Section: Anaesthesia

Original Research Article

COMPARATIVE EVALUATION OF INTRATHECAL NALBUPHINE AND FENTANYL AS ADJUVANTS TO 0.5% HYPERBARIC BUPIVACAINE FOR SPINAL ANAESTHESIA IN LOWER ABDOMINAL AND LOWER LIMB SURGERIES: AN OBSERVATIONAL STUDY

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ABSTRACT

Background: Spinal anaesthesia is a widely used regional technique for lower limb and lower abdominal surgeries. While 0.5% hyperbaric bupivacaine provides effective anaesthesia, its duration of postoperative analgesia is limited. Opioid adjuvants such as fentanyl and nalbuphine are often added intrathecally to enhance and prolong analgesia. This study aimed to compare the safety and efficacy of intrathecal nalbuphine and fentanyl as adjuvants to 0.5% hyperbaric bupivacaine in patients undergoing lower abdominal and lower limb surgeries.

Materials and Methods: This observational comparative study included 60 patients (ASA I–II), aged 18–70 years, undergoing elective lower limb and abdominal surgeries under spinal anaesthesia. Patients were randomly divided into two groups of 30 each. Group A received 3 mL of 0.5% hyperbaric bupivacaine with 0.4 mg nalbuphine, and Group B received 3 mL of 0.5% hyperbaric bupivacaine with 25 µg fentanyl intrathecally. Onset and duration of sensory and motor block, duration and quality of analgesia, hemodynamic parameters, and side effects were recorded and analyzed statistically.

Results: The onset of sensory and motor block was faster in Group B (fentanyl), while the duration of both sensory and motor block was significantly longer in Group A (nalbuphine). Duration of postoperative analgesia was also significantly greater in the nalbuphine group (245.9 ± 23.62 min) compared to the fentanyl group (217.67 ± 22.89 min; $p < 0.0001$). Nalbuphine was associated with fewer side effects, particularly pruritus (0% vs 10% in fentanyl group). Hemodynamic stability was maintained in both groups.

Conclusion: Intrathecal nalbuphine is a safe and effective adjuvant to bupivacaine, providing longer analgesia and fewer side effects compared to fentanyl. It may be preferred in clinical settings where prolonged postoperative pain relief is desirable.

Keywords: Intrathecal nalbuphine, Intrathecal fentanyl, Spinal anaesthesia, Bupivacaine, Postoperative analgesia.

INTRODUCTION

Spinal anaesthesia is one of the most commonly employed regional anaesthetic techniques for lower abdominal and lower limb surgeries due to its rapid onset, predictable efficacy, minimal drug requirement, and cost-effectiveness.[1] However, the primary limitation of spinal anaesthesia using local anaesthetics alone is its limited duration of postoperative analgesia. Therefore, various adjuvants are added intrathecally to prolong the duration of

analgesia and improve patient comfort without significantly increasing side effects.[2]

Bupivacaine, a long-acting amide-type local anaesthetic, is frequently used intrathecally in a hyperbaric form for its dense sensory and motor block. To extend its analgesic effect and reduce postoperative opioid requirements, adjuvants such as opioids are often co-administered.[3] Among these, fentanyl, a potent μ-opioid receptor agonist, is widely used due to its rapid onset and synergistic action with local anaesthetics.[4] However, its use can be limited by adverse effects such as nausea, vomiting, pruritus, and respiratory depression.[5]

Nalbuphine, on the other hand, is a mixed agonist-antagonist opioid—acting as a κ-receptor agonist and μ-receptor antagonist. This profile makes nalbuphine a promising alternative, as it can provide effective analgesia while attenuating μ-opioid-related side effects.[6] Its intrathecal administration has shown potential for enhancing sensory and motor block characteristics and extending postoperative analgesia.[7] Unlike fentanyl, nalbuphine is also not classified as a narcotic in many jurisdictions, making it more accessible and potentially safer for routine clinical use.[8]

Several comparative studies have investigated the efficacy of intrathecal nalbuphine versus fentanyl when added to hyperbaric bupivacaine. These studies have reported mixed findings. Some suggest nalbuphine provides a longer duration of postoperative analgesia and fewer opioid-related side effects,[9] while others find fentanyl to be more effective in terms of rapid onset and early postoperative pain control.[10] This discrepancy highlights the need for further research in diverse patient populations and surgical settings.

Given the increasing interest in optimizing intrathecal adjuvant use for spinal anaesthesia, it is important to determine which opioid adjuvant—fentanyl or nalbuphine—offers superior analgesic efficacy, hemodynamic stability, and safety when combined with 0.5% hyperbaric bupivacaine. Particularly in resource-limited settings, where cost and drug availability are major concerns, identifying a more effective and safer alternative is clinically relevant. This study was thus undertaken to compare the safety, efficacy, and side-effect profile of intrathecal nalbuphine versus fentanyl as adjuvants to bupivacaine in patients undergoing lower limb and lower abdominal surgeries.

MATERIALS AND METHODS

This observational, comparative study was conducted in the Department of Anaesthesiology at a tertiary medical college over a period of 24 months (September 2022 to December 2023). After obtaining approval from the Institutional Ethics Committee and written informed consent from all participants, a total of 60 adult patients undergoing elective lower abdominal or lower limb surgeries under spinal anaesthesia were enrolled. The study adhered to the ethical principles outlined in the Declaration of Helsinki (2013) and the ICMR National Ethical Guidelines for Biomedical and Health Research (2017).

Patients were randomly allocated into two equal groups of 30 each using a simple random sampling technique. Group A received 0.5% hyperbaric bupivacaine with intrathecal nalbuphine, while Group B received 0.5% hyperbaric bupivacaine with intrathecal fentanyl. Inclusion criteria comprised ASA physical status I or II, aged between 18 and 70 years, and scheduled for eligible surgical procedures under spinal anaesthesia. Patients with ASA status III or higher, known hypersensitivity to study drugs, local infection, neurological deficits, psychiatric illness, bleeding disorders, or unwillingness to participate were excluded.

All patients were premedicated and maintained nil per oral status for at least 8 hours prior to surgery. In the operating room, standard monitoring was instituted, including non-invasive blood pressure, electrocardiography, and pulse oximetry. Baseline vital parameters were recorded, and preloading was done with Ringer's lactate solution. Following aseptic precautions, subarachnoid block was administered in the L3–L4 or L4–L5 interspace using a 25G Quincke spinal needle. Patients in Group A received 3 mL of 0.5% hyperbaric bupivacaine with 0.4 mg nalbuphine, while Group B received 3 mL of 0.5% hyperbaric bupivacaine with 25 μg fentanyl.

Following drug administration, patients were positioned supine, and sensory and motor block characteristics were assessed at regular intervals using sterile pin-prick method and Modified Bromage Scale, respectively. Hemodynamic parameters (heart rate, systolic, diastolic, and mean arterial pressure, and SpO_2) were recorded at baseline, 1, 3, 5, 10, 15 minutes, and every 15 minutes for the first hour, followed by every 30 minutes up to 180 minutes.

The onset and duration of sensory and motor blocks, duration of analgesia, and any adverse events were recorded. Data were collected using a structured proforma and analyzed using appropriate statistical methods, with qualitative data expressed in proportions and quantitative data as mean ± standard deviation.

RESULTS

A total of 60 patients were included in the study, divided equally into two groups. The demographic variables such as age, weight, and height were comparable between the two groups. The mean age in Group A (Nalbuphine) was 41 ± 15.98 years, while in Group B (Fentanyl) it was 45 ± 14.32 years ($p > 0.05$). Although the weight was significantly higher in Group B (68 ± 4 kg) compared to Group A (63 ± 5.1 kg), the difference in height was not statistically significant. [Table 1]

The onset of sensory block was slightly faster in the fentanyl group (2.47 ± 0.49 min) than the nalbuphine group (2.73 ± 0.64 min), with a statistically significant difference ($p = 0.032$). However, the duration of sensory block was significantly prolonged in the nalbuphine group (189.5 ± 20.63 min) compared to the fentanyl group (170.83 ± 20.8 min; $p = 0.0001$). Similarly, the onset of motor block was quicker with fentanyl (3.68 ± 0.47 min) than nalbuphine (4.36 ± 0.63 min), while the duration of motor block was longer in the nalbuphine group (163.7 ± 19.67 min) compared to the fentanyl group (143.33 ± 15.29 min), both differences being statistically significant ($p < 0.0001$). [Table 2]

In terms of analgesic profile, nalbuphine provided a significantly longer duration of postoperative analgesia (245.9 ± 23.62 min) than fentanyl (217.67 ± 22.89 min), with a p-value < 0.0001. Although the onset of analgesia was faster with fentanyl, nalbuphine offered superior quality of analgesia as reflected by a lower mean VAS score (2.33 ± 0.71 vs 2.7 ± 0.65; $p = 0.009$). [Table 3]

Hemodynamic parameters remained stable in both groups throughout the intraoperative and early postoperative period. Heart rate and mean arterial pressure values were slightly lower in Group A but within normal clinical limits at all time points. No significant differences in oxygen saturation were noted. [Table 4]

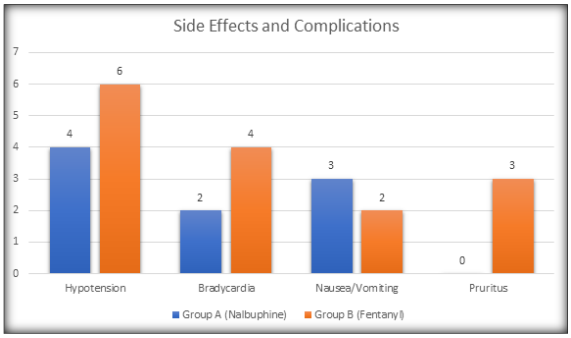

Figure 1: Side Effects and Complications

Side effects such as hypotension and bradycardia were observed in both groups but were more frequent in the fentanyl group. Pruritus was seen in 10% of patients receiving fentanyl, while none in the nalbuphine group experienced it. Nausea and vomiting occurred in both groups, but without statistical significance. Importantly, no patient in either group developed respiratory depression.

Table 1: Demographic & Baseline Characteristics

Variable	Group A (Nalbuphine)	Group B (Fentanyl)	p-value	Interpretation
Age (years)	41 ± 15.98	45 ± 14.32	> 0.05	Not significant
Weight (kg)	63 ± 5.1	68 ± 4	< 0.05	Significant
Height (cm)	165 ± 4	166 ± 3.5	> 0.05	Not significant

Table 2: Sensory & Motor Block Characteristics

Parameter	Group A (Nalbuphine)	Group B (Fentanyl)	p-value
Onset of Sensory Block (min)	2.73 ± 0.64	2.47 ± 0.49	0.032
Duration of Sensory Block (min)	189.5 ± 20.63	170.83 ± 20.8	0.0001
Onset of Motor Block (min)	4.36 ± 0.63	3.68 ± 0.47	0.0001
Duration of Motor Block (min)	163.7 ± 19.67	143.33 ± 15.29	0.0001

Table 3: Analgesia Parameters

Parameter	Group A (Nalbuphine)	Group B (Fentanyl)	p-value
Onset of Analgesia (min)	4.36 ± 0.63	3.68 ± 0.47	0.0001
Duration of Analgesia (min)	245.9 ± 23.62	217.67 ± 22.89	0.0001
Quality of Analgesia (VAS Score)	2.33 ± 0.71	2.7 ± 0.65	0.009

Table 4: Hemodynamic Parameters (HR and MAP)

Time Point	HR - Group A	HR - Group B	MAP - Group A	MAP - Group B
Baseline	86.67	87.67	95.67	96.87
5 min	82.8	85.3	88.2	90.3
10 min	78.83	81.87	85.4	87.6
15 min	77.9	81.53	83.8	86.4
30 min	77.7	81.17	82.1	85.0
60 min	78.2	81.4	84.0	86.7
90 min	80.7	82.87	85.7	87.3
120 min	79.33	82.27	86.0	88.2
180 min	82.7	83.73	87.9	89.5

DISCUSSION

The present study aimed to compare the efficacy and safety of intrathecal nalbuphine versus fentanyl as adjuvants to 0.5% hyperbaric bupivacaine in patients undergoing lower abdominal and lower limb surgeries. Our findings demonstrated that nalbuphine, when used as an intrathecal adjuvant, provided a longer duration of sensory and motor block, as well as more prolonged postoperative analgesia, compared to fentanyl, while maintaining a comparable side effect profile.

In our study, the onset of sensory block was significantly faster in the fentanyl group (2.47 ± 0.49 min) than in the nalbuphine group (2.73 ± 0.64 min), while the duration of sensory block was significantly prolonged in the nalbuphine group (189.5 ± 20.63 min vs 170.83 ± 20.8 min). These findings align closely with those of Satapathy et al., who reported a sensory block duration of 388 ± 24.88 min in the nalbuphine group and 304.70 ± 15.76 min in the fentanyl group during orthopaedic lower limb surgeries, confirming the longer-lasting analgesic effect of nalbuphine as an adjuvant to bupivacaine.[1]

The motor block duration in our study was also longer in the nalbuphine group (163.7 ± 19.67 min) compared to the fentanyl group (143.33 ± 15.29 min). This was consistent with findings by Garg et al., who found motor block duration of 210.6 ± 19.8 min with nalbuphine and 194.4 ± 21 min with fentanyl in urological procedures, supporting nalbuphine's efficacy in prolonging spinal block without significantly increasing side effects.[2]

Regarding the duration of postoperative analgesia, our results (245.9 ± 23.62 min for nalbuphine vs 217.67 ± 22.89 min for fentanyl) were in agreement with Sharma et al., who found 323.18 ± 57.39 min in the nalbuphine group and 287.05 ± 78.87 min in the fentanyl group in orthopaedic surgeries[3]. Similarly, Deshmukh et al. reported 366.4 ± 37.32 min with nalbuphine and 361.39 ± 43.96 min with fentanyl, though the difference was not statistically significant in their study.[4] These findings suggest a consistent trend toward longer analgesia duration with nalbuphine.

In contrast, Nath et al. reported lower VAS scores beyond 6 hours in the fentanyl group compared to nalbuphine, implying better late postoperative analgesia with fentanyl in abdominal surgeries. However, they also noted a higher incidence of adverse effects such as nausea and vomiting in the fentanyl group, though not statistically significant.[5]

Our findings also showed a higher occurrence of pruritus (10%) in the fentanyl group, while none was observed in the nalbuphine group, a trend supported by several studies including Deshmukh et al. and Sharma et al.[34]

In terms of hemodynamic stability, both groups in our study maintained stable heart rate and blood pressure, without significant differences. Similar hemodynamic profiles were reported in the studies by Satapathy et al. and Hameed et al., both showing no significant hemodynamic disturbances with either drug.[16]

Taken together, our findings support the use of intrathecal nalbuphine as a superior alternative to fentanyl for enhancing spinal anaesthesia with hyperbaric bupivacaine, especially when prolonged postoperative analgesia is desired. Nalbuphine offers longer duration of sensory and motor block, more sustained analgesia, and fewer opioid-related side effects such as pruritus, without compromising hemodynamic stability. These results are in alignment with several high-quality studies and affirm nalbuphine's growing role as a safe and effective intrathecal adjuvant.

CONCLUSION

This observational study demonstrated that intrathecal nalbuphine, when used as an adjuvant to 0.5% hyperbaric bupivacaine, provides significantly longer sensory and motor block durations and prolonged postoperative analgesia compared to intrathecal fentanyl. While fentanyl showed a faster onset of action, nalbuphine was associated with a more favorable side effect profile, particularly in terms of reduced incidence of pruritus and comparable hemodynamic stability.

Based on these findings, nalbuphine may be recommended as a safer and more effective alternative to fentanyl in spinal anaesthesia for lower limb and lower abdominal surgeries, particularly where prolonged postoperative analgesia is clinically desirable.

However, this study had certain limitations. The sample size was relatively small, and long-term outcomes, such as late postoperative pain and patient satisfaction, were not assessed. Additionally, the study design being observational limits the generalizability of results compared to randomized controlled trials. Future larger multicenter randomized studies are recommended to validate these findings and explore optimal dosing strategies.

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