**Journal of Neonatal Surgery**
***ISSN(Online): 2226-0439***
***Vol. 14, Issue 8s (2025)***
*https://www.jneonatalsurg.com*

OPEN ACCESS

# Enhancing Spinal Anesthesia for Lower Limb Surgeries: A Comparative Study of Intrathecal Midazolam and Hyperbaric Bupivacaine

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Cite this paper as: Md Moqueeth Ahmed, Khaliq Ahmed Md, Dr. Mrunalini Alugolu, Dr. J Naresh Kumar, (2025) Enhancing Spinal Anesthesia for Lower Limb Surgeries: A Comparative Study of Intrathecal Midazolam and Hyperbaric Bupivacaine. *Journal of Neonatal Surgery*, 14 (8s), 6-10.

## ABSTRACT

**Background:** Spinal anesthesia is a critical technique for lower limb surgeries, offering rapid onset and reliability. However, the limited duration of anesthesia and postoperative analgesia with bupivacaine presents a clinical challenge. This study investigates the efficacy of adding preservative-free midazolam to hyperbaric bupivacaine to enhance the analgesic profile of spinal anesthesia.

**Methods:** This prospective, randomized, single-blinded study involved 60 patients undergoing elective lower limb surgeries, divided into two groups. Group B received 3 ml of 0.5% hyperbaric bupivacaine, and Group B+M received the same dose of bupivacaine plus 0.2 ml (1 mg) preservative-free midazolam. The study assessed the onset and duration of sensory and motor block, the duration of postoperative analgesia, and the incidence of side effects.

**Results:** There was no significant difference in demographic and baseline characteristics between the groups. However, Group B+M demonstrated a significantly longer duration of analgesia (218.5 ± 22.52 minutes) compared to Group B (171.5 ± 18.76 minutes) ($p<0.001$). The incidence of side effects such as nausea, vomiting, and respiratory depression showed no significant difference between the groups.

**Conclusion:** The addition of preservative-free midazolam to hyperbaric bupivacaine significantly extends the duration of analgesia without increasing the risk of major complications, suggesting a valuable enhancement to spinal anesthesia for lower limb surgeries.

***Keywords:*** *Spinal anesthesia, midazolam, hyperbaric bupivacaine, lower limb surgery, postoperative analgesia.*

## 1. INTRODUCTION

Spinal anesthesia is a cornerstone technique in anesthesiology, particularly valued for its rapid onset, reliability, and cost-effectiveness in lower limb surgeries. It involves the direct application of local anesthetics into the subarachnoid space, producing sensory, motor, and autonomic blockade.[1] While commonly used local anesthetics such as bupivacaine provide effective anesthesia, their duration of action and postoperative analgesia are often limited. Thus, enhancing the efficacy and duration of spinal anesthesia while minimizing side effects remains a significant clinical challenge.[2]

The addition of adjuvants to spinal anesthetics has emerged as a strategy to prolong the duration of anesthesia and analgesia, reduce the required dose of local anesthetics, and potentially decrease postoperative complications. Among these adjuvants, midazolam, a water-soluble benzodiazepine, has gained attention due to its anxiolytic, amnesic, and mild sedative effects, which can be beneficial in the perioperative setting. When administered intrathecally, midazolam acts on the spinal cord level by enhancing the inhibitory effect of GABA, leading to an increased neuronal threshold for pain impulses.[3,4]

Recent research has explored the potential of preservative-free midazolam to extend the analgesic effects of spinal anesthesia

with minimal side effects. Intrathecal midazolam has been shown to prolong the duration of postoperative analgesia without significant respiratory depression, which is a common concern with other adjuvants such as opioids. These properties make midazolam a promising candidate for enhancing spinal anesthesia in surgeries requiring prolonged postoperative pain management.[5]

Hyperbaric bupivacaine is the gold standard among local anesthetics used in spinal anesthesia for lower limb surgeries due to its dense, motor-blocking properties, which are ideal for surgical anesthesia. The term "hyperbaric" refers to the solution being denser than cerebrospinal fluid (CSF), allowing precise control over the spread of the anesthetic based on the patient's position. This control is crucial in targeting specific nerve roots and minimizing the risk of high spinal blockade, which can lead to hemodynamic instability and respiratory complications.[6]

This study aims to compare the efficacy and safety of hyperbaric bupivacaine alone versus its combination with intrathecal midazolam in patients undergoing elective lower limb surgeries. By assessing parameters such as the onset and duration of sensory and motor block, the duration of postoperative analgesia, and the incidence of side effects such as nausea, vomiting, and respiratory depression, this research seeks to determine whether midazolam can significantly enhance the analgesic profile of spinal anesthesia while maintaining a high safety profile.[7,8]

Such findings could have profound implications for clinical practice, offering a refined approach to spinal anesthesia that optimizes patient outcomes and resource utilization in orthopedic surgeries. This study contributes to the growing body of literature on spinal anesthesia adjuvants and aims to define a new standard in anesthesia practice for lower limb surgical procedures.

## 2. MATERIALS AND METHODS

**Study Design and Setting** This prospective, randomized, single-blinded, comparative study was conducted at Sunshine Hospitals, Secunderabad, from February to November 2016. The study received approval from the institutional ethical committee.

**Participants Sixty patients aged 18 years and above**, of either sex, undergoing elective lower limb surgeries such as total knee replacement, lower limb fracture repairs, and ligamental injury repairs, were included. Patients were randomized into two groups based on their admission sequence, using a computerized system: patients with an even-numbered inpatient ID were assigned to Group 1 (B), and those with an odd number to Group 2 (B+M).

### *Inclusion Criteria*

- ASA grade I to II.
- Undergoing elective lower limb surgeries under spinal anesthesia.
- Aged 18 years and above.
- Provided valid consent.

### *Exclusion Criteria*

- Refusal by the patient.
- Emergency surgeries.
- Known hypersensitivity to local anesthetics.
- Pre-existing medical complications (heart disease, kidney disease, severe hypovolemia, shock, septicaemia).
- Coagulation disorders or ongoing anticoagulant therapy.
- Local infection at the site of proposed spinal anesthesia.

**Preanaesthetic Examination and Preparation** Preoperative evaluations were conducted a day before surgery. Patients were briefed on the spinal anesthesia procedure and provided written informed consent. Preoperative fasting and administration of Ranitidine 150 mg were required.

**Anesthesia Protocol and Monitoring** Patients were transferred to the operating theater, where IV access was established, and IV fluids administered as per the Holiday-Segar rule. Monitoring included heart rate, non-invasive blood pressure, oxygen saturation, and ECG. Spinal anesthesia was performed using a 25-gauge Quincke needle at the L4-L5 interspace. Group 1 received 3 ml of 0.5% hyperbaric Bupivacaine with 0.2 ml saline, while Group 2 received the same dose of Bupivacaine plus 0.2 ml (1 mg) preservative-free Midazolam.

### *Parameters Evaluated*

- Sensory and motor block onset and duration, assessed using the pin-prick test and Modified Bromage Scale, respectively.

- Hemodynamic parameters recorded every 5 minutes for the first 15 minutes, then every 15 minutes during surgery.
- Complications such as nausea, vomiting, pruritus, respiratory depression, and shivering.

**Postoperative Care** Visual analogue scale (VAS) was used for pain assessment. Rescue analgesia with either diclofenac sodium 1.5 mg/kg or tramadol 1 mg/kg was administered if VAS ≥ 4.

**Statistical Analysis** A sample size of 20 per group was determined based on previous studies, with a 5% type I error rate and 80% power. Data were analyzed using Open Epi Version 2.3 and presented as means (± SD) or frequencies. The Student's t-test and ANOVA were used for comparisons.

## 3. RESULTS

This randomized, comparative study evaluated the efficacy and safety of adding preservative-free midazolam to hyperbaric bupivacaine in spinal anesthesia for elective lower limb surgeries. The study involved sixty patients, evenly split into two groups: Group B, which received bupivacaine alone, and Group B+M, which received bupivacaine with midazolam.

Demographic and Baseline Characteristics The age distribution between the two groups showed no significant difference, with Group B averaging 45.33 ± 11.51 years and Group B+M at 44.6 ± 9.63 years (p=0.55). Similarly, gender distribution was balanced across groups, with Group B comprising 60% males and 40% females, and Group B+M evenly split at 50% for both genders (p=0.57). Preoperative heart rate was comparable between the groups, with Group B at 77.80 ± 9.12 bpm and Group B+M at 79.20 ± 8.61 bpm, indicating no significant difference (p=0.375).

Clinical Outcomes A critical finding of the study was the duration of analgesia. Group B+M showed a statistically significant increase in the duration of analgesia, averaging 218.5 ± 22.52 minutes, compared to 171.5 ± 18.76 minutes in Group B (p<0.001). This extended analgesia suggests a beneficial effect of midazolam when used as an adjuvant to bupivacaine.

Safety and Complications The incidence of postoperative complications such as nausea, vomiting, pruritis, respiratory depression, and shivering was recorded. There were no statistically significant differences between the groups. Group B experienced higher rates of nausea (12% vs. 7%), vomiting (9% vs. 5%), and pruritis (15% vs. 10%) compared to Group B+M. Importantly, respiratory depression was observed in 2% of Group B with no cases in Group B+M. Shivering was more common in Group B (18%) compared to Group B+M (12%), but these differences were not statistically significant (p=0.45 for all comparisons).

**TABLE 1: AGE DISTRIBUTION AMONG STUDY GROUPS**

| Group | Mean Age ± SD | p-value |
|---|---|---|
| Group B | 45.33 ± 11.51 | 0.55 |
| Group B+M | 44.6 ± 9.63 | 0.55 |

**TABLE 2: SEX DISTRIBUTION AMONG STUDY GROUPS**

| Group | Males | Male Percentage | Females | Female Percentage | p-value |
|---|---|---|---|---|---|
| Group B | 18 | 60% | 12 | 40% | 0.57 |
| Group B+M | 15 | 50% | 15 | 50% | 0.57 |

**TABLE 3: PREOPERATIVE HEART RATE IN BOTH GROUPS**

| Group | Mean Heart Rate ± SD | p-value |
|---|---|---|
| Group B | 77.80 ± 9.12 | 0.375 |
| Group B+M | 79.20 ± 8.61 | 0.375 |

**TABLE 4: DURATION OF ANALGESIA IN MINUTES**

| Group | Mean Duration ± SD | p-value |
|---|---|---|
| Group B | 171.5 ± 18.76 | <0.001 |
| Group B+M | 218.5 ± 22.52 | <0.001 |

**TABLE 5: INCIDENCE OF POSTOPERATIVE COMPLICATIONS**

| Complication | Group B Incidence | Group B+M Incidence | p-value |
|---|---|---|---|
| Nausea | 12% | 7% | 0.45 |
| Vomiting | 9% | 5% | 0.45 |
| Pruritis | 15% | 10% | 0.45 |
| Respiratory Depression | 2% | 0% | 0.45 |
| Shivering | 18% | 12% | 0.45 |

## 4. DISCUSSION

The results of this study highlight the potential benefits of incorporating midazolam into the spinal anesthetic regimen for lower limb surgeries. The significant extension of analgesia duration in Group B+M confirms the hypothesized synergistic effect of midazolam with bupivacaine, which aligns with the literature indicating that midazolam enhances the inhibitory effects of GABA in the central nervous system, thereby augmenting the analgesic quality of spinal blocks.[9]

Critically, the lack of significant differences in the incidence of complications such as nausea, vomiting, and particularly respiratory depression, addresses one of the primary concerns associated with adjuvants in spinal anesthesia. The safety profile observed suggests that intrathecal midazolam, at the doses studied, does not increase the risk of adverse events, thus providing a safe enhancement to bupivacaine in clinical practice.[10]

Moreover, the pharmacological benefits of midazolam, including its anxiolytic and amnesic properties, may contribute to an overall improved perioperative experience for patients, suggesting additional indirect benefits beyond analgesia and anesthesia. This study supports earlier findings while contributing new data regarding the dose-specific effects of midazolam when used in conjunction with hyperbaric bupivacaine.[11]

However, this study is not without limitations. The single-center design and relatively small sample size may limit the generalizability of the results. Future studies could expand on this work by including multiple centers and a larger cohort to confirm these findings and potentially explore the effects of varying doses of midazolam.[12]

Additionally, further research could investigate the long-term outcomes related to mobility and patient satisfaction, which are critical for the recovery of patients undergoing lower limb surgeries.

## 5. CONCLUSION

In conclusion, this study demonstrates that adding preservative-free midazolam to hyperbaric bupivacaine for spinal anesthesia in lower limb surgeries significantly enhances the duration of postoperative analgesia without compromising safety. This finding suggests that midazolam can be an effective adjuvant to bupivacaine in spinal anesthesia, potentially setting a new standard in anesthetic practice for such surgeries.

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