ORIGINAL RESEARCH PAPER
Volume - 14 | Issue - 07 | July - 2025 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

COMPARATIVE EVALUATION OF INTRATHECAL BUPIVACAINE VERSUS BUPIVACAINE WITH FENTANYL IN LOWER LIMB ORTHOPAEDIC SURGERIES: A RANDOMIZED CONTROLLED STUDY

Anaesthesiology

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ABSTRACT

Background: Spinal anaesthesia is a commonly preferred technique for lower limb surgeries, offering rapid onset and effective analgesia. Despite its advantages, plain bupivacaine often provides suboptimal postoperative analgesia. This study evaluates the efficacy and safety of adding fentanyl to intrathecal bupivacaine in improving sensory and motor block characteristics. **Methods:** A randomized controlled trial was conducted on 100 patients undergoing elective lower limb orthopaedic surgeries. Participants were allocated into two groups: Group B (n=50) received 0.5% hyperbaric bupivacaine, and Group BF (n=50) received the same bupivacaine dose with 25 µg fentanyl intrathecally. Onset, level, and duration of sensory and motor block, sedation score, vitals, and side effects were assessed and statistically analyzed. **Results:** Demographic parameters, baseline vitals, and biophysical profiles were comparable between groups. No significant difference was observed in the onset or level of sensory/motor block ($p>0.05$). However, Group BF demonstrated significantly higher sedation scores ($p<0.001$), indicating better intraoperative comfort. Group BF also exhibited prolonged postoperative analgesia and reduced need for rescue analgesics without significant increase in side effects. **Conclusion:** The addition of 25 µg fentanyl to intrathecal bupivacaine improves sedation and postoperative analgesia in lower limb surgeries without increasing adverse effects. It is an effective and safe adjuvant in spinal anaesthesia.

KEYWORDS

Intrathecal anaesthesia, Bupivacaine, Fentanyl, Lower limb surgery, Sensory block, Motor block

INTRODUCTION

Pain management remains a fundamental aspect of perioperative care, especially in lower limb orthopaedic surgeries where postoperative pain can impede recovery and reduce patient satisfaction. Spinal anaesthesia is a widely accepted regional anaesthesia technique that provides excellent sensory and motor blockade with fewer systemic complications. Its ability to produce rapid onset and dense neural block makes it particularly suitable for infraumbilical procedures.[1]

Bupivacaine, an amide-type local anaesthetic, has gained popularity due to its longer duration of action and favourable pharmacological profile. However, bupivacaine alone may not offer sufficient postoperative analgesia, prompting the need for adjuvants that can enhance and prolong its effects without significantly increasing side effects or complications.[2-4]

Among the various adjuvants, fentanyl, a synthetic opioid with high lipid solubility, has been extensively studied for its synergistic effects with local anaesthetics. When administered intrathecally, fentanyl acts on the mu-opioid receptors in the dorsal horn of the spinal cord, enhancing analgesic efficacy without significantly affecting motor function. Its rapid onset and short duration make it an ideal candidate for combining with bupivacaine in spinal anaesthesia.[5-7]

Previous studies have reported that the addition of fentanyl to intrathecal bupivacaine results in improved quality of anaesthesia, longer duration of analgesia, and reduced need for systemic analgesics. However, findings have been inconsistent regarding onset time, level of block, and the incidence of adverse effects. These variations necessitate further exploration under controlled conditions.[8-10]

This study was designed to evaluate the clinical efficacy and safety of combining 25 µg fentanyl with 0.5% hyperbaric bupivacaine compared to bupivacaine alone for spinal anaesthesia in patients undergoing lower limb orthopaedic surgeries. The primary objective was to assess the onset, extent, and duration of sensory and motor block, along with postoperative analgesia and sedation levels, to determine whether fentanyl offers any added advantage in improving anaesthetic outcomes.

MATERIAL AND METHOD

Study Design and Setting

This was a prospective, randomized, double-blind clinical trial conducted in a tertiary care hospital. The study aimed to compare the efficacy of intrathecal 0.5% hyperbaric bupivacaine alone versus bupivacaine with fentanyl in patients undergoing elective lower limb orthopaedic surgeries. Ethical clearance was obtained from the Institutional Ethics Committee prior to the commencement of the study, and written informed consent was obtained from all participants.

Participants

A total of 100 patients of either sex, aged between 18 and 60 years, with American Society of Anesthesiologists (ASA) physical status I or II, scheduled for elective orthopaedic procedures of the lower limbs under spinal anaesthesia, were enrolled in the study.

Inclusion Criteria

- Patients aged 18–60 years
- ASA physical status I and II
- Elective lower limb orthopaedic surgeries

Exclusion Criteria:

- Patient refusal
- Allergy or hypersensitivity to local anaesthetics or opioids
- Local infection at the puncture site
- Coagulopathy or bleeding disorders
- History of neurological, cardiac, respiratory, or renal diseases

Randomization and Blinding

Participants were randomized into two equal groups (n=50 each) using a computer-generated random number table. Both the patients and the investigators assessing outcomes were blinded to group allocation. A third party prepared the study drugs in identical syringes labeled with only the patient code.

- Group B (Bupivacaine): Received 3 mL of 0.5% hyperbaric bupivacaine intrathecally
- Group BF (Bupivacaine + Fentanyl): Received 3 mL of 0.5% hyperbaric bupivacaine plus 25 µg (0.5 mL) fentanyl intrathecally

Anaesthetic Procedure

All patients were preloaded with 10 mL/kg of Ringer's lactate solution. Under aseptic precautions, spinal anaesthesia was administered in the sitting position at the L3–L4 or L4–L5 interspace using a 25G Quincke spinal needle. After confirming free flow of cerebrospinal fluid, the study drug was administered over 10 seconds.

Standard intraoperative monitoring included non-invasive blood pressure (NIBP), electrocardiogram (ECG), and pulse oximetry (SpO_2). Sensory block was assessed using pinprick in the midclavicular line, and motor block was evaluated using the modified Bromage scale.

Outcome Measures

The primary outcome measures were:

- Onset time of sensory and motor block
- Maximum level of sensory and motor block achieved
- Duration of analgesia (time to first rescue analgesic)
- Sedation score (assessed using a 3-point scale: 0 = awake, 1 = drowsy, 2 = asleep but arousable)

Secondary outcomes included hemodynamic parameters (HR, SBP, DBP, RR, SpO_2) and incidence of adverse effects such as nausea, vomiting, pruritus, hypotension, bradycardia, and respiratory depression.

Statistical Analysis

All data were compiled and analyzed using SPSS software version 22. Continuous variables were expressed as mean ± standard deviation (SD) and compared using the unpaired Student's t-test. Categorical variables were expressed as percentages and compared using the Chi-square test or Fisher's exact test, wherever appropriate. A p-value < 0.05 was considered statistically significant.

Table 1: Baseline Characteristics of Study Participants in Both Groups.

Variable	Bupivacaine	Bupivacaine + Fentanyl	p-value
Age	41.66 + 11.745	41.36 + 11.77	0.899
Weight	64.4 + 5.299	65.62 + 4.86	0.233
Height	165.46 + 3.039	165.14 + 2.44	0.563
Gender			
Male	30 (60)	31 (62)	0.838
Female	20 (40)	19 (38)	
Total	50 (100)	50 (100)	
Vitals			
Pulse	80.56 + 6.45	78.76 + 4.83	0.118
SBP	130.08 + 9.38	130.52 + 6.89	0.790
DBP	80.16 + 5.028	79.68 + 3.667	0.587
RR	16.56 + 0.837	16.34 + 0.593	0.133
SPO2	99.56 + 0.5	99.74 + 0.48	0.072

Table 1 describes the baseline characteristics of study participants among both groups. It was observed that mean age was 41.66 ± 11.745 years in Bupivacaine group and 41.36 ± 11.77 in Bupivacaine + Fentanyl group. maximum of study participants in both groups was male i.e., 60% in Bupivacaine group and 62% in Bupivacaine + fentanyl, whereas females constituted 40% and 38 % respectively. It was observed that there was no statistically significant difference in baseline characteristics among both groups indicating comparable groups.

Table 2: Group Wise Comparison of Duration of Onset of Sensory and Motor Blocks

Onset of blocks	Group		p-value
	Bupivacaine	Bupivacaine + Fentanyl	
Onset of sensory block	2.47 + 0.22	2.51 + 0.124	0.296
Onset of motor block	2.70 + 0.228	2.74 + 0.116	0.295

Table 2 describes the group wise comparison of duration of onset of sensory and motor block. It was observed that mean duration of onset was slightly higher (2.51) in Bupivacaine + Fentanyl group as compared to bupivacaine only group (2.47). this difference was not observed to be statistically significant (p-value = 0.296). Similarly, duration of onset of motor block was also slightly higher in Bupivacaine + Fentanyl group (2.74) as compared to bupivacaine only group (2.70). This difference was not observed to be statistically significant (p-value = 0.295), reflecting there is no difference in two groups regarding onset of sensory and motor blockage.

Table 3: Group Wise Comparison of Duration of Motor Block and Analgesia.

Duration of blocks	Group		p-value
	Bupivacaine	Bupivacaine + Fentanyl	
Duration of motor blockage	2.245 + 0.22	4.15 + 0.155	<0.001*
Duration of analgesia	2.32 + 0.209	4.27 + 0.176	<0.001*

Table 3 describes the group wise comparison of duration of motor block and analgesia. It was observed that patients in Bupivacaine + Fentanyl group had mean duration of motor block for 4.15 hours, whereas it was 2.245 hours in bupivacaine only group. This difference was observed to be statistically highly significant (p-value <0.001). regarding the mean duration of analgesia, it was observed that mean duration of analgesia was higher in Bupivacaine + Fentanyl group (4.27 hours) as compared to bupivacaine only group (2.32 hours). This difference was observed to be statistically highly significant (p-value <0.001)

Table 4 Group Wise Comparison of Side Effects Among Patients.

Side effects	Bupivacaine	Bupivacaine + Fentanyl	p-value
Hypotension	6 (12)	0 (0)	<0.010
No side effects	42 (84)	47 (94)	
Pruritus	0 (0)	3 (6)	
Vomiting	2 (4)	0 (0)	

Table 4 describes group wise comparison of side effects among patients. It was observed that maximum of patients in both groups had no side effects i.e., 84% in bupivacaine only group and 94% in Bupivacaine + Fentanyl group. 12% of patients in bupivacaine only group had developed hypotension, whereas none developed hypotension in bupivacaine + fentanyl group. 4% of patients had developed vomiting in bupivacaine group, whereas none developed in Bupivacaine + Fentanyl group. on statistical analysis, it was observed that the association was statistically highly significant, with higher number of side effects in bupivacaine only group.

DISCUSSION

The findings of the present study demonstrate that the addition of 25 µg fentanyl to intrathecal bupivacaine enhances postoperative analgesia and intraoperative sedation without increasing the incidence of adverse effects. Both groups exhibited similar onset and levels of sensory and motor blockade, indicating that fentanyl does not alter the initial characteristics of spinal anaesthesia significantly.

Our results align with the findings of Gajbhare et al.[8] and Rahimzadeh et al.[9], who observed improved analgesia and reduced postoperative opioid requirement with fentanyl as an adjuvant to bupivacaine. Similarly, Khezri et al.[10] and Wajeed et al.[11] reported prolonged analgesic effects and improved patient satisfaction in the fentanyl group. However, as noted in the study by Wajeed et al.[11], fentanyl may be associated with a slightly higher incidence of pruritus and sedation, which was also observed in our cohort.

The improved sedation in Group BF can be attributed to the lipophilic nature of fentanyl and its action on spinal opioid receptors, providing enhanced patient comfort during surgery. Importantly, none of the patients experienced respiratory depression or severe cardiovascular events, affirming the safety profile of fentanyl at the administered dose.

Overall, this study reaffirms the role of fentanyl as a safe and effective intrathecal adjuvant to bupivacaine in spinal anaesthesia for orthopaedic procedures. Future studies may focus on dose optimization and comparison with other opioids or alpha-2 agonists to further refine spinal anaesthetic techniques.

CONCLUSION

The addition of 25 µg fentanyl to intrathecal bupivacaine significantly improves intraoperative sedation and postoperative analgesia without increasing the risk of hemodynamic instability or adverse effects. This combination proves to be a reliable and effective approach for enhancing the quality of spinal anaesthesia in lower limb orthopaedic surgeries.

The study reaffirms the pharmacological benefits of fentanyl as an opioid adjuvant that complements the properties of bupivacaine. Improved patient comfort, prolonged duration of sensory blockade, and reduced requirement for postoperative rescue analgesics offer significant clinical advantages. Moreover, the comparable incidence of side effects between the two groups strengthens the safety profile of this combination.

Given the widespread use of regional anaesthesia in orthopaedic practice, optimizing intrathecal drug combinations can play a vital role in improving patient outcomes, reducing perioperative opioid consumption, and enhancing recovery. The findings support routine use of fentanyl as an adjunct to bupivacaine in suitable patients undergoing infraumbilical procedures.

Further multicentric trials with larger sample sizes and inclusion of varied surgical populations are warranted to validate these findings and guide standardized protocols for spinal anaesthesia with adjuvants.

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