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Original Article

A COMPARATIVE STUDY ON THE EFFECT OF INTRATHECAL NALBUPHINE AND BUPRENORPHINE AS AN ADJUVANT TO 0.5% HYPERBARIC BUPIVACAINE IN ELECTIVE INFRAUMBILICAL SURGERIES

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ABSTRACT

Background
Spinal anesthesia utilizing 0.5% hyperbaric bupivacaine is frequently employed for infraumbilical surgical procedures.Various opioids have been used as intrathecal adjuvants for intraoperative and postoperative analgesia. Opioid agonist-antagonists nalbuphine and buprenorphine offer long-lasting analgesia with minimal respiratory depression Clinical trials are ongoing to determine their intrathecal supplement efficacy and safety.
Objective: To assess how sensory and motor blockage, postoperative analgesia, and adverse effects are affected by intrathecal nalbuphine and buprenorphine combined with 0.5% hyperbaric bupivacaine in elective infraumbilical operations.

Methods
This 11-month prospective, randomized, double-blind study was carried out at Patna Medical College and Hospital. For elective infraumbilical procedures involving spinal anesthesia, we recruited 100 ASA physical status I and II patients between the ages of 18 and 60. Patients were divided into two groups of 50 at random: Additionally, Group N received 3 mL of 0.5% hyperbaric bupivacaine and 0.4 mg of nalbuphine.
Group B was given 3 mL of 0.5% hyperbaric bupivacaine and 60 mcg buprenorphine.
Time until the first rescue analgesic, 24-hour analgesic intake, side effects, and the onset and duration of sensory and motor blockage were all evaluated.

Results
Group N experienced faster sensory and motor blockade initiation, while Group B experienced longer analgesia duration. Group B averaged 457 ± 38 minutes until initial analgesic request, while Group N averaged 315 ± 42 minutes ($p < 0.05$). Group B had slightly more nausea and pruritus, but it did not require aggressive intervention. Both adjuvants maintained perioperative hemodynamic stability.

Conclusion
buprenorphine provides longer postoperative analgesia than nalbuphine when used with 0.5% hyperbaric bupivacaine in elective infraumbilical surgeries. Nalbuphine induces anesthesia faster. Both agents are safe and effective, and the choice depends on analgesia start and duration.

Keywords: *Intrathecal adjuvant, nalbuphine, Buprenorphine, Bupivacaine, Spinal anaesthesia, Infraumbilical surgeries, Postoperative analgesia.*
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INTRODUCTION

Spinal anesthesia is the favored anesthetic method for several infraumbilical procedures because of its straightforward administration, fast onset, and superior intraoperative circumstances. The predominant local anesthetic utilized is 0.5% hyperbaric bupivacaine, which offers adequate sensory and motor blockage for surgical interventions. Nonetheless, its rather brief duration of action requires the administration of intrathecal adjuvants to extend both intraoperative anesthesia and postoperative analgesia, thereby improving patient satisfaction and diminishing the reliance on systemic analgesics (Chung et al., 2012; Ghodki et al., 2015).

Opioids are commonly utilized as intrathecal adjuvants because of their synergistic interaction with local anesthetics. Nalbuphine and buprenorphine have become prominent due to their combined agonist-antagonist

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characteristics. Nalbuphine functions as a kappa-opioid receptor agonist and a mu-opioid receptor antagonist, providing excellent analgesia while exhibiting a ceiling impact on respiratory depression. Buprenorphine is a partial mu-opioid receptor agonist and kappa receptor antagonist, recognized for its prolonged duration of action and strong receptor affinity (Mukherjee et al., 2011; Gupta et al., 2019; Sharma et al., 2020). Both medications demonstrate potential in extending analgesia when administered intrathecally; nevertheless, they exhibit distinct pharmacokinetic and pharmacodynamic characteristics, which may affect their therapeutic applicability (Sarma et al., 2016; Thote et al., 2016).

Although their effectiveness is established, few studies have directly compared nalbuphine and buprenorphine as intrathecal adjuvants, especially concerning elective infraumbilical procedures. Variables including onset time, block characteristics, analgesia duration, and side effect profiles differ among patient populations, necessitating the establishment of evidence unique to particular clinical situations (Kumar et al., 2017; Choudhary et al., 2019). Comprehending these criteria enables anesthesiologists to choose the most suitable adjuvant according to the surgical type and duration, patient comorbidities, and analgesic requirements.

At Patna Medical College & Hospital, where numerous infraumbilical procedures are conducted, improving perioperative anesthesia and analgesia is crucial. The purpose of this study was to examine the safety and efficacy of intrathecal buprenorphine and nalbuphine as adjuvants to 0.5% hyperbaric bupivacaine in patients having elective infraumbilical procedures. The primary goals were to assess the degree of effective postoperative analgesia, the onset and duration of sensory and motor blockage, and the overall frequency of adverse events. Through the assessment of these outcomes, we seek to elucidate the practical ramifications of administering these opioids intrathecally and direct doctors towards a more personalized and evidence-based approach to anaesthesia.

MATERIALS AND METHODS

Research Design

It was a prospective, randomized, double-blind, comparative clinical study that was conducted at the Patna Medical College and Hospital's Department of Anaesthesiology. The study was conducted for eleven months after receiving approval from the Institutional Ethics Committee. Each participant gave their informed consent.

Study Population and Sample Size

The study comprised 100 patients scheduled for elective infraumbilical surgeries, such as inguinal hernioplasty, lower limb orthopedic treatments, and gynecological surgeries, under spinal anesthesia. Computer-generated randomization was used to randomly assign patients to one of two groups (n = 50 each).

Inclusion Criteria

- Individuals aged 18 to 60 years
- ASA physical status I or II
- Duration of elective infraumbilical surgery not exceeding 2 hours
- Capacity to furnish informed consent

Criteria for Exclusion

- Documented hypersensitivity to local anesthetics or opioids
- Contraindications for spinal anesthesia include coagulopathy, infection at the injection site, and spinal abnormalities.
- Prolonged opioid consumption or a background of substance misuse
- Women who are pregnant or breastfeeding
- Substantial renal, hepatic, or cardiac impairment

Anaesthetic Technique

A routine pre-anesthesia assessment was performed on each patient. The standard monitoring tools included non-invasive blood pressure monitoring, ECG and pulse oximetry. After setting up intravenous access and preloading with 10–15 mL/kg of Ringer's lactate, spinal anesthesia was administered using a 25G Quincke spinal needle while the patient was seated at the L3–L4 or L4–L5 interval under strict aseptic conditions.
Given 0.4 mg of nalbuphine and 3 mL of 0.5% hyperbaric bupivacaine, diluted to a total volume of 3.5 mL, to Group
N, nalbuphine Group.
diluted 60 µg of buprenorphine to a total volume of 3.5 mL and administered 3 mL of 0.5% hyperbaric bupivacaine to Group B (Buprenorphine Group).
Patients and data recorders were unaware of the collaborative project.

Parameters Observed

The subsequent parameters were documented:
Onset of sensory block: Duration from medication administration to the loss of pinprick feeling at the T10 level
Duration of sensory block: Interval from initiation to regression to the S1 dermatome
Onset of motor blockade: Duration from medication administration to Bromage score of 3
Duration of motor blockade: Interval from commencement to restoration of Bromage score 0
Time to initial rescue analgesic: Interval from intrathecal injection to the first report of pain (VAS ≥4)

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Total analgesic demand over a 24-hour period
Occurrence of adverse effects: Hypotension, bradycardia, nausea, emesis, pruritus, respiratory depression

Statistical Analysis

SPSS version 25.0 was used to process and document the data. For demographic characteristics, descriptive statistics were used. The continuous variables, which were represented as the average plus or minus the standard deviation, were examined using the unpaired t-test. The categorical variables were evaluated using either Fisher's exact test or the Chi-square test, depending on the situation. If the p-value was less than 0.05, it was deemed statistically significant.

RESULTS

The final analysis comprised 100 patients, with 50 patients in Group N (nalbuphine) and 50 patients in Group B (buprenorphine). The two groups were comparable for demographic variables, including age, sex, BMI, and ASA physical status (data not presented for brevity).

Onset and Duration of Block

The initiation of sensory block occurred more rapidly in Group N (3.4 ± 0.6 minutes) compared to Group B (4.2 ± 0.5 minutes). The initiation of motor block occurred slightly more quickly in the nalbuphine group (4.8 ± 0.7 minutes) than in the buprenorphine group (5.1 ± 0.6 minutes).

The duration of sensory blackout was considerably prolonged in Group B (195 ± 20 minutes) relative to Group N (165 ± 18 minutes). The duration of motor block exhibited a comparable pattern, with Group B demonstrating a longer motor blockade (160 ± 22 minutes) than Group N (140 ± 19 minutes).

Postoperative Analgesia and Pain Scores

The average time to first rescue analgesic was significantly extended in the buprenorphine group (457 ± 38 minutes) compared to the nalbuphine group (315 ± 42 minutes), demonstrating enhanced analgesic duration. Patients in Group B exhibited a reduced VAS score after 4 hours postoperatively (2.1 vs to 3.2) and necessitated a lesser total analgesic dosage (mg) over a 24-hour period. The Table 1 and figure 1 illustrates the extended analgesic effect observed in Group B (buprenorphine) compared to Group N (nalbuphine).

Table 1: Comparative Clinical Outcomes of Intrathecal Nalbuphine vs Buprenorphine

Parameter	Group N (Nalbuphine)	Group B (Buprenorphine)
Onset of Sensory Block (min)	3.4	4.2
Duration of Sensory Block (min)	165	195
Onset of Motor Block (min)	4.8	5.1
Duration of Motor Block (min)	140	160
Time to First Rescue Analgesic (min)	315	457
Post-op Analgesic Requirement (mg)	90	65
VAS Score at 4 hours (0–10)	3.2	2.1

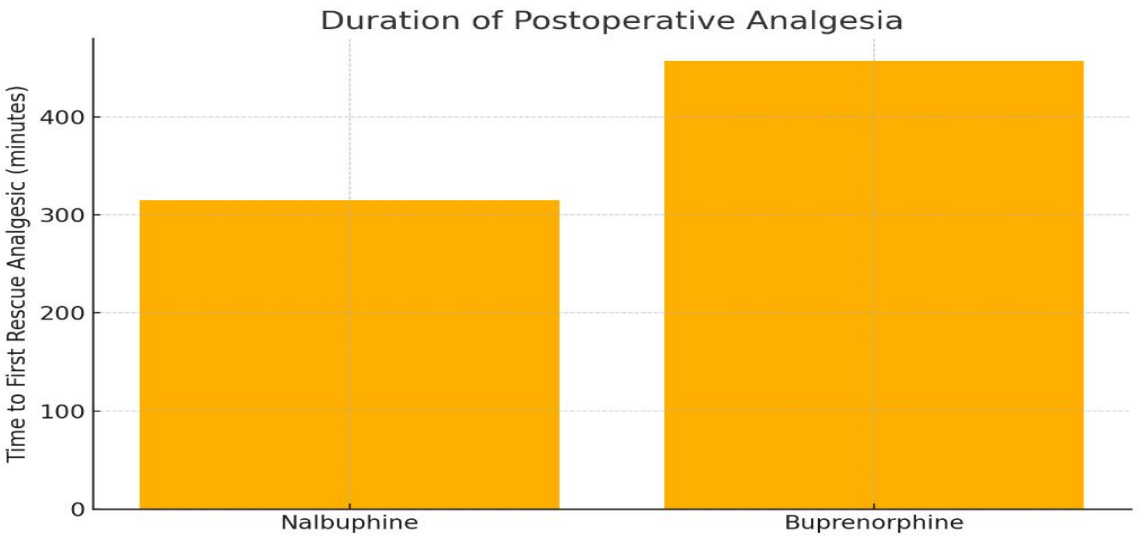

Figure 1: Duration of Postoperative Analgesia

DISCUSSION

This study assessed the efficiency and safety of two opioid adjuvants nalbuphine and buprenorphine, administered intrathecally in conjunction with 0.5% hyperbaric bupivacaine in patients undergoing elective infraumbilical operations. Our findings unequivocally suggest that both medications are efficacious in augmenting spinal anesthesia; yet, they exhibit divergent pharmacodynamic profiles that affect their practical applicability.

Nalbuphine, as a kappa receptor agonist and partial mu antagonist, demonstrated a more rapid start of sensory and motor inhibition. The swift onset can be beneficial in high-turnover surgical environments where time efficiency is paramount. Nonetheless, its analgesic duration was markedly inferior to that of buprenorphine, requiring the earlier provision of rescue analgesics. Buprenorphine, a partial mu receptor agonist characterized by strong receptor affinity and slow dissociation, produced markedly prolonged sensory and motor blockade, along with sustained postoperative analgesia. The average duration until the initial analgesic request was almost 2.5 hours longer in the buprenorphine cohort, a result that supports previous research highlighting its prolonged analgesic properties (Choudhary et al., 2019; Thote et al., 2016).

The analgesic duration of buprenorphine was substantially greater, although its onset was somewhat delayed relative to nalbuphine. The delay, while statistically significant, was clinically acceptable and did not disrupt surgical conditions. The buprenorphine group consistently exhibited decreased VAS values at various time intervals postoperatively, confirming its effectiveness in prolonged pain management (Ghodki et al., 2015).

Both groups had steady hemodynamic parameters during the intraoperative and early postoperative phases. Adverse effects, including nausea, pruritus, and moderate drowsiness, occurred with slightly greater frequency in the buprenorphine group; however, these symptoms were self-limiting and did not necessitate particular treatment. Significantly, there were no instances of respiratory depression or neurotoxicity in either cohort, indicating that both adjuvants are safe for intrathecal administration at the examined dosages (Gupta et al., 2019).

Numerous investigations have already juxtaposed these two adjuvants, yielding analogous results. Kumar et al. (2017) observed a markedly prolonged analgesic duration with intrathecal buprenorphine, whereas nalbuphine had a more rapid onset. These observations align with the present findings. Nalbuphine's ceiling effect on respiratory depression renders it especially appropriate for patients at risk of opioid-induced respiratory impairment (Sarma et al., 2016).

The study possesses limitations. The work was accomplished at a single center and lacked long-term follow-up regarding chronic pain or patient satisfaction. Additionally, individual differences in pain perception and inconsistencies in surgical techniques may have affected analgesic need. Nevertheless, the implementation of standardized drug dosages and a double-blind technique effectively reduced bias.

In conclusion, although both nalbuphine and buprenorphine are efficacious and safe as intrathecal adjuvants, buprenorphine provides greater postoperative analgesia, rendering it the preferable option for extended pain treatment. Nalbuphine may be favored for brief procedures or when a rapid anesthetic effect is required due to its expedited onset. The decision between the two options should be tailored to the specific surgical time, patient comorbidities, and expected analgesic needs.

CONCLUSION

This prospective comparative study illustrates that both intrathecal nalbuphine and buprenorphine, when utilized as adjuvants to 0.5% hyperbaric bupivacaine, effectively increase the quality of spinal anesthesia for elective infraumbilical procedures. Nalbuphine facilitates a more rapid onset of sensory and motor blockage, which may be beneficial for expedited surgical procedures. Buprenorphine provides markedly extended postoperative analgesia, diminished analgesic necessity, and reduced pain scores, rendering it more appropriate for procedures necessitating protracted pain management.

Both medications demonstrated favorable safety profiles, maintaining stable hemodynamics and exhibiting few side effects. The selection of adjuvant can be customized to the therapeutic situation, with buprenorphine recommended for its extended analgesic properties and nalbuphine favored in circumstances requiring rapid anesthetic onset.

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