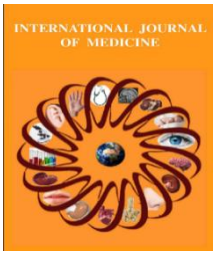

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Original Research

Comparison of Duration of Postoperative Analgesia with 0.5% Hyperbaric Bupivacaine with Nalbuphine versus 0.5% Hyperbaric Bupivacaine with Butorphanol in Spinal Anaesthesia for Lower Limb Orthopaedic Surgeries: A Randomized Double-Blind Study

Dr. Rajashekar Reddy Banda[1], Dr Ravulakol Alekhya[2], Dr. Prashanth M[3]
[1]*Assistant Professor, Department of Anaesthesiology, Government Medical College, Nalgonda, Telangana, India*
[2]*Assistant Professor, Department of Anaesthesiology, Government Medical College, Nalgonda, Telangana, India*
[3]*Assistant Professor, Department of Anaesthesiology, Government Medical College, Nalgonda, Telangana, India*

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Abstract

Background: Effective postoperative analgesia after lower limb orthopaedic surgery improves comfort, facilitates early recovery, and reduces rescue analgesic use. Hyperbaric bupivacaine provides reliable spinal anaesthesia, but its analgesic duration is limited. Nalbuphine and butorphanol, as mixed opioid agonist-antagonists, are useful intrathecal adjuvants with relatively favourable respiratory safety profiles. **Objectives:** To compare the duration of postoperative analgesia, onset and duration of sensory and motor blockade, rescue analgesia requirement, visual analogue scale scores, haemodynamic changes, and adverse effects between intrathecal nalbuphine and intrathecal butorphanol when added to 0.5% hyperbaric bupivacaine. **Methods:** This prospective randomized double-blind study included 60 adult patients aged 18-70 years with American Society of Anesthesiologists physical status I-II undergoing lower limb orthopaedic surgeries. Patients were allocated into two equal groups. Group I received 0.5% hyperbaric bupivacaine 12.5 mg with nalbuphine 800 microg, and Group II received 0.5% hyperbaric bupivacaine 12.5 mg with butorphanol 25 microg. Block characteristics, pain scores, rescue analgesia, vitals, and adverse effects were assessed up to 24 hours. **Results**: Baseline demographic and physiological variables were comparable. Group I showed faster onset of sensory block and motor block, longer duration of analgesia, later first rescue analgesic request, lower total postoperative analgesic requirement, and lower pain scores from 60 minutes to 12 hours. Adverse effects were infrequent and comparable between groups. **Conclusion:** Intrathecal nalbuphine 800 microg with 0.5% hyperbaric bupivacaine provided superior postoperative analgesia compared with intrathecal butorphanol 25 microg, while maintaining a similar safety profile.

Keywords: *Butorphanol; Hyperbaric bupivacaine; Intrathecal adjuvant; Lower limb orthopaedic surgery; Nalbuphine; Postoperative analgesia; Spinal anaesthesia.*

Introduction

Postoperative pain following lower limb orthopaedic surgery is often intense during the early recovery period because of osseous handling, soft-tissue trauma, tourniquet-related discomfort, and inflammatory nociceptive input. Poorly controlled pain delays mobilisation, increases sympathetic activation, worsens patient satisfaction, and raises the need for systemic analgesics. Neuraxial anaesthesia remains a central component of perioperative care because it provides dense surgical anaesthesia, reduces stress responses, and contributes to better postoperative outcomes in selected surgical populations [1]. Spinal anaesthesia with hyperbaric bupivacaine is especially valuable in lower limb procedures because of its rapid onset, predictable block, technical simplicity, and avoidance of airway instrumentation [2].

The major limitation of single-shot spinal anaesthesia is the finite duration of postoperative analgesia. Once the block regresses, patients require rescue analgesics, often during the period when monitoring workload is high and mobilisation is beginning. Intrathecal opioids have therefore been used as adjuvants to local anaesthetics to enhance spinal analgesia through direct action on opioid receptors in the dorsal horn and modulation of nociceptive transmission [3,4]. However, neuraxial opioids are associated with adverse effects such as nausea, vomiting, pruritus, urinary retention, sedation, and respiratory depression, making drug selection and dose optimisation clinically important [5].

Nalbuphine is a kappa-opioid receptor agonist and mu-opioid receptor antagonist. This receptor profile provides analgesia while limiting some mu-mediated adverse effects, particularly severe respiratory depression; a ceiling effect for respiratory depression has been described with nalbuphine [6]. Butorphanol is also a mixed agonist-antagonist opioid with prominent kappa activity and partial mu-antagonist properties. Both drugs have been investigated as intrathecal adjuvants to bupivacaine, but their comparative value in lower limb orthopaedic surgery remains a practical clinical question [7,8]. Earlier dose-finding and comparative studies support nalbuphine as an effective intrathecal adjuvant with prolonged analgesia and acceptable safety, although outcomes vary across surgical setting, dose, and local anaesthetic combination [9,10].

Address for Correspondence Dr. Rajashekar Reddy Banda, 1Assistant Professor, Department of Anaesthesiology, Government Medical College, Nalgonda, Telangana, India

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This study was undertaken to compare intrathecal nalbuphine hydrochloride 800 microg and intrathecal butorphanol 25 microg as adjuvants to 12.5 mg of 0.5% hyperbaric bupivacaine in adult patients undergoing lower limb orthopaedic surgeries. The objectives were to assess and compare onset of sensory and motor blockade, maximal block characteristics, regression profile, duration of postoperative analgesia, visual analogue scale scores, time to first rescue analgesia, total rescue analgesic requirement, haemodynamic trends, and adverse effects between the two study groups

Materials and Methods

Study design and setting: This prospective randomized double-blind comparative study was conducted in the Department of Anaesthesiology, Government General Hospital, Nalgonda, Telangana, India, from June 2024 to April 2025. The protocol was approved by the Institutional Ethics Committee before enrolment. Written informed consent was obtained from all participants.

Study population: Adult patients aged 18-70 years, of either sex, with American Society of Anesthesiologists physical status I or II, scheduled for elective lower limb orthopaedic surgeries under spinal anaesthesia were included. Patients were excluded when written consent was not available, when there was local infection at the puncture site, neurological or musculoskeletal disease, significant cardiovascular, respiratory, hepatic, or renal disease, bleeding disorder, anticoagulant use, pregnancy, morbid obesity, or known allergy to local anaesthetics or opioids.

Sample size and randomization: The sample size was based on the randomized study by Kumari et al., which compared intrathecal nalbuphine and butorphanol as adjuvants to hyperbaric bupivacaine [7]. Sixty patients were enrolled and randomized into two equal groups of 30 each using a slip-in-box technique. Allocation concealment and blinding were maintained by preparing equal study volumes, and observations were recorded by an assessor unaware of group allocation.

Intervention: All patients received standard preoperative evaluation, fasting advice, and premedication with ranitidine 150 mg, metoclopramide 10 mg, and alprazolam 0.5 mg on the night before surgery. In the operating room, electrocardiography, non-invasive blood pressure, and pulse oximetry were applied. Intravenous access was secured with an 18G cannula, and Ringer lactate 10 ml/kg was administered. Group I received 0.5% hyperbaric bupivacaine 12.5 mg with nalbuphine 800 microg, diluted to 3 ml. Group II received 0.5% hyperbaric bupivacaine 12.5 mg with butorphanol 25 microg, total volume 3 ml.

Anaesthetic technique and assessment: With the patient in right lateral decubitus position, subarachnoid block was performed at the L3-L4 interspace using a 25G Quincke needle by the midline approach. After free cerebrospinal fluid flow, the study drug was injected at approximately 0.2 ml/second. Sensory block was assessed by pinprick in the mid-clavicular line, and motor block was assessed using the modified Bromage scale. Surgery was started after adequate sensory and motor block. The visual analogue scale was explained preoperatively and used for postoperative pain assessment [11]. Rescue analgesia with diclofenac was administered when the score reached 4 or more.

Statistical analysis: Data were entered in a confidential database and analysed using IBM SPSS version 26. Quantitative variables were summarized as mean and standard deviation, while categorical variables were expressed as frequency and percentage. Student t-test and chi-square test were used as appropriate. A p-value less than 0.05 was considered statistically significant.

Results

A total of 60 patients were included, with 30 patients in each group. Group I received 0.5% hyperbaric bupivacaine with nalbuphine, and Group II received 0.5% hyperbaric bupivacaine with butorphanol. The two groups were comparable for age, sex, weight, height, ASA physical status, and baseline vitals, confirming adequate baseline matching (Table 1).

Table 1. Baseline demographic and preoperative profile of the study groups

Variable	Group I: Bupivacaine + Nalbuphine	Group II: Bupivacaine + Butorphanol	Test value	p-value	Significance
Mean age (years)	44.73 ± 8.41	44.67 ± 9.19	t=0.029	0.976	NS
Male/Female	19 (63.33%)/11 (36.67%)	18 (60.00%)/12 (40.00%)	χ^2=0.0	1.000	NS
Mean weight (kg)	72.67 ± 9.79	72.03 ± 10.05	t=0.247	0.805	NS
Mean height (cm)	164.67 ± 5.89	165.30 ± 7.17	t=-0.37	0.710	NS
ASA I/II	23 (76.67%)/7 (23.33%)	22 (73.33%)/8 (26.67%)	χ^2=0.0	1.000	NS
Baseline pulse (beats/min)	73.6 ± 17.0	74.0 ± 16.5	t=-0.04	0.960	NS
Baseline SBP/DBP (mmHg)	138.1 ± 13.7 / 85.3 ± 10.2	137.8 ± 14.5 / 84.2 ± 9.6	t=0.05/0.29	0.960/0.770	NS
Baseline SpO2 (%)	97.2 ± 1.3	97.5 ± 1.2	t=-0.23	0.820	NS

The onset of sensory block at T10 and onset of complete motor block were significantly faster in Group I. The time to maximum sensory and motor blockade was also shorter in Group I. Duration of motor blockade was significantly longer in Group I. Sensory regression to L1 differed significantly, with a longer regression time recorded in Group II (Table 2).

Table 2. Comparison of sensory and motor block characteristics

Block characteristic	Group I Mean ± SD	Group II Mean ± SD	t-value	p-value	Significance
Onset of sensory block at T10 (min)	3.43 ± 0.50	6.07 ± 0.87	-14.37	<0.001	S
Onset of motor blockade (min)	3.60 ± 0.50	5.63 ± 0.49	-15.93	<0.001	S
Time to maximum sensory level (min)	6.70 ± 1.56	12.23 ± 1.38	-14.56	<0.001	S
Time to maximum motor level (min)	5.53 ± 0.51	7.93 ± 0.83	-13.54	<0.001	S
Regression of sensory block to L1 (min)	143.60 ± 17.38	212.37 ± 16.79	-15.59	<0.001	S
Duration of motor blockade (min)	140.20 ± 24.43	99.20 ± 12.54	8.18	<0.001	S

A significantly higher proportion of patients in Group I achieved upper sensory levels at T4 and T6, whereas Group II more frequently attained T8 to T12 levels. The difference in maximal sensory block distribution was statistically significant (Table 3).

Table 3. Maximal sensory block level attained

Maximal sensory level	Group I n (%)	Group II n (%)
T4	5 (16.67)	1 (3.33)
T6	12 (40.00)	2 (6.67)
T8	4 (13.33)	12 (40.00)
T10	7 (23.33)	10 (33.33)
T12	2 (6.67)	5 (16.67)
Total	30 (100.00)	30 (100.00)
Chi-square; p-value	χ^2=15.62	p=0.003; Significant

The primary analgesic outcomes favoured Group I. The mean duration of analgesia was longer with nalbuphine. First rescue analgesic request occurred later in Group I, and the total postoperative analgesic requirement during 24 hours was significantly lower in Group I (Table 4).

Table 4. Postoperative analgesic outcomes

Analgesic outcome	Group I Mean ± SD	Group II Mean ± SD	t-value	p-value	Significance
Duration of analgesia (min)	243.37 ± 35.06	177.80 ± 37.64	6.98	<0.001	S
First rescue analgesic request (min)	687.17 ± 58.07	591.67 ± 80.83	5.25	0.001	S
Total postoperative analgesic requirement in 24 h (mg)	90.00 ± 60.74	120.83 ± 47.38	-2.19	0.032	S

Pain scores were similar at 30 minutes and 90 minutes, but Group I showed significantly lower scores from 60 minutes and again from 120 minutes to 12 hours. At 24 hours, the scores were comparable between groups (Table 5).

Table 5. Visual analogue scale scores during postoperative follow-up

Time point	Group I Mean ± SD	Group II Mean ± SD	t-value	p-value	Significance
30 min	0.53 ± 0.57	0.60 ± 0.50	-0.48	0.630	NS
60 min	0.70 ± 0.53	1.00 ± 0.37	-2.52	0.010	S
90 min	1.80 ± 0.61	1.93 ± 0.64	-0.83	0.410	NS
120 min	1.90 ± 0.48	3.40 ± 0.89	-8.09	<0.0001	S
4 h	2.07 ± 0.58	5.03 ± 0.96	-14.42	<0.0001	S
6 h	2.00 ± 0.59	4.93 ± 1.14	-12.51	<0.0001	S
8 h	2.07 ± 0.58	5.13 ± 1.04	-14.07	<0.0001	S
12 h	2.07 ± 0.58	4.70 ± 1.18	-10.97	<0.0001	S
24 h	3.33 ± 1.06	3.73 ± 0.98	-1.52	0.130	NS

Haemodynamic variables were generally stable in both groups. Preoperative values were comparable. Significant differences were observed at selected postoperative periods, with lower pulse rates in Group I between 3 and 12 hours and at 16 hours, and lower systolic and diastolic pressures in Group I between 4 and 8 hours (Table 6).

Table 6. Summary of haemodynamic trends

Parameter	Pattern observed	Statistical interpretation
Preoperative pulse, SBP, DBP, SpO2	Comparable in both groups	All p>0.05
Pulse rate	Group I lower at 3, 4, 5, 6, 8, 10, 12 and 16 h	p=0.01 to 0.04 at significant points
Systolic blood pressure	Group I lower at 4, 5, 6 and 8 h	p<0.001 at significant points
Diastolic blood pressure	Group I lower at 4, 5, 6 and 8 h	p<0.001 at significant points
Other time points	No consistent clinically concerning difference	p>0.05

Adverse effects were infrequent. Hypotension, nausea, and shivering were recorded in both groups, but the distribution was not statistically different. No major respiratory adverse event was recorded in either group (Table 7).

Table 7. Distribution of side effects

Side effect	Group I n (%)	Group II n (%)
Nil	18 (60.00)	14 (46.67)
Hypotension	4 (13.33)	5 (16.67)
Nausea	5 (16.67)	7 (23.33)
Shivering	3 (10.00)	4 (13.33)
Total	30 (100.00)	30 (100.00)
Chi-square; p-value	χ^2=1.964	p=0.58; Not significant

Discussion

The present randomized double-blind study compared nalbuphine 800 microg and butorphanol 25 microg as intrathecal adjuvants to 12.5 mg of 0.5% hyperbaric bupivacaine for lower limb orthopaedic surgeries. The principal finding was that nalbuphine produced longer postoperative analgesia, delayed first rescue analgesic demand, reduced total analgesic requirement, and lowered pain scores for a clinically relevant period after surgery. These findings support the role of nalbuphine as an effective intrathecal adjuvant when early postoperative pain control is a priority.

Baseline variables were well balanced, which strengthens internal validity. Similarity in age, sex, anthropometric profile, ASA status, and preoperative vitals reduces the likelihood that differences in analgesic outcome were driven by confounding. The observed faster sensory and motor onset in the nalbuphine group is consistent with earlier clinical evidence showing that intrathecal nalbuphine enhances block characteristics and postoperative analgesia when combined with bupivacaine [7,9,10]. The greater proportion of higher sensory levels in the

nalbuphine group also suggests stronger early neuraxial effect.

The analgesic advantage of nalbuphine was evident across multiple endpoints. The longer duration of analgesia and delayed rescue analgesic request are comparable with previous trials that reported prolonged postoperative analgesia with nalbuphine as an intrathecal adjuvant [7,12,13]. In the present study, the reduction in 24-hour rescue analgesic consumption further confirms clinical benefit. Lower VAS scores from 120 minutes to 12 hours are important because this interval corresponds with block regression and rising surgical site pain. A stable analgesic profile during this window supports smoother recovery room and ward management.

Butorphanol has documented efficacy as an intrathecal adjuvant and has provided effective anaesthesia and analgesia in lower limb orthopaedic surgery [8]. However, in this cohort, nalbuphine performed better for postoperative analgesia and several block parameters. The kappa agonist and mu antagonist profile of nalbuphine offers analgesia with reduced risk of dose-dependent mu-related respiratory effects, while the ceiling effect for respiratory depression provides an additional safety rationale [6]. Adverse effects were statistically comparable between groups, and no major respiratory complication was observed, supporting the tolerability of both regimens at the selected doses [5].
One important finding requiring careful interpretation is sensory regression to L1, which was longer in the butorphanol group despite better analgesic outcomes in the nalbuphine group. This shows that sensory regression time alone does not fully represent patient-centred postoperative analgesia. Pain scores, first analgesic request, and total rescue dose provide a more direct reflection of clinically useful analgesic duration. Therefore, the overall evidence from this study favours nalbuphine for early postoperative pain control.

Generalizability: These findings are applicable to adult ASA I-II patients undergoing lower limb orthopaedic surgeries under single-shot spinal anaesthesia in similar tertiary care settings. The results are most relevant where hyperbaric bupivacaine 12.5 mg is routinely used and where nalbuphine 800 microg or butorphanol 25 microg is available. Extrapolation to high-risk patients, geriatric frailty, obstetric populations, day-care procedures, and different local anaesthetic doses requires separate evaluation.

LIMITATIONS

This study was conducted at a single centre with 60 patients, limiting external validity. The follow-up period was restricted to 24 hours, so late analgesic outcomes were not assessed. Only one dose of nalbuphine and butorphanol was compared. Objective sedation scoring, patient satisfaction, and functional recovery parameters were not included. Surgical heterogeneity within lower limb orthopaedic procedures also influenced pain intensity.

Conclusion

Intrathecal nalbuphine 800 microg added to 12.5 mg of 0.5% hyperbaric bupivacaine provided superior postoperative analgesia compared with intrathecal butorphanol 25 microg in patients undergoing lower limb orthopaedic surgeries. Nalbuphine produced faster onset of sensory and motor blockade, shorter time to maximal block, longer duration of analgesia, delayed first rescue analgesic demand, lower postoperative analgesic requirement, and lower VAS scores during the early postoperative period. Haemodynamic changes were acceptable, and adverse effects were comparable between groups. These results support nalbuphine as a clinically useful intrathecal adjuvant for improving early postoperative comfort after lower limb orthopaedic procedures.

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