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Original Research Article

Epidural Nalbuphine and Bupivacaine vs. Bupivacaine Alone in Infraumbilical Surgeries: A Comparative Study

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Abstract

Introduction and Objective: Epidural anaesthesia is a neuraxial technique in which anaesthetic agents are injected into the epidural space to block sensory and motor nerves supplying the thoracic, abdominal, pelvic, and lower limb regions. Many drugs are administered via the epidural route, most commonly local anaesthetics (lidocaine, bupivacaine, ropivacaine) and opioids (fentanyl, morphine, nalbuphine), along with adjuvants such as dexamethasone, ketamine, magnesium, midazolam, neostigmine, ziconotide, and baclofen. There are not many studies that directly compare bupivacaine alone versus epidural nalbuphine in combination.

Aim: The study aims to compare the effects of epidural Nalbuphine and 0.5% Bupivacaine with those of 0.5% Bupivacaine alone in infra-umbilical surgeries.

Methods: This prospective, randomized, comparative study included 60, ASA I-II patients undergoing elective infraumbilical surgeries. Patients were allocated into two groups: Group N received 0.5% bupivacaine with nalbuphine, and Group B received 0.5% bupivacaine alone. Outcomes assessed included onset and duration of sensory and motor blockade, postoperative analgesia using VAS scores, hemodynamic parameters, and adverse effects.

Results: The onset of sensory and motor block was comparable between groups ($p > 0.05$). The duration of sensory and motor blockade was significantly longer in Group N compared to Group B ($p < 0.001$ and $p = 0.006$, respectively). Postoperative analgesia was superior in Group N, with significantly lower VAS scores ($p < 0.001$). Hemodynamic stability was better maintained in Group N, with no incidence of hypotension, whereas 20% of patients in Group B experienced hypotension. Adverse effects were minimal in both groups.

Conclusion: The addition of nalbuphine to epidural bupivacaine significantly prolongs sensory and motor blockade, improves postoperative analgesia, and maintains stable hemodynamics with minimal side effects. Nalbuphine is a safe and effective adjuvant to bupivacaine for epidural anaesthesia in infraumbilical surgeries.

Keywords: Epidural anaesthesia, Nalbuphine, Bupivacaine, Infraumbilical surgeries.

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Introduction

Epidural anaesthesia is a type of neuraxial pain control in which anaesthetic drugs are injected into the epidural space to block sensory and motor spinal nerve roots in the thoracic, abdominal, pelvic, and lower extremity areas [1]. Corning used epidural analgesia for the first time in 1885. According to his hypothesis, drugs injected into the spinal canal will be absorbed by the rich plexus of blood vessels surrounding the spinal cord and transported into the substance of the cord, allowing for direct medication of the cord, which is used to treat neurological conditions and provide surgical analgesia [2]. To manage chronic pain, postoperative pain, obstetric analgesia, and operational anaesthesia, epidural procedures are frequently employed. The approach can be administered as a single shot or in conjunction with a catheter that permits continuous infusion and/or intermittent boluses [3]. Epidural anaesthesia is preferred over spinal anaesthesia because it gives greater control throughout anaesthesia and improves analgesia both during and after surgery [4]. Additionally, top-up doses of anaesthetics and analgesics can be administered, allowing for the desired block levels to be reached without causing major haemodynamic disruptions [3]. Numerous medications have been administered via the epidural route; the most often used medications are opioids (Fentanyl, Morphine, and nalbuphine) and local anaesthetics (Lidocaine, Bupivacaine, and Ropivacaine). Dexamethasone, Ketamine, Magnesium, Midazolam, Neostigmine, Ziconatide, Baclofen, and other miscellaneous adjuvants are frequently used [5]. Bupivacaine is a long-acting

amide local anaesthetic, structurally similar to ropivacaine. Its epidural onset ranges from 15 to 30 minutes, and this delayed onset previously limited its use [6]. Nalbuphine is a 14-hydroxymorphine derivative with mixed κ-agonist and μ-antagonist activity in the spinal cord's dorsal horn. It has analgesic potency comparable to morphine but shows a ceiling effect on respiratory depression [7]. Nalbuphine can preserve or enhance μ-opioid analgesia while reducing μ-opioid side effects. It causes less respiratory depression and fewer adverse effects such as nausea, vomiting, urinary retention, pruritus, and gastrointestinal inhibition, offering a wider safety margin [8].

There is limited research directly comparing the combination of epidural nalbuphine with bupivacaine to bupivacaine alone. Such comparisons are important for optimizing clinical practice and enhancing pain control. Hence, this study aims to evaluate the effects of adding nalbuphine to 0.5% bupivacaine versus using 0.5% bupivacaine alone in infraumbilical surgeries.

Aim: The study aims to compare the effects of epidural Nalbuphine and 0.5% Bupivacaine with that of 0.5% Bupivacaine alone in infra-umbilical surgeries with respect to:

- Onset of sensory blockade
- Onset of motor blockade
- Postoperative analgesia
- The quality of analgesia

Methodology

Study design: This study was a prospective, randomized, comparative study. The study's approval was obtained from the Institutional Ethics Committee of Telangana Vaidya Vidhana Parishad, Karimnagar, before starting the study. Approximately 60 Patients undergoing elective lower limb and infra-umbilical surgeries were included as subjects in this study.

Study setting: The study was conducted at Government General Hospital (GGH) in Karimnagar, a tertiary care teaching hospital, in Telangana. The study was conducted from May 2023 to April 2024. During this period of 12 months, the patients undergoing elective lower limb and infra-umbilical surgeries attending the hospital from May 2023 to April 2024 were evaluated.

Study duration: The duration of the study was 12 months.

Study subjects: About 60 patients (30 in each group) undergoing elective lower limb and infra-umbilical surgeries were allocated to this study.

Study tool and data collection: Patients undergoing infra-umbilical surgeries were evaluated based on the onset of sensory blockade, the onset of motor blockade, postoperative analgesia, and the quality of analgesia. The collected data were analysed statistically to obtain the results of the efficacy of epidural Nalbuphine and 0.5% Bupivacaine compared to 0.5% Bupivacaine alone in infra-umbilical surgeries.

Inclusion Criteria: Patients aged 20-60 years with ASA physical status I–II scheduled for elective infraumbilical surgery under epidural anaesthesia (e.g., hernia repair, lower-limb orthopaedic procedures, gynaecological procedures confined below the umbilicus) and willing to provide informed consent were included in the study.

Exclusion Criteria: Patients aged <20 and >60 yrs, with ASA grade 3 or 4, with known hypersensitivity reactions, spinal deformities, local skin infection, bleeding disorders, anticoagulant therapy, psychiatric illness, undergoing emergency surgery, and those who were not willing to give informed consent were excluded from this study.

Materials and Methodology: A prospective, randomized, comparative study was conducted at the Government General Hospital (GGH) in Karimnagar. A total of 60 patients scheduled for elective infraumbilical surgery under epidural anaesthesia were evaluated. A detailed history, including the present, past, family, diet, and drug history, was taken, and a thorough preanesthetic assessment was performed to identify any systemic illnesses that could complicate anesthesia. Patients were briefed on using the 0-10 Numeric Rating Pain Scale. Then the patients who met the inclusion criteria (60 patients) were grouped into 2 groups (Group-N & Group-B) by random allocation using computer software.

Group-N (Nalbuphine Group): Patients received 15 ml of 0.5% bupivacaine (14 ml) with nalbuphine 10 mg (1 ml).

Group-B (Bupivacaine Alone Group): Patients of this group received 15 ml of 0.5% bupivacaine alone.

Materials

The following equipment was prepared before administering epidural anaesthesia:

- Boyle's machine with an oxygen source.
- Working laryngoscope and appropriate size endotracheal tubes.
- Suctioning apparatus.
- Vasopressors.
- All emergency drugs.
- Epidural tray containing necessary items like sponge holding forceps, sterile gauze pieces, bowl with antiseptic solutions, sterile towels, 5 ml syringe with 24 G needle, 18 G Huber point

Tuohy needle, and 10 ml loss of resistance syringe.

Method

A detailed evaluation of baseline investigations, such as pulse rate, blood pressure, respiratory rate, and oxygen saturation were noted. An intravenous line with Ringer's lactate solution was started for fluid management.

Patients were positioned in the sitting position on a horizontal table. Using aseptic precautions, the L2-L3 intervertebral space was identified. An 18-G Huber point Tuohy needle was used to identify the epidural space with the loss-of-resistance technique. An epidural catheter was inserted and secured with 4 cm of the catheter inside the epidural space. Aspiration was performed to rule out subarachnoid or intravascular placement of the catheter. A test dose of 3 ml of 2% lignocaine with 5 micrograms of adrenaline was injected through the catheter. The total dose of either 15 ml of 0.5% bupivacaine with nalbuphine (Group N) or 15 ml of 0.5% bupivacaine alone (Group B) was injected through the catheter. Patients were positioned for surgery once the maximum level of sensory blockade (assessed every 2 minutes) was achieved. The time to achieve sensory blockade at T10 and the maximum level of block were noted. The time to achieve grade 3 motor block (Bromage scale) was also recorded. Surgeons proceeded with surgery only after confirming the maximum level of blockade. The duration of the 2-segment regression was recorded. Pulse rate, blood pressure, respiratory rate, and oxygen saturation were monitored every 5 minutes. Hypotension (defined as a 20% reduction in systolic blood pressure from baseline) was managed with intravenous fluids, oxygen, and vasopressors. After surgery, patients were observed in the recovery room for two hours before being transferred to the postoperative ward.

Statistical Analysis: The collected data were entered into Excel and analysed using SPSS version 25. For continuous variables, mean and standard deviation were calculated, while frequencies and percentages were used for categorical variables. For normally distributed continuous variables, the independent t-test was used. A p-value of ≤ 0.05 was considered statistically significant.

Results

A total of 60 patients grouped into group-N & group-B with ASA grade 1 or 2 undergoing lower limb and infraumbilical surgeries were studied. Patients of age groups ranging from 20 to 60 years were evaluated, and the mean age for the Bupivacaine and Nalbuphine group was 39.60 years with a standard deviation of 10.682, while the Bupivacaine group had a mean age of 39.07 years with a standard deviation of 10.632. In Group N, 22 males (73.3%) and 8 females (26.7%) were included. In Group B, there were 21 males (70%) and 9 females (30%). The mean duration of surgery for group N was 66.27 minutes (SD 13.861), while group B had a mean of 66.60 minutes (SD 9.619). The baseline characteristics of the study population are shown in Table -1.

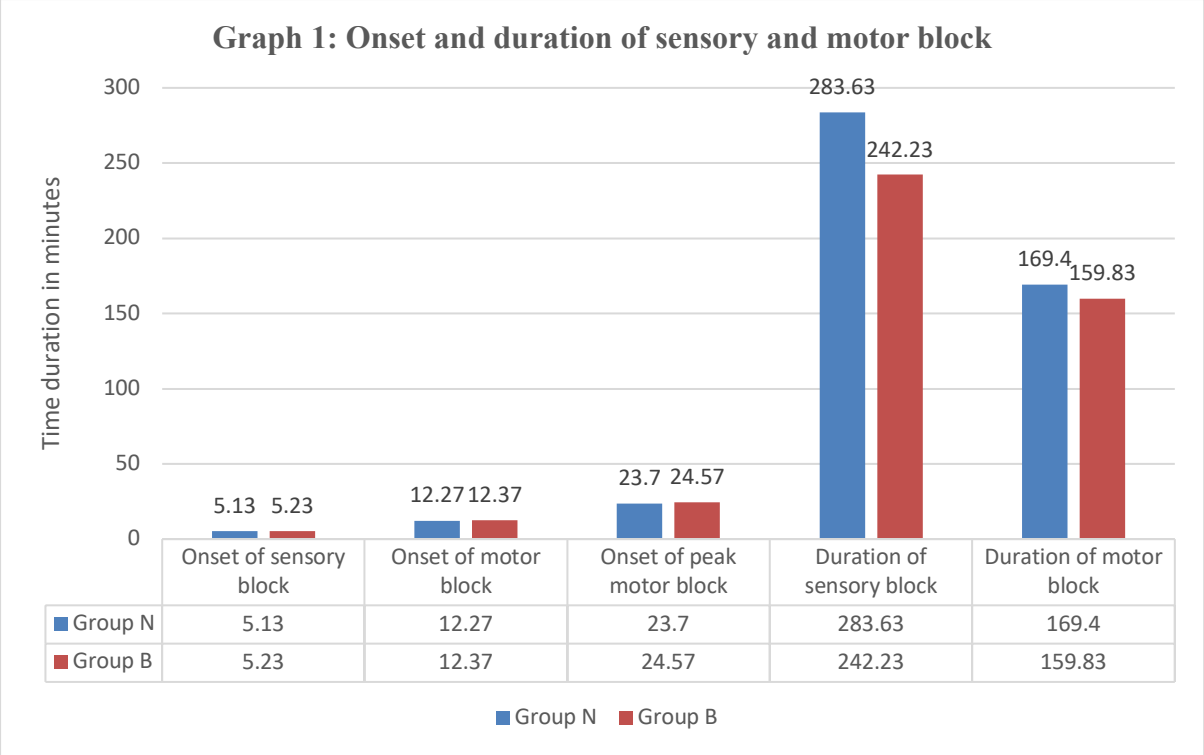
Table 1: Baseline characteristics.

Factors	Group N	Group B
Mean Age group (20-60 yrs)	39.6	39.07
Male-to-female ratio	73:27	70:30
Duration of surgery	66.27 minutes	66.60 minutes

The mean onset time for sensory block in the Group N (Bupivacaine + Nalbuphine group) was 5.13 minutes (SD = 1.167), while in the Group B (Bupivacaine group), it was 5.23 minutes (SD = 1.251). The difference in the onset of sensory block between the two groups is not statistically significant (p-value-0.750).

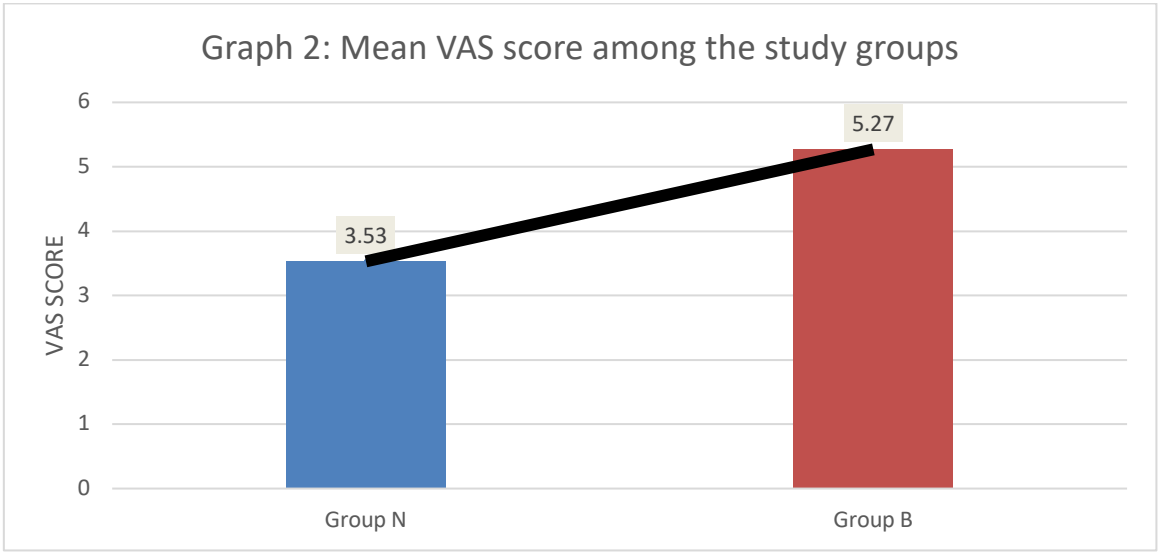
The mean onset and peak onset of motor block in the group N were 12.27 minutes (SD = 1.337), while in the group B, it was 12.37 minutes (SD = 1.217), with no statistically significant difference between the two groups. The mean duration of sensory block in the group N was 283.63 minutes (SD = 33.014) compared to 242.23 minutes (SD = 21.358) in the group B. The independent t-test yielded a p-value of less than 0.001, indicating a statistically significant difference between the two groups.

The mean duration of motor block for the group N was 169.40 minutes with a standard deviation of 14.197, while the group B had a mean duration of 159.83 minutes with a standard deviation of 11.674. The independent t-test yielded a p-value of 0.006, indicating a statistically significant difference between the two groups. Graph 1 depicts the onset and duration of sensory and motor blocks.



Graph 1: Onset and duration of sensory and motor block

The mean VAS score for the group N was 3.53 with a standard deviation of 1.224, while the mean VAS score for the group B was 5.27 with a standard deviation of 1.461. The difference in mean VAS scores between the two groups was statistically significant ($p < 0.001$), as determined by an independent t-test. Graph 2 shows the mean VAS scores among the study groups.



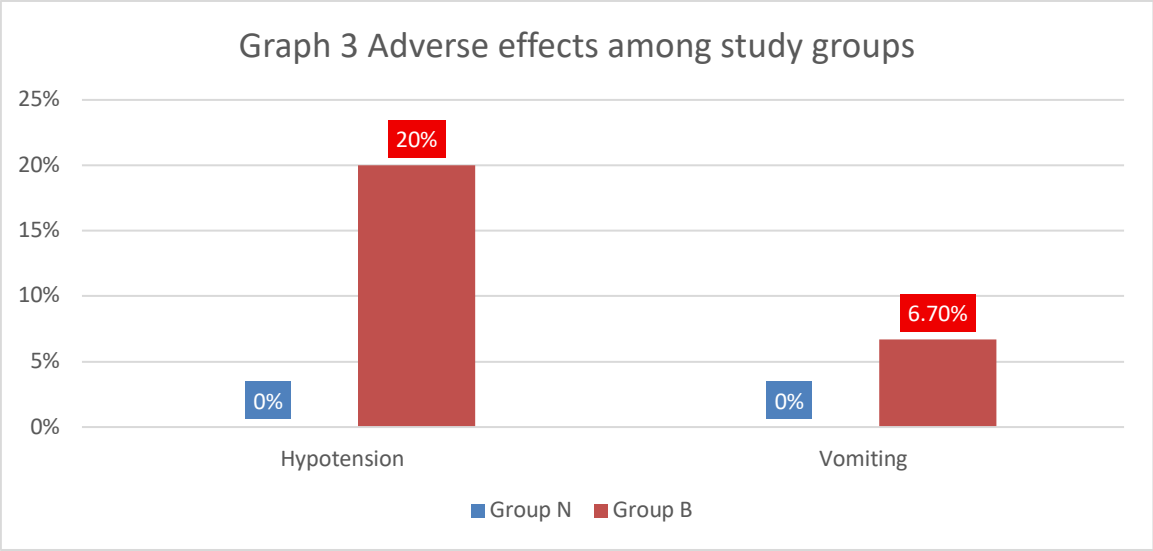
Graph 2: Mean VAS score among the study groups

Heart rates were significantly higher in group N at various time points, particularly at 10 minutes (76.50 vs. 85.17, $p = 0.003$) and 15 minutes (71.97 vs. 83.40, $p < 0.001$). Systolic blood pressure (SBP) showed significant differences at multiple intervals, with group N and the values were lower at 5 minutes (116.70 vs. 100.30, $p < 0.001$) and 10 minutes (116.13 vs. 104.97, $p < 0.001$). Diastolic blood pressure (DBP) was also significantly different, particularly immediately after administration (70.83 vs. 68.87, $p = 0.021$). Table 2 explains the mean Heart rate (HR), Systolic Blood Pressure (SBP), and Diastolic Blood Pressure (DBP) among the study participants.

Table 2: Vital parameters among the study groups

Time	Group N Mean HR	Group B Mean HR	Group N Mean SBP	Group B Mean SBP	Group N Mean DBP	Group B Mean DBP
Baseline	80.17	80.27	116.97	120.17	75.67	75.20
Immediately	81.00	78.37	110.70	114.17	70.83	68.87
5 mins	78.00	77.87	116.70	100.30	66.17	65.27
10 mins	80.03	78.00	116.13	104.97	65.80	64.93
15 mins	82.63	80.30	118.37	110.00	66.67	65.03
20 mins	81.03	79.33	112.80	117.50	67.10	65.67
25 mins	80.07	76.77	111.40	105.37	67.10	65.67
30 mins	80.87	75.93	113.00	106.40	68.17	66.43
35 mins	81.80	80.73	110.93	99.30	68.17	66.57
40 mins	80.87	77.90	121.00	115.97	70.17	68.73
45 mins	81.80	79.70	114.80	110.17	72.00	70.93
50 mins	84.90	82.50	115.63	107.77	74.77	72.10
55 mins	83.13	81.43	115.63	108.00	78.70	77.57
60 mins	81.17	77.77	119.97	109.87	78.70	78.00

In group N, no participants (0%) experienced hypotension, whereas 6 participants (20%) in the Bupivacaine group did, with this difference being statistically significant (p-value = 0.012). Vomiting was observed in 2 participants (6.7%) in group B, but none in group N, with the difference not statistically significant (p-value = 0.246).



Graph 3: Adverse effects among the study groups

Discussion

The medical world is steadily advancing, with innovative anaesthesia techniques improving pain management outcomes. During the past two decades, 0.5% hyperbaric bupivacaine has emerged as a commonly preferred drug for epidural and spinal anaesthesia.

The addition of adjuvant drugs to bupivacaine enhances its duration of anaesthesia and contributes to an antinociceptive effect. Intrathecal opioid adjuvants promote an earlier onset of sensory and motor blockade and extend postoperative pain relief. Nalbuphine acts as a μ-receptor antagonist and κ-receptor agonist, providing effective analgesia with fewer μ-agonist-related side effects [9]. This study aims to assess the impact of adding nalbuphine to hyperbaric bupivacaine in epidural block, comparing its efficacy and safety to bupivacaine alone. There was no statistically significant difference in age, gender, or surgical duration among the study groups. These results were consistent with a similar study by Kavyashree et al [10]. The mean onset of sensory block and motor block was almost the same in both groups, with no statistical significance. These results were consistent with a similar study conducted by Sagar et al [11]. In contrast to these results, there was a significant onset of sensory and motor blockade in the Nalbuphine group when compared to the Bupivacaine alone group in a study conducted by Sanjay. P et al [12]. In the current study, the mean

duration of sensory block was significantly longer in group N compared to group B, indicating that the addition of nalbuphine effectively prolongs sensory blockade. These results were consistent with a similar study conducted by Nagarjuna Chakravarthy et al, who concluded that epidural nalbuphine combined with 0.5% bupivacaine provides longer sensory block duration and superior postoperative analgesia compared with fentanyl, while maintaining stable hemodynamics and causing fewer side effects [13].

In the present study, the mean duration of motor block was significantly longer in group N when compared to group B, indicating a statistically significant difference. These results were consistent with a similar study conducted by Nusrat Anjum et al. They observed that the addition of Nalbuphine to Bupivacaine has a similar onset of sensory and motor blockade but significantly prolongs the duration of sensory and motor blockade [14].

The mean VAS score in patients receiving Nalbuphine was lower than that of the Bupivacaine group. This indicates that the addition of Nalbuphine to Bupivacaine significantly reduces pain levels compared to Bupivacaine alone. These findings were consistent with a similar study by Modi S et al, where they compared epidural Nalbuphine/Fentanyl as an adjuvant to Bupivacaine for postoperative analgesia in infraumbilical surgeries and concluded that up to 8 hours Nalbuphine group has a significantly lower VAS score compared to the Fentanyl group [15].

The Nalbuphine group demonstrated significantly higher mean heart rate along with elevated systolic and diastolic blood pressures, compared to the lower values in the Bupivacaine-only group.

This suggests that the addition of Nalbuphine results in fewer hemodynamic disturbances, likely due to its modulatory action on opioid receptors, influencing cardiovascular responses. Comparable observations were reported by Manoj Prabhakar et al., who noted that the mean SBP, DBP, and MAP were significantly lower in the Fentanyl group than in the Nalbuphine group during the first 1-8 postoperative hours, concluding that Nalbuphine as an epidural adjuvant to Bupivacaine provides superior postoperative analgesia with minimal hemodynamic fluctuations [16].

No hypotension occurred in the group N, while 20% of the Bupivacaine group experienced it; vomiting occurred only in 6.7% of the Bupivacaine group. Nagaraj et al. reported slightly higher rates of nausea and vomiting, hypotension, bradycardia, and shivering in the bupivacaine group compared to the nalbuphine group, though the differences were not statistically significant [3].

Limitations:

This study was done with a small sample size, and long-term adverse effects were not observed, so the results of this study may not apply to the general population. Long-term follow-up studies are needed to evaluate the continued efficacy and safety of Nalbuphine. Exploring various dosing regimens and combinations of Nalbuphine with local anaesthetics is necessary to determine the most effective therapeutic approach.

Conclusion

Epidural Nalbuphine combined with Bupivacaine prolonged sensory and motor block duration, enhanced postoperative analgesia, and maintained stable hemodynamics. No hypotension occurred in the Nalbuphine group compared to 20% in the Bupivacaine group, and adverse effects were minimal. Overall, Nalbuphine serves as an effective and safe adjuvant to Bupivacaine in epidural anaesthesia.

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