Original Research

COMPARATIVE EVALUATION OF INTRATHECAL BUPIVACAINE (0.5% HEAVY) WITH MIDAZOLAM 1 MG VERSUS 2 MG AS AN ADJUVANT IN SUBARACHNOID BLOCK FOR ELECTIVE LOWER ABDOMINAL SURGERIES

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ABSTRACT

Background: Spinal anaesthesia is widely used for lower abdominal surgeries due to its rapid onset and effective analgesia. However, limited duration of action remains a concern. Intrathecal midazolam, acting via GABA receptors, has been shown to enhance analgesic effects when used as an adjuvant to bupivacaine. This study aims to compare the efficacy and safety of two doses (1 mg and 2 mg) of intrathecal midazolam combined with 0.5% hyperbaric bupivacaine.

Methods: 80 patients (ASA I–II, aged. 18–60) undergoing elective lower abdomen operations participated in a prospective, randomised, single-centre trial. Two groups of patients were created: bupivacaine and 1 mg of midazolam were given to Group M1, while bupivacaine and 2 mg of midazolam were given to Group M2. The onset and duration of sensory and motor block, sedation scores, time to rescue analgesia, haemodynamic alterations, and side effects were among the parameters evaluated. The t-test and chi-square test were used for statistical analysis, with significance set at $p<0.05$.

Results: Group M2 showed significantly faster onset of sensory (1.23 vs 1.78 min) and motor block (1.78 vs 2.25 min). The duration of sensory and motor block was significantly prolonged in Group M2 (191.25 vs 154.13 min and 238.35 vs 196.50 min, respectively). Time to rescue analgesia was longer in Group M2 (272.73 vs 235.88 min). Sedation scores were higher in Group M2 but remained clinically acceptable. Hemodynamic parameters were stable and comparable in both groups, with minimal and statistically insignificant adverse effects.

Conclusion: Intrathecal midazolam 2 mg as an adjuvant to 0.5% hyperbaric bupivacaine provides superior analgesia, prolonged block duration, faster onset, and acceptable sedation without significant adverse effects compared to a 1 mg dose.

Keywords: Intrathecal Midazolam, Bupivacaine, Subarachnoid Block, Postoperative Analgesia, Sedation, Lower Abdominal Surgery.

INTRODUCTION

Spinal anaesthesia is one of the most used regional anaesthetic techniques for lower abdominal and lower limb surgery because of its rapid onset, dense neuronal blocking, convenience of application, and lower systemic drug exposure than general anaesthesia.[1] It offers superior intraoperative circumstances with reduced stress response and a decreased risk of postoperative problems such as

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respiratory depression, nausea, and vomiting. Because of its consistent sensory and motor blockage and prolonged duration of action, 0.5% hyperbaric bupivacaine is a popular choice among the various local anaesthetics.[2] Higher dosages, however, are linked to side effects such as bradycardia, hypotension, and delayed motor recovery, which can lengthen hospital stays and lower patient satisfaction.[3]

To enhance the efficacy of spinal anaesthesia while minimizing drug-related side effects, various intrathecal adjuvants have been studied. These include opioids, clonidine, dexmedetomidine, and benzodiazepines, each with specific advantages and limitations.[4] Midazolam, a water-soluble benzodiazepine, has emerged as a promising intrathecal adjuvant due to its analgesic, anxiolytic, and sedative properties. It acts by binding to GABA-A receptors in the spinal cord, leading to modulation of nociceptive transmission and enhanced inhibitory neurotransmission.[5]

Experimental and clinical studies have demonstrated that intrathecal midazolam provides effective postoperative analgesia without significant neurotoxicity. Its addition to bupivacaine has been shown to improve the quality of sensory and motor blockade, prolong the duration of analgesia, and reduce the need for rescue analgesics.[6] Furthermore, midazolam offers the advantage of producing mild sedation and amnesia without causing significant respiratory depression, which is commonly seen with opioid adjuvants.[7]

Several studies have evaluated different doses of intrathecal midazolam. A dose of 2 mg has been associated with prolonged duration of sensory block and better postoperative pain relief.[8] Lower doses such as 1 mg have also demonstrated beneficial effects but may provide a comparatively shorter duration of analgesia.[9]

The study aimed to compare the efficacy of perioperative and postoperative analgesia between intrathecal midazolam 1 mg and 2 mg when used as an adjuvant to 0.5% hyperbaric bupivacaine under subarachnoid block. The objectives were to evaluate and compare the onset and duration of sensory and motor blockade, including time to maximum block and regression, as well as the time to rescue analgesia. Additionally, the study assessed secondary parameters such as haemodynamic stability, degree of sedation, and the incidence of adverse effects, including hypotension, nausea, and vomiting, in order to determine the overall safety and effectiveness of the two doses.

METHODOLOGY

This prospective randomized study included 80 patients aged 18–60 years belonging to ASA physical status I and II undergoing elective lower abdominal surgeries, who were randomly allocated into two groups of 40 each using the sealed envelope method. Ethical clearance was obtained for the study from institutional ethical committee.After obtaining informed consent, all patients underwent preoperative evaluation and routine investigations. In the operating room, an intravenous line was secured with an 18G cannula and patients were preloaded with 500 ml of Ringer lactate. Standard monitoring including pulse rate, electrocardiogram, non-invasive blood pressure, mean arterial pressure, and oxygen saturation was instituted and baseline parameters were recorded. Under strict aseptic precautions, subarachnoid block was performed at the L3–L4 interspace using a 25G or 26G Quincke spinal needle in the sitting position. Preservative-free midazolam with a concentration of 5 mg/ml was used as the adjuvant; in Group M1, 0.2 ml (1 mg) of midazolam was diluted with normal saline to make a total volume of 1 ml, and in Group M2, 0.4 ml (2 mg) of midazolam was similarly diluted to 1 ml. Following confirmation of free flow of cerebrospinal fluid, Group M1 received 3 ml of 0.5% hyperbaric bupivacaine combined with 1 ml of the prepared 1 mg midazolam solution, while Group M2 received 3 ml of 0.5% hyperbaric bupivacaine combined with 1 ml of the prepared 2 mg midazolam solution, thereby ensuring that the total intrathecal injectate volume was equal (4 ml) in both groups. Patients were then placed in the supine position, and sensory block was assessed using the pinprick method while motor block was evaluated using the modified Bromage scale at regular intervals.

Parameters recorded included onset and duration of sensory and motor block, time to maximum block, regression time, sedation using Ramsay sedation score, time to rescue analgesia, haemodynamic variables, and any adverse effects. Statistical analysis was performed using appropriate statistical software, with continuous variables expressed as mean ± standard deviation and categorical variables as number and percentage. Intergroup comparison of continuous variables was carried out using Student’s independent t-test, while categorical variables were analyzed using Chi-square test or Fisher’s exact test as appropriate, and a p-value of less than 0.05 was considered statistically significant.

RESULTS

Parameter	Group M1 (n=40)	Group M2 (n=40)	P value
Age (Mean ± SD)	40.8 ± 12.01	Comparable	>0.05

Gender (M/F)	27/13	31/9	0.453
ASA I/II (%)	70/30	70/30	1.000
Height (cm)	160.95 ± 5.09	162.05 ± 5.88	0.374
Weight (kg)	62.40 ± 8.31	61.95 ± 7.25	0.797
Table 1: Demographic Characteristics of Study Population			

Table 1 shows that there were no statistically significant variations between the two groups' demographic data, including age, gender, ASA grade, height, and weight.

Parameter	Group M1	Group M2	P value
Sensory onset (min)	1.78 ± 0.80	1.23 ± 0.53	0.001**
Motor onset (min)	2.25 ± 0.84	1.78 ± 0.69	0.010*
Table 2: Onset of Sensory and Motor Block			

Table 2 demonstrates that, in comparison to Group M1, Group M2 experienced a noticeably quicker onset of both sensory and motor block.

Parameter	Group M1	Group M2	P value
Max sensory block (min)	5.60 ± 1.82	4.73 ± 1.58	0.023*
Max motor block (min)	5.53 ± 1.79	4.63 ± 1.48	0.036*
Table 3: Time to Maximum Block			

Table 3 demonstrates that Group M2 achieved maximum sensory and motor blockade significantly earlier than Group M1.

Parameter	Group M1	Group M2	P value
Sensory regression to L1 (min)	154.13 ± 35.20	191.25 ± 52.43	<0.001**
Motor regression (min)	196.50 ± 41.67	238.35 ± 58.53	<0.001**
Table 4: Duration of Sensory and Motor Block			

According to Table 4, Group M2's sensory and motor blockage lasted noticeably longer than Group M1's.

Sedation Score	Group M1 (%)	Group M2 (%)
1	80	47.5
2	15	37.5
3	2.5	12.5
≥4	2.5	2.5
P value		**0.011**
Table 5: Sedation Score Distribution		

Table 5 shows that higher sedation scores were more frequently observed in Group M2, indicating significantly better sedation compared to Group M1.

Parameter	Group M1	Group M2	P value
Mean sedation score	1.28 ± 0.64	1.73 ± 0.87	0.003**
Rescue analgesia time (min)	235.88 ± 58.48	272.73 ± 67.22	0.005**
Table 6: Sedation Score (Mean) and Rescue Analgesia			

Table 6 reveals that Group M2 had significantly higher sedation scores and prolonged time to rescue analgesia compared to Group M1.

Parameter	Group M1	Group M2	P value
Hypotension (%)	2.5	2.5	
Bradycardia (%)	2.5	7.5	
No side effects (%)	95	90	0.805
Hemodynamic parameters	Stable	Stable	NS
Table 7: Adverse Effects and Hemodynamic Stability			

Table 7 shows that adverse effects were minimal and comparable between both groups, with no statistically significant differences. Hemodynamic parameters remained stable throughout the study.

DISCUSSION

Because of its quick onset, efficient neural blocking, and good safety profile, spinal anaesthesia is frequently utilised for lower abdominal procedures. However, because of its short duration, adjuvants must be used to prolong block characteristics and improve analgesia. The current study assessed intrathecal midazolam as an adjuvant to 0.5% hyperbaric bupivacaine at dosages of 1 mg and 2 mg. The findings demonstrated that 2 mg of midazolam provided faster onset, prolonged duration of block, improved postoperative analgesia, and better sedation without significant hemodynamic instability.

The demographic characteristics in both groups were comparable, ensuring homogeneity and validity of the study results. Similar comparability has been reported in previous studies, confirming that baseline characteristics do not influence the observed effects of intrathecal midazolam.[6,10]

In the current investigation, the 2 mg group experienced sensory and motor blockage much more quickly than the 1 mg group. "This observation is consistent with the findings of Bharti et al.,[6] and Yun et al.,[9] who reported that intrathecal midazolam enhances the onset of spinal anaesthesia when used with bupivacaine. The mechanism underlying this effect is attributed to the action of midazolam on GABA-A receptors in the spinal cord, which enhances inhibitory neurotransmission and potentiates the effect of local anesthetics."[5]

The higher dose group also experienced a much quicker period to reach maximum sensory and motor blockages. This is in agreement with earlier studies that demonstrated improved block characteristics with the addition of midazolam.[6] The synergistic interaction between midazolam and bupivacaine likely facilitates faster spread and action of the anaesthetic agent.

The substantial extension of sensory and motor block in the 2 mg group was one of the study's main conclusions. The duration of sensory regression and motor recovery was markedly increased compared to the 1 mg group. These findings are consistent with multiple studies, including those by Bharti et al.,[6] Prakash et al.,[10] and Tucker et al.,[11] all of which demonstrated that intrathecal midazolam prolongs the duration of spinal anaesthesia. This prolongation is likely due to modulation of nociceptive pathways in the dorsal horn via benzodiazepine receptors.

Postoperative analgesia, as assessed by the time to rescue analgesia, was significantly prolonged in patients receiving 2 mg midazolam. This is in accordance with the findings of Prakash et al.[10] who reported that higher doses of intrathecal midazolam significantly extend postoperative pain relief. Similar observations have been reported by Agarwal et al.[12] further supporting the analgesic efficacy of midazolam.

Sedation scores were higher in the 2 mg group, indicating better intraoperative sedation without excessive sedation or respiratory depression. This finding is consistent with previous studies that reported mild and clinically acceptable sedation with intrathecal midazolam.[9,10] Such sedation is beneficial in reducing anxiety and improving patient comfort during surgical procedures. Heart rate, blood pressure, and oxygen saturation are examples of haemodynamic measures that stayed constant and similar between the two groups over the course of the study. This observation aligns with previous studies, which have consistently reported that intrathecal midazolam does not significantly affect cardiovascular stability.[6,12]

A good safety profile was shown by the low and similar occurrence of side events such as bradycardia and hypotension in both groups. Similar findings have been reported in earlier studies, which demonstrated minimal side effects with intrathecal midazolam.[10,12]

The results of this study show that intrathecal midazolam is a safe and effective adjuvant to bupivacaine, which is consistent with previous research. In terms of quicker onset, longer block duration, improved surgical analgesia, and better sedation without increased side effects, the 2 mg dose in particular provides superior clinical benefits.

Limitations

Several studies have evaluated the role of intrathecal midazolam as an adjuvant in subarachnoid block, either alone or in combination with other agents. However, studies directly comparing two doses-1 mg and 2 mg-of intrathecal midazolam in SAB are relatively limited. Furthermore, the current study was carried out in a single location with a somewhat limited sample size, which would restrict how broadly the results can be applied. Additionally, there was no long-term monitoring or evaluation of uncommon side events.

CONCLUSION

Our research shows that intrathecal midazolam 2 mg is better than 1 mg when used as an adjuvant to 0.5% hyperbaric bupivacaine for subarachnoid blocks in lower abdominal procedures. It offers sufficient sedation, maintains stable haemodynamic parameters, greatly extends sensory and motor blockage, lengthens the duration of postoperative

analgesia, and has few side effects. Further large-scale, multicentric investigations are needed to confirm these results and determine the ideal dose for clinical use because there is little literature comparing various intrathecal midazolam doses.

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