Section: Anesthesiology

Original Research Article

A PROSPECTIVE RANDOMIZED STUDY COMPARING INTRATHECAL MIDAZOLAM AND BUPRENORPHINE AS ADJUVANTS TO 0.5% HYPERBARIC BUPIVACAINE IN LOWER ABDOMINAL SURGERIES

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ABSTRACT

Background: Pain—both physical and psychological—remains one of the most distressing consequences of surgery. Providing effective postoperative analgesia continues to be a major challenge for anesthesiologists. Multimodal analgesic strategies, including intrathecal adjuvants such as opioids and benzodiazepines, are commonly used to enhance spinal anesthesia. **Aim:** To evaluate and compare the efficacy of intrathecal midazolam versus buprenorphine as adjuvants to 0.5% hyperbaric bupivacaine in patients undergoing lower abdominal surgeries.

Materials and Methods: This randomized clinical trial was conducted in the Department of Anesthesiology, Government Tiruvannamalai Medical College, from March 2024 to December 2025. Sixty patients scheduled for elective lower abdominal surgeries were randomized into two groups (30 each): Group BB: 15 mg of 0.5% hyperbaric bupivacaine + 60 µg buprenorphine Group BM: 15 mg of 0.5% hyperbaric bupivacaine + 2 mg midazolam Data were analyzed using SPSS version 23. A p-value <0.05 was considered statistically significant.

Results: The mean onset of sensory block was significantly faster in Group BB (2.03 ± 0.27 min) compared to Group BM (2.35 ± 0.54 min). The duration of analgesia was significantly longer in Group BB (478 ± 25.18 min) compared to Group BM (309.66 ± 17.65 min). Motor block duration was also longer in the buprenorphine group.

Conclusion: Intrathecal buprenorphine, when used as an adjuvant to hyperbaric bupivacaine, provides a faster onset of sensory and motor blockade and a longer duration of postoperative analgesia compared to midazolam.

Keywords: Bupivacaine, Midazolam, Buprenorphine, Spinal anesthesia.

INTRODUCTION

Spinal anesthesia using hyperbaric bupivacaine is widely employed for lower abdominal surgeries due to its reliable sensory and motor blockade and hemodynamic stability1. However, the limited duration of single-shot spinal anesthesia has led to the use of intrathecal adjuvants to prolong analgesia, accelerate onset, and reduce systemic opioid requirements.Buprenorphine, a partial opioid agonist with prolonged analgesic action, and midazolam, a benzodiazepine with spinal antinociceptive effects, have both been used as intrathecal adjuvants. This study compares their efficacy when combined with intrathecal bupivacaine.

MATERIALS AND METHODS

Study Design
Randomized controlled study

Study Setting
Department of Anesthesiology, Tiruvannamalai Medical College Hospital
Study Duration
March 2024 to September 2025
Sample Size
Sixty patients were enrolled and randomly allocated into two groups of 30 each.
Inclusion Criteria
- ASA physical status I and II
- Age 20–65 years
- Patients undergoing elective lower abdominal surgery
- Informed written consent

Exclusion Criteria
- Refusal of spinal anesthesia
- ASA physical status III–V
- Allergy to local anesthetics
- Coagulopathy

After obtaining clearance from the Institutional Ethics Committee, the study was initiated following written informed consent from the patients. A total of 60 participants recruited during the study period underwent routine preoperative investigations and pre-anaesthetic evaluation. After obtaining informed written consent, patients were kept fasting for six hours prior to surgery and were administered tablet alprazolam 0.5 mg orally on the night before surgery. On arrival in the operating room, standard ASA monitors including non-invasive blood pressure, pulse oximetry, and electrocardiography were attached, and baseline vital parameters were recorded. Heart rate and rhythm were continuously monitored using ECG. An intravenous line was secured using an 18-gauge cannula, and all patients were preloaded with lactated Ringer's solution at 15 ml/kg. Under strict aseptic precautions, patients were positioned on a neutrally leveled operating table in either the left lateral recumbent or sitting position. Lumbar subarachnoid block was performed at the L3–L4 interspace using the classic midline approach with a 23G or 25G Quincke-Babcock spinal needle after local infiltration of the skin with 2 ml of 2% lignocaine. After confirming uninterrupted flow of cerebrospinal fluid and negative aspiration for blood, the prepared study drug was administered slowly and steadily. Following completion of the injection, patients were immediately positioned supine with adequate head support, and haemodynamic parameters were monitored throughout the procedure. Double blinding was ensured by assigning another anaesthetist to prepare bupivacaine with the specified spinal adjuvants, who did not participate further in the study or postoperative follow-up. Both the attending anaesthetist and the patients were blinded to the drug composition in the preloaded sterile syringes. Sensory blockade was assessed using the pinprick method with a blunt needle along the mid-clavicular line over the chest, trunk, and lower limbs bilaterally. Motor blockade was assessed using the Modified Bromage Scale.
Patients were educated preoperatively regarding the Visual Analogue Scale (VAS) for pain assessment. Supplemental oxygen was provided during surgery. Sedation was assessed by using Ramsey sedation score as 0=none (alert patient), 1= Mild (sleepy patient but easily arousable), 2= Moderate (drowsy patient but arousable), and 3= Severe(difficult to arouse).In the postoperative period, pain was assessed using the Visual Analogue Scale, where a score of "0" indicated no pain and a score of "10" indicated the worst imaginable pain. Intraoperative and postoperative complications such as hypotension, heart rate variations, nausea, vomiting, pruritus, and other adverse effects were recorded.
The following parameters were observed after the block:
1. Time of onset of sensory block
2. Time to achieve highest sensory level (T6)
3. Time taken for complete motor blockade
4. Duration of analgesia
5. Sedation score
6. Haemodynamic parameters

7. **Side effects**

Rescue analgesia with intravenous tramadol 100 mg was administered when the VAS score was ≥4 or upon patient request in both groups, and the time of administration was recorded.

RESULT

Table 1: Demographic profile of the study participants

Baseline characteristics	BB group	BM group	P value
Age	43.7 ± 7.26	41.7 ± 8.23	0.322
Sex Male Female	 23 (76.7) 7 (23.3)	 27 (90) 3 (10)	0.08
Weight distribution	65.33 ±8.11	64.90 ±6.91	0.825
ASA I/II	13/17	18/12	0.09

Table 2: Comparison of onset of sensory block in minutes between the groups

S.No	BB group (N= 30)	BM group (N=30)	P value
	2.03 ± 0.27	2.35 ± 0.54	0.005*

Table 3: Comparison for level of highest sensory blockade T6 between the groups

S.No	BB group (N= 30)	BM group (N=30)	P value
1.	4.10 ± 2.14	4.59 ± 2.28	0.394

Table 4: Time taken for complete motor block in minutes between the groups

S.No	BB group (N= 30)	BM group (N=30)	P value
	2.78 ± 0.48	2.29 ± 0.88	0.009*

Table 5: Comparison of duration of motor blockade between the groups

S.No	BB group (N= 30) (mins)	BM group (N=30) (mins)	P value
1	295 ± 18.17	245 ± 13.56	<0.0001*

Table 6: Comparison of duration of analgesia between the groups

S.No	BB group (N= 30)	BM group (N=30)	P value
1	478 ± 25.18	309.66 ± 17.65	<0.0001*

Table 7: Comparison of side effects between group BD and BF

SIDE EFFECTS	BB group (N=30) (%)	BM group (N=30) (%)	P value
Pruritis	**3**	**0**	0.03*
Nausea/vomiting	**2**	**2**	0.50
Hypotension	**2**	**3**	0.32
Urinary retention	1	0	0.15

Table 8: Sedation score

Sedation score	BB group (N=30)	BM group (N=30)	P value
0	19	23	
1	11	7	0.13
2	0	0	
3	0	0	

Sixty patients undergoing lower abdominal surgeries were enrolled in the study and randomly allocated into two groups: Group BB and Group BM. The demographic variables such as age, sex, weight, and ASA physical status were comparable between the two groups, with no statistically significant difference (P > 0.05) [Table 1].

The mean time for onset of sensory block was 2.03 ± 0.27 minutes in Group BB and 2.35 ± 0.54 minutes in Group BM. A statistically significant difference was observed between the two groups with respect to the time required to achieve sensory block up to the T10 level (P < 0.05) [Table 2].

The highest sensory level achieved was T6. The mean time to reach this level was 4.10 ± 2.14 minutes in Group BB and 4.59 ± 2.28 minutes in Group BM [Table 3].The duration of motor block was longer in Group BB 295 ± 18.17 minutes compared to Group BM [Table 5].

The duration of analgesia was significantly prolonged in Group BB (478 ± 25.18 minutes) when compared to Group BM (309.66 ± 17.65 minutes) [Table 6].There was no statistically significant difference between the two groups with respect to systolic blood pressure, diastolic blood pressure, heart rate, and SpO_2 throughout the duration of surgery.

A few complications such as nausea, pruritus, hypotension, and bradycardia were observed. Pruritus was noted in three patients and nausea/vomiting in two patients in the buprenorphine group. In the midazolam group, hypotension was observed in three patients; however, this difference was not statistically significant.

DISCUSSION

Opioids have been widely used for providing postoperative pain relief, and the advantages of neuraxial narcotics over systemic narcotics are well established[2]. Buprenorphine is a long-acting, highly lipophilic opioid that has proven to be a promising analgesic when administered via epidural and intrathecal routes. It exhibits a mixed agonist–antagonist action, has high lipid solubility, and a

strong affinity for opioid receptors[3]. These properties contribute to its prolonged duration of action, making it a suitable choice for intrathecal and peripheral nerve site administration[4].

Midazolam is a short-acting, water-soluble, and potent benzodiazepine with a rapid onset of action mediated through the benzodiazepine–GABA receptor complex, the major inhibitory neurotransmitter system in the central nervous system[5,6]. Binding sites for benzodiazepine receptors have been demonstrated in the spinal cord, with the highest density located in lamina II of the dorsal horn, a region that plays a crucial role in processing nociceptive information[7,8]. Various studies have suggested that an effective and safe dose of intrathecal midazolam ranges from 1–2 mg[9] .Hence, in the present study, 2 mg of intrathecal midazolam was used in combination with buprenorphine and bupivacaine to evaluate its effects on spinal anesthesia and postoperative analgesia.

In the present study,the mean time for onset of sensory block was 2.03 ± 0.27 minutes in Group BB and 2.35 ± 0.54 minutes in Group BM consistent with the results of Shah et al. The buprenorphine group demonstrated a faster onset of motor block as well as an earlier attainment of peak sensory level compared to the midazolam group. Similar findings were reported by Bharati et al[10]. and Thomas et al[11].

In the present study, the mean duration of analgesia in the buprenorphine group was 478 ± 25.18 minutes, which was significantly longer than that observed in the midazolam group 309.66 ± 17.65 minutes. In contrast, studies conducted by Shah et al[12]. and Batra et al[13]. reported a significantly longer duration of analgesia in the midazolam group compared to the buprenorphine group.

However, consistent with our results, these studies also concluded that both drugs are effective adjuvants to intrathecal bupivacaine in prolonging the duration of analgesia.

CONCLUSION

Our study concludes that buprenorphine is a superior adjuvant to intrathecal bupivacaine compared with midazolam for lower abdominal surgeries, as it provides an earlier onset of sensory and motor block and a significantly prolonged duration of analgesia.

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Competing Interest

There is no competing interest

Authors Contribution

All authors in our study contributed to the data collection of the patients

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