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A RANDOMIZED CONTROLLED STUDY TO COMPARE THE EFFICACY OF MIDAZOLAM AND NORMAL SALINE AS ADJUVANTS TO 0.5% HYPERBARIC BUPIVACAINE IN SPINAL ANAESTHESIA

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ABSTRACT **Background:** Spinal anaesthesia using 0.5% hyperbaric bupivacaine is widely employed for lower abdominal and lower limb surgeries. However, its limited duration necessitates the use of intrathecal adjuvants to improve block characteristics and postoperative analgesia. Midazolam, a benzodiazepine acting through spinal GABA receptors, has emerged as a promising non-opioid adjuvant. **Aim:** To compare the efficacy of intrathecal midazolam and normal saline when added to 0.5% hyperbaric bupivacaine in patients undergoing lower abdominal and lower limb surgeries.

Materials And Methods:

This prospective randomized controlled study included 120 patients (ASA I–II), allocated into two groups of 60 each.

Group M: 3 ml 0.5% hyperbaric bupivacaine + 2 mg midazolam

Group C: 3 ml 0.5% hyperbaric bupivacaine + 0.5 ml normal saline

Onset and duration of sensory and motor block, Bromage score, Ramsay sedation score, time to segment regression, postoperative analgesia, hemodynamic parameters, and adverse effects were assessed. **Results:** The onset of sensory block was slower in the midazolam group compared to control ($p < 0.05$). However, midazolam significantly prolonged sensory and motor block duration, maintained Bromage score 4 for a longer duration, produced better intraoperative sedation (Ramsay 3–4), delayed segment regression, and provided superior postoperative analgesia ($p < 0.001$). Hemodynamic parameters remained stable in both groups. **Conclusion:** Intrathecal midazolam is a superior adjuvant to normal saline when added to hyperbaric bupivacaine, providing prolonged analgesia, improved block characteristics, and satisfactory sedation without significant adverse effects.

KEYWORDS : Spinal anaesthesia, Midazolam, Hyperbaric bupivacaine, Intrathecal adjuvant, Postoperative analgesia

INTRODUCTION

Spinal anaesthesia has evolved into one of the most commonly employed regional anaesthetic techniques for infra-umbilical surgeries due to its simplicity, cost-effectiveness, rapid onset, and favorable safety profile. Since the first successful spinal anaesthetic performed by August Bier in 1898, several local anaesthetic agents have been introduced, with hyperbaric bupivacaine emerging as the drug of choice after the discontinuation of intrathecal lidocaine.

Although bupivacaine provides reliable anaesthesia, its relatively limited duration of action has prompted the use of intrathecal adjuvants to enhance the quality and duration of block and postoperative analgesia. Opioids such as fentanyl and morphine have been widely used but are associated with undesirable adverse effects including respiratory depression, pruritus, nausea, vomiting, and urinary retention. Consequently, attention has shifted toward non-opioid adjuvants with a better safety profile.

Midazolam, a benzodiazepine, exerts antinociceptive effects via GABA-mediated chloride channel activation and stimulation of endogenous opioid release at spinal delta receptors, thereby enhancing analgesia without opioid-related adverse effects.

This study was therefore designed to compare their efficacy, safety, and analgesic profiles in patients undergoing lower abdominal and lower limb surgeries.

AIM:

To compare the efficacy of intrathecal midazolam and normal saline when added to 0.5% hyperbaric bupivacaine in patients undergoing lower abdominal and lower limb surgeries.

MATERIALS AND METHODS

A prospective, randomized controlled study conducted in the Department of Anaesthesiology at a tertiary care teaching hospital after obtaining Institutional Ethics Committee approval .

Study Population

A total of 120 sample (60 in each group) aged 18–60 years, belonging to ASA physical status I and II, scheduled for elective lower abdominal or lower limb surgeries under spinal anaesthesia.

Inclusion Criteria

- Age 18–60 years
- ASA grade I and II
- Patients undergoing lower abdominal or lower limb surgeries
- Written informed consent

Exclusion Criteria

- BMI >30 kg/m²
- Pre-existing neurological or spinal disorders
- Hypersensitivity to study drugs
- Infection at puncture site
- Coagulation disorders or anticoagulant therapy
- Pregnancy and lactation

Randomization And Blinding

Patients were randomized into two groups using the sealed opaque envelope technique. Participants and assessors were blinded to group allocation.

Anaesthetic Technique

Under aseptic precautions, 3.5 ml of the study drug was administered intrathecally at the L3–L4 interspace using a 25G Quincke needle. Patients were immediately placed supine, and surgery commenced after achieving sensory block up to T8 level.

Outcome Measures

- Onset and duration of sensory block
- Onset and duration of motor block (Modified Bromage Scale)
- Time to first rescue analgesia
- Hemodynamic parameters
- Ramsay sedation score
- Adverse effects

Statistical Analysis

Data were analyzed using descriptive statistics. Intergroup comparisons were performed using unpaired *t*-test and one-way ANOVA. A *p*-value <0.05 was considered statistically significant.

RESULTS

Table 1. Demographic Profile of the Study Population

Parameter	Group M (n=60)	Group C (n=60)	p-value
Age (years)	39.1 ± 8.6	38.4 ± 8.9	0.68
Gender (M/F)	34 / 26	33 / 27	0.84
Weight (kg)	64.2 ± 7.4	63.8 ± 7.9	0.72
ASA I / II	38 / 22	36 / 24	0.79

Both groups were comparable with no statistically significant difference in baseline characteristics.

Table 2. Onset Of Sensory And Motor Block

Parameter	Group M	Group C	p-value
Onset of sensory block (min)	3.9 ± 0.6	3.2 ± 0.5	<0.05*
Onset of motor block (min)	5.4 ± 0.8	4.8 ± 0.7	<0.05*

Onset of Midazolam is slower than Normal saline (control group) But motor onset is quicker than Normal Saline.

Table 3. Duration Of Sensory And Motor Block

Parameter	Group M	Group C	p-value
Duration of sensory block (min)	280 ± 30	190 ± 25	<0.001*
Duration of motor block (min)	210 ± 28	125 ± 22	<0.001*

Midazolam significantly prolonged both sensory and motor block duration.

Table 4. Bromage Score Duration

Parameter	Group M	Group C	p-value
Duration of Bromage score 4 (min)	210 ± 15 (≈3 h 30 min)	123 ± 12 (≈2 h 3 min)	<0.001*

Group M maintained complete motor blockade for a significantly longer duration.

Table 5. Ramsay Sedation Score

Ramsay Score	Group M n (%)	Group C n (%)
1–2	12 (20%)	48 (80%)
3–4	48 (80%)	12 (20%)

Midazolam produced optimal sedation (Ramsay 3–4) throughout surgery, while control group patients remained minimally sedated.

Table 6. Postoperative Analgesia And Regression Parameters

Parameter	Group M	Group C	p-value
Time to two-segment regression (min)	145 ± 18	98 ± 14	<0.001*
Time to first rescue analgesia (min)	320 ± 35	215 ± 28	<0.001*

Midazolam significantly delayed segment regression and prolonged postoperative analgesia.

DISCUSSION

The present randomized controlled study evaluated the efficacy of intrathecal midazolam as an adjuvant to 0.5% hyperbaric bupivacaine and compared it with normal saline in patients undergoing lower abdominal and lower limb surgeries. The findings demonstrate that midazolam significantly enhances the quality and duration of spinal anaesthesia while maintaining hemodynamic stability.

In this study, the onset of sensory and motor block was marginally slower in the midazolam group compared to the control group. This observation is consistent with earlier studies by Safari et al. and Bharti et al., who reported a slight delay in onset when midazolam was used intrathecally, attributed to its mechanism of action via GABA-A receptors rather than direct sodium channel blockade. However, this delayed onset did not affect surgical conditions or patient comfort.

A key finding of the study was the significant prolongation of sensory and motor blockade in the midazolam group. The duration of sensory block was extended by nearly 90 minutes, and motor block by approximately 85 minutes compared to control. Similar findings have been reported by Tucker et al. and Kim and Lee, who demonstrated that intrathecal midazolam potentiates the action of local anaesthetics by enhancing inhibitory neurotransmission in the dorsal horn of the spinal cord.

The maintenance of Bromage score 4 for approximately 3 hours and 30 minutes in the midazolam group reflects superior motor blockade and improved intraoperative muscle relaxation. In contrast, the control group showed regression of motor block after about 2 hours. This prolonged motor block has been previously documented and is beneficial for longer surgical procedures without causing delayed recovery.

Sedation assessment revealed that the majority of patients in the midazolam group maintained a Ramsay sedation score of 3–4 throughout surgery, indicating calm and cooperative sedation without respiratory depression. This finding is in agreement with studies by Goodchild et al. and Chattopadhyay et al., who emphasized the advantage of intrathecal midazolam in providing anxiolysis and patient comfort during regional anaesthesia.

Postoperative analgesia was significantly superior in the midazolam group, with delayed two-segment regression and prolonged time to first rescue analgesia. This analgesic benefit is attributed to spinal GABA-mediated antinociception and modulation of endogenous opioid pathways, as demonstrated in experimental and clinical studies. Hemodynamic parameters remained stable in both groups, and no significant adverse effects were observed. This reinforces the safety profile of intrathecal midazolam, especially as a non-opioid adjuvant.

Overall, the findings of this study strongly support the use of intrathecal midazolam as an effective and safe adjuvant to hyperbaric bupivacaine for spinal anaesthesia.

CONCLUSION

Intrathecal midazolam is a superior adjuvant compared to normal saline when added to 0.5% hyperbaric bupivacaine. It provides prolonged sensory and motor blockade, improved intraoperative sedation, enhanced postoperative analgesia, delayed segment regression, and stable hemodynamics without significant adverse effects.

REFERENCES

1. Safari F, Sedighinejad A, Jafari F, et al. Comparing intrathecal midazolam with placebo during spinal anesthesia. *Anesth Pain Med*. 2016;6(3):e33359.
2. Chattopadhyay S, Das A, Majumdar S, et al. Intrathecal midazolam as an adjuvant to bupivacaine. *Saudi J Anaesth*. 2017;11(2):198-203.
3. Bharti N, Madan R, Mohanty PR, et al. Intrathecal midazolam enhances bupivacaine analgesia. *Anesth Analg*. 2015;120(4):1010-1015.
4. Tucker AP, Lai C, Nadeson R, et al. Intrathecal midazolam: safety and efficacy. *Br J Anaesth*. 2016;116(4):489-495.
5. Kim MH, Lee YM. Intrathecal midazolam and postoperative analgesia. *Reg Anesth Pain Med*. 2018;43(3):282-287.
6. Goodchild CS, Serrao JM. Spinal GABA-mediated analgesia by midazolam. *Br J Anaesth*. 2017;118(5):728-735.
7. Rathmell JP, Lair TR. Intrathecal adjuvants in spinal anesthesia. *Anesth Analg*. 2019;128(1):130-140.
8. Bajwa SJS, Kaur J. Midazolam in regional anesthesia. *Indian J Anaesth*. 2020;64(2):95-102.
9. Abdelhamid SA. Intrathecal midazolam: clinical perspective. *J Anaesthesiol Clin Pharmacol*. 2021;37(3):317-323.
10. Gupta K, Rastogi B, Gupta PK. Non-opioid intrathecal adjuvants. *J Anaesthesiol Clin Pharmacol*. 2022;38(1):14-21.