in Group N. Most were 40-50 years, with 11 (36.7%) and 10 (33.3 %) in Group N, respectively, followed by 30-40 years with 10 (33.3 %) and 8 (26.7 %) in groups B and N, respectively. Ages 20-30 years had 4 (13.3%) patients in Group B and 7 (23.3%) patients in Group N. Ages 50-60 years comprised 3 (10.0%) in both groups, while those aged ≤20 years comprised 1 (3.3%) in Group B and 2 (6.7%) in Group N. One (3.3%) patient in Group B was 60-70 years; and none were in Group N. The age distribution was not significant (p=0.346). There were 23 (76.7%) males and 7 (23.3 %) females in each group. The gender distribution was not significant (p=1.000).

The mean height of Group B was 1.64 ± 0.077 m vs. 1.59 ± 0.09 m in Group N, with no significant difference (p=0.543). The mean weight was 66.03 ± 6.27 kg in Group B and 62.33 ± 5.68 kg in Group N. Most weighed 40-50 kg, with 11 (36.7%) in Group B and 10 (33.3%) in Group N, followed by 30-40 kg with 10 (33.3%) in Group B and 8 (26.7%) in Group N. Weights ≤30 kg was 5 (16.7%) in Group B and 9 (30.0%) in Group N. In the 50-60 kg category, there were 3 (10.0%) patients in both groups, with 1 (3.3%) patient in Group B in the 60-70 kg category and none in Group N. The difference in weight distribution was not significant (p=0.432). [Table 1]

Table 1: Comparison of demographic characteristics

		Group B (n=30)	Group N (n=30)	P value
Age (years)	≤20	1 (3.3%)	2 (6.7%)	-
	20-30	4 (13.3%)	7 (23.3%)	
	30-40	10 (33.3%)	8 (26.7%)	
	40-50	11 (36.7%)	10 (33.3%)	
	50-60	3 (10%)	3 (10%)	
	60-70	1 (3.3%)	0	
	Mean ± SD	41.47 ± 10.90	38.77 ± 11.13	0.346
Gender distribution	Male	23 (76.7%)	23 (76.7%)	>0.05
	Female	7 (23.3%)	7 (23.3%)	
Height (m)		1.64 ± 0.077	1.59 ± 0.09	0.543
Weight (kg)	≤30	5 (16.7%)	9 (30%)	-
	30-40	10 (33.3%)	8 (26.7%)	
	40-50	11 (36.7%)	10 (33.3%)	
	50-60	3 (10%)	3 (10%)	
	60-70	1 (3.3%)	0	
	Mean ± SD	66.03 ± 6.27	62.33 ± 5.68	0.432

The mean preoperative HR was 83.03 ± 5.04 beats/min in Group B and 84.5 ± 2.60 beats/min in Group N. At 5 min, the HR was 84.67 beats/min in Group B and 86 beats/min in Group N, whereas at 10 min, it was 83.85 beats/min in Group B and 84.81 beats/min in Group N. Group N had slightly higher heart reates than Group B preoperatively, but the difference was not statistically significant (p=0.12).

The mean preoperative MAP was 91.82 ± 5.83 mmHg in Group B and 91.73 ± 5.28 mmHg in Group N. At 5 min, it was 94.15 mmHg in Group B and 92.82 mmHg in Group N, whereas at 10 min, it was 92.32 mmHg in Group B and 92.07 mmHg in Group N. The MAP values were comparable between the groups, with no significant difference (p=0.951). [Table 2]

Table 2: Comparison of preoperative hemodynamic parameters

		Group B	Group N	P value
HR (beats/min)	Preoperative	83.03	84.5	-
	5 min	84.67	86	
	10 min	83.85	84.81	
	Mean ± SD	83.03 ± 5.04	84.67 ± 2.60	0.12
MAP (mmHg)	Preoperative	91.82	91.73	-
	5 min	94.15	92.82	
	10 min	92.32	92.07	
	Mean ± SD	91.82 ± 5.83	91.73 ± 5.28	0.951

Group B had a mean intraoperative HR of 85.3 ± 3.12 beats/min, whereas Group N had 84.93 ± 2.66 beats/min. The heart rates were stable and similar, with minimal variation. Group N had higher values, but the difference was not significant (p=0.626). [Figure 1]

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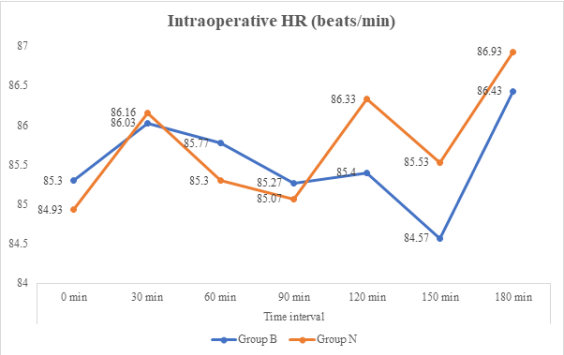

Figure 1: Comparison of intraoperative HR

The mean intraoperative MAP was 91 ± 4.48 mmHg in Group B and 97.02 ± 13.92 mmHg in Group N. Group N consistently had higher values, but the pressure remained stable and comparable between the groups. The difference was not statistically significant (p=0.609). [Figure 2]

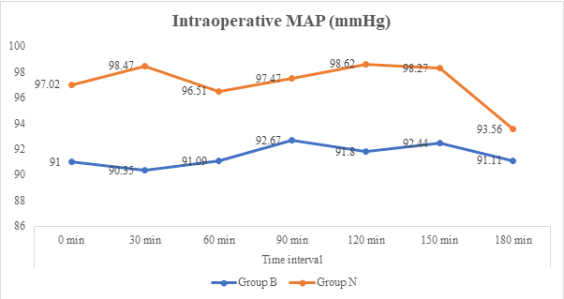

Figure 2: Comparison of intraoperative MAP

The mean postoperative HR was 86.43 ± 1.85 beats/min in Group B and 89.6 ± 2.37 beats/min in Group N. Group N had higher heart rates early postoperatively, whereas Group B had higher rates later. The postoperative HR remained stable and comparable between the groups. The difference was not statistically significant (p=0.564). [Figure 3]

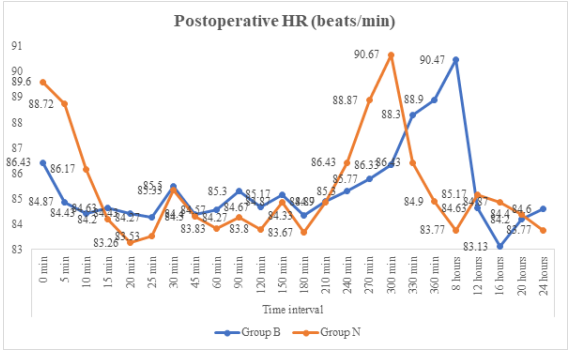

Figure 3: Comparison of postoperative HR

The mean postoperative MAP was 89.09 ± 5.33 mmHg in Group B and 85.78 ± 7.46 mmHg in Group N. Group B had higher values initially, whereas Group N had slightly higher values later. The MAP remained stable and comparable between the groups, with no significant difference (p=0.063). [Figure 4]

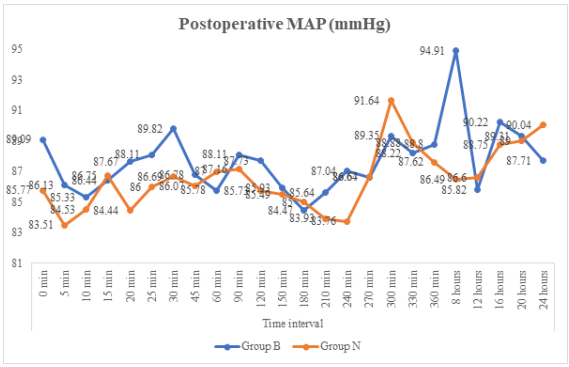

Figure 4. Comparison of postoperative MAP

The mean onset of action was earlier in Group B (11.3 ± 1.12 min) than in Group N (14.2 ± 1.26 min), with a significant difference (p<0.001). Analgesia duration was longer in Group B (480.07 ± 7.55 min) than in Group N (289.87 ± 7.96 min) (p<0.001). Sedation occurred in three (10%) patients in both groups. Vomiting was noted in 4 (13.3%) patients in Group B and 3 (10%) patients in Group N. Pruritus was absent in both groups. [Table 3]

Table 3: Comparison of analgesic characteristics and adverse effects

		Group B	Group N	P value
		Mean ± SD/ n (%)		
Onset of action (min)		11.3 ± 1.12	14.2 ± 1.26	<0.001
Duration of action (min)		480.07 ± 7.55	289.87 ± 7.96	<0.001
Adverse effects	Sedation	3 (10%)	3 (10%)	>0.05
	Vomiting	4 (13.3%)	3 (10%)	>0.05
	Pruritus	0	0	>0.05

DISCUSSION

Effective postoperative pain management is important in abdominal and lower limb surgeries, as inadequate analgesia can delay recovery and prolong hospital stay. Epidural opioid adjuvants with local anaesthetics offer superior analgesia and reduce the need for systemic opioids. Our study compared epidural butorphanol and nalbuphine in terms of analgesia onset, duration, haemodynamic stability, and adverse effects. Demographic variables, such as age, sex, height, and weight, were similar between the groups, indicating population homogeneity. Deo et al. found mean ages of 42.6 years in the butorphanol group and 46.1 years in the tramadol group for lower limb surgeries.[17] Banerjee et al. showed comparable demographics among butorphanol, fentanyl, and nalbuphine groups in

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lower abdominal surgeries with mean ages of approximately 34 years.[18] Harichandan et al. also noted no demographic differences between the nalbuphine and fentanyl groups in lower limb surgeries.[19] These findings suggest that the analgesic outcomes were due to the study drugs and not demographic differences.

Haemodynamic stability was comparable among the groups preoperatively, intraoperatively, and postoperatively. The mean intraoperative HR was 85.3 beats/min in Group B and 84.93 beats/min in Group N, with MAPs of 91 mmHg and 97.02 mmHg, respectively, showing no significant differences. Banerjee et al. reported no significant changes in pulse rate and arterial pressure among the epidural butorphanol, fentanyl, and nalbuphine groups.[18] Harichandan et al. demonstrated stable HR and pressure postoperatively with nalbuphine and fentanyl, with changes only after the regression of analgesia.[19] Ramanna et al. reported hypotension in 16.7% of patients and bradycardia only in the fentanyl group, suggesting cardiovascular stability with nalbuphine.[20] Our findings reinforce that butorphanol and nalbuphine provide adequate analgesia without significant haemodynamic instability.

The onset of action was significantly earlier with epidural butorphanol than with nalbuphine. The mean onset was 11.3 ± 1.12 min in Group B and 14.2 ± 1.26 min in Group N ($p<0.001$). Banerjee et al. found similar results, with butorphanol onset at 11.24 ± 2.989 min versus nalbuphine at 14.64 ± 2.234 min.18 Deo et al. reported a faster onset with butorphanol (7.4 ± 0.9 min) than with tramadol (12.7 ± 1.5 min).17 Kumar et al., found that nalbuphine onset (1.45 ± 0.51 min) was quicker than that of butorphanol (4.45 ± 0.61 min).[21] Differences may arise from drug concentrations, anaesthetic combinations, procedures, and analgesia assessment criteria used.

The duration of action was significantly longer with butorphanol than with nalbuphine. The mean duration was 480.07 ± 7.55 min in Group B and 289.87 ± 7.96 min in Group N ($p < 0.001$). Banerjee et al. also showed that epidural butorphanol had the longest duration (481.68 min) compared to nalbuphine (294.68 min) and fentanyl (178.60 min).[18] Harichandan et al. found a longer duration of action with nalbuphine (398.45 ± 62.245 min) than with fentanyl (222.88 ± 51.382 min).19 Ramanna et al. reported prolonged analgesia with thoracic epidural nalbuphine (381 min) compared to fentanyl (285 min).20 Deo et al. noted a shorter duration of action with butorphanol (317.1 ± 99.1 min) than with tramadol (438.8 ± 136.6 min).[17] Variations may be due to comparator drugs, techniques, populations, and regimens.

Adverse effects were low in both groups. Sedation occurred in 10% of patients in both groups, vomiting in 13.3% of Group B and 10% of Group N, while pruritus was absent in all patients. Banerjee et al. observed sedation mainly with butorphanol and pruritus with fentanyl, which was absent with nalbuphine.[18] Harichandan et al. found sedation in 27.5% with nalbuphine and 7.5% with fentanyl, and vomiting in 10% and 30%, respectively, with no pruritus.[19] Deo et al. reported higher sedation with butorphanol and more nausea and vomiting with tramadol administration.17 These findings align with our study, which also demonstrated minimal and comparable adverse effects between groups.

Limitations

The study was conducted in a single centre with a relatively small sample size, which may limit the generalisation of the findings. Only short-term postoperative outcomes were assessed, and long-term analgesic efficacy and complications were not evaluated. Further multicentric studies with larger populations are recommended.

CONCLUSION

Epidural administration of butorphanol and nalbuphine provided effective postoperative analgesia for abdominal and lower limb surgeries, with stable haemodynamic and minimal adverse effects. Butorphanol had a significantly earlier onset and longer duration of action than nalbuphine. The haemodynamic variables were comparable, indicating cardiovascular stability with both agents. The incidence of sedation and vomiting was low and similar, with no pruritus. These findings suggest that both drugs are safe and effective for postoperative pain management. Butorphanol exhibited superior analgesic efficacy due to its faster onset and longer duration of pain relief, thereby reducing the need for additional analgesics. Therefore, epidural butorphanol may be a more effective alternative to nalbuphine for postoperative analgesia in patients undergoing abdominal and lower limb surgeries.

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