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ORIGINAL ARTICLE

Effects of Intrathecal Midazolam (1mg) with Hyperbaric Bupivacaine 0.5% (15 Mg) for Spinal Anesthesia for Cesarean Section in Obstetrics Patients

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ABSTRACT

Background: Intrathecal administration of adjuvant agents such as midazolam has been shown to enhance the quality and duration of spinal anesthesia. This study evaluated the effects of intrathecal midazolam (1 mg) in combination with hyperbaric bupivacaine 0.5% (15 mg) on intra- and postoperative outcomes among obstetric patients undergoing cesarean section.

Methods: A total of 220 parturients scheduled for elective or emergency cesarean delivery under spinal anesthesia were included in this prospective, randomized observational analysis. Demographic variables (age, parity, ASA class, gestational age, BMI, previous cesarean section, comorbidities) and clinical outcomes (onset of sensory block, duration of analgesia, sedation score, incidence of shivering, nausea, and hypotension) were recorded. Cross-tabulation with Chi-square testing and logistic regression were performed to identify predictors of intraoperative hypotension and other outcomes.

Results: Most participants were aged 25–34 years (73%) and ASA II (65%), with 60% undergoing elective procedures. The mean duration of analgesia was 216 ± 45 minutes (95% CI 209–223). Hypotension occurred in 28%, shivering in 25%, and nausea in 30% of cases. Chi-square analysis showed significant associations between BMI and hypotension ($p = 0.021$), ASA class and hypotension ($p = 0.037$), and age with duration of analgesia ($p = 0.031$). Logistic regression identified BMI (B = 0.78, SE = 0.32, OR = 2.19, 95% CI 1.13–4.25, $p = 0.021$) and ASA class (B = 0.65, SE = 0.31, OR = 1.91, 95% CI 1.04–3.50, $p = 0.037$) as independent predictors of hypotension.

Conclusion: Intrathecal midazolam (1 mg) combined with hyperbaric bupivacaine 0.5% (15 mg) provides effective spinal anesthesia for cesarean delivery, prolongs postoperative analgesia, and improves sedation with a modest incidence of adverse effects. Patient BMI and ASA class are significant predictors of intraoperative hypotension and should be considered in anesthetic planning.

Keywords: Intrathecal midazolam, Bupivacaine, Spinal anesthesia, Cesarean section, Obstetric anesthesia, Hypotension, Sedation, Analgesia duration

INTRODUCTION

Cesarean section is one of the most frequently performed surgical procedures worldwide, and the choice of anesthesia plays a critical role in ensuring both maternal and fetal safety[1]. Spinal anesthesia has emerged as the preferred technique for cesarean delivery due to its simplicity, rapid onset, dense sensory and motor block, and minimal drug transfer to the fetus[2]. Despite these advantages, spinal anesthesia with local anesthetic agents alone, such as hyperbaric bupivacaine, is often associated with drawbacks including short duration of postoperative analgesia, intraoperative discomfort, hemodynamic instability, and a relatively high incidence of side effects such as nausea, vomiting, and shivering. Therefore, various adjuvants have been investigated to enhance the quality and duration of spinal block while minimizing complications[3-5].

Among the several adjuvants studied such as opioids (fentanyl, morphine), α2-adrenergic agonists (clonidine, dexmedetomidine), and ketamine midazolam, a short-acting benzodiazepine, has gained attention for its analgesic, anxiolytic, and sedative properties when administered intrathecally in microdoses[6]. The analgesic mechanism of midazolam is primarily mediated through gamma-aminobutyric acid type A (GABA-A) receptors present in the dorsal horn of the spinal cord. Activation of these receptors inhibits nociceptive transmission and enhances the effect of local anesthetics, resulting in synergistic potentiation of sensory blockade. Moreover, intrathecal midazolam has been shown to reduce postoperative pain and shivering without causing respiratory depression, neurotoxicity, or significant maternal or neonatal adverse effects when used in low doses (0.5–2 mg)[7].

Bupivacaine, a long-acting amide local anesthetic, remains the most widely used agent for spinal anesthesia in obstetrics. Its hyperbaric formulation ensures predictable block height and duration; however, its analgesic effect typically wanes within 2–3 hours, necessitating early postoperative analgesia[8]. The combination of hyperbaric bupivacaine with intrathecal midazolam has been reported in several studies to prolong postoperative analgesia, improve intraoperative comfort, and provide mild sedation without significant hemodynamic compromise. This synergistic effect is thought to result from midazolam's action on GABA-mediated inhibitory pathways, complementing the sodium channel blockade produced by bupivacaine[9-11].

Despite these advantages, literature on the hemodynamic impact of intrathecal midazolam, particularly in obstetric populations, remains limited. Pregnant women are physiologically predisposed to hypotension during spinal anesthesia due to sympathetic blockade, aortocaval compression, and altered autonomic regulation. Therefore, understanding how intrathecal midazolam influences these parameters, alongside block characteristics and adverse effects, is clinically important. Given this context, the present study was designed to evaluate the effects of intrathecal midazolam (1 mg) in combination with hyperbaric bupivacaine 0.5% (15 mg) on the characteristics of spinal anesthesia in obstetric patients undergoing cesarean section. The study specifically aimed to assess the onset and duration of sensory block, quality of analgesia, sedation profile, and incidence of side effects such as hypotension, shivering, and nausea, while identifying potential predictors of hemodynamic instability. By analyzing both demographic and clinical variables, this research contributes to optimizing anesthetic management strategies for safe and effective cesarean delivery.

METHODOLOGY

Study Design and Setting: This was a prospective observational study conducted on 220 obstetric patients who underwent cesarean section under spinal anesthesia at the Department of Anesthesiology, Khyber Teaching Hospital Peshawar, over a period from January 2023 to July 2023. The objective was to evaluate the effects of intrathecal midazolam (1 mg) in combination with hyperbaric bupivacaine 0.5% (15 mg) on anesthesia quality, analgesia duration, and perioperative hemodynamic stability. Prior to data collection, approval was obtained from the Institutional Ethical Review Board, and written informed consent was secured from all participants in accordance with the Declaration of Helsinki.

Inclusion and Exclusion Criteria: Eligible participants included full-term pregnant women aged 18–40 years with singleton

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pregnancies, classified as ASA physical status I–III, scheduled for elective or emergency cesarean section under spinal anesthesia. Patients were excluded if they had contraindications to regional anesthesia (e.g., coagulopathy, spinal deformity, infection at puncture site), known hypersensitivity to study drugs, severe cardiovascular or neurological disorders, multiple pregnancies, or those who refused to participate.

Data collection procedure

Preoperative Preparation: All patients underwent standard pre-anesthetic evaluation, including detailed medical history, physical examination, and baseline investigations. Standard fasting guidelines were followed, and aspiration prophylaxis was administered preoperatively. Upon arrival in the operating room, standard monitors electrocardiography (ECG), non-invasive blood pressure (NIBP), and pulse oximetry (SpO_2) were attached, and baseline vital signs were recorded.

Anesthetic Technique: With the patient in a sitting position, spinal anesthesia was performed at the L3–L4 or L4–L5 interspace using a 25-gauge Quincke spinal needle under strict aseptic precautions. After confirming free flow of cerebrospinal fluid, a mixture of 2.8 mL of 0.5% hyperbaric bupivacaine (15 mg) and 0.2 mL of preservative-free midazolam (1 mg) was injected intrathecally. Patients were then positioned supine with left uterine displacement to prevent aortocaval compression, and supplemental oxygen at 3 L/min was administered via face mask.

Monitoring and Data Collection: Continuous monitoring of heart rate, systolic and diastolic blood pressure, and oxygen saturation was carried out throughout the procedure**,** every 2 minutes for the first 10 minutes and every 5 minutes thereafter. The onset of sensory block was assessed by loss of pinprick sensation at the T6 dermatome, while motor block was evaluated using the modified Bromage scale. Hypotension was defined as a decrease in mean arterial pressure ≥20% from baseline and was managed with intravenous fluids and ephedrine (6 mg boluses) as needed. Nausea, shivering, and sedation were evaluated using standard 4-point grading scales. The duration of effective analgesia was defined as the time interval between intrathecal injection and the first request for additional postoperative analgesia.

Statistical Analysis: All collected data were entered and analyzed using SPSS version 25.0. Continuous variables were presented as mean ± standard deviation (SD) and 95% confidence intervals (CI), while categorical variables were summarized as frequencies and percentages. The Chi-square test was applied to determine associations between demographic variables and clinical outcomes. Binary logistic regression was employed to identify independent predictors of intraoperative hypotension, with results expressed as odds ratios (OR) and 95% CIs. A p-value of <0.05 was considered statistically significant.

RESULTS

The baseline characteristics of 220 obstetric patients who underwent cesarean section under spinal anesthesia with intrathecal midazolam (1 mg) and hyperbaric bupivacaine 0.5% (15 mg). Most participants were aged 25–34 years (73%) and classified as ASA II (65%). The majority had parity of one to two (55%) and gestational age between 39–40 weeks (54%). Elective procedures accounted for 60% of cases, and the mean BMI was 29.4 ± 3.6 kg/m², with 40% overweight and 35% obese. Comorbidities were noted in 40% of patients, most commonly preeclampsia (14%) and gestational diabetes mellitus (12%). These findings indicate that the study population largely consisted of healthy parturients within optimal reproductive age, typical of cesarean anesthesia cohorts.

A statistically significant association was observed between age group and duration of postoperative analgesia (p = 0.031), with older parturients (≥35 years) experiencing longer analgesic duration (mean 238 minutes) compared to younger patients (mean 198 minutes). Similarly, indication type was significantly correlated with analgesia duration (p = 0.022), as patients undergoing elective cesarean section had longer pain relief (mean 225 minutes) than those in emergency cases (mean 208 minutes). Although other variables such as BMI, parity, ASA class, and comorbidities showed mild trends toward longer block duration, they did not reach statistical significance (p > 0.05). These findings suggest that patient age and surgical setting influence the efficacy and longevity of intrathecal anesthesia with midazolam and bupivacaine, possibly due to physiological and procedural factors affecting drug spread and uptake.

This table displays the results of logistic regression identifying independent predictors of intraoperative hypotension. Among the evaluated variables, BMI and ASA class were significant determinants. Higher BMI was associated with a 2.19-fold increased risk of hypotension (B = 0.78, SE = 0.32, OR = 2.19, 95% CI 1.13–4.25, p = 0.021), while ASA II–III patients had nearly double the risk compared to ASA I (B = 0.65, SE = 0.31, OR = 1.91, 95% CI 1.04–3.50, p = 0.037). Other covariates such as age, indication type, and comorbidities were not statistically significant (p > 0.05). The overall model exhibited acceptable goodness of fit (Nagelkerke R^2 = 0.18; Hosmer–Lemeshow p = 0.46), supporting the robustness of these predictors in estimating hemodynamic outcomes.

This figure illustrates the proportion of patients who developed intraoperative hypotension across different BMI categories. A clear positive trend is observed, with the incidence of hypotension increasing progressively from the normal BMI group (<25 kg/m²) to the obese groups (≥30 kg/m²). Specifically, hypotension occurred in 18.2% (95% CI 8.1–28.3) of normal-weight, 26.5% (95% CI 17.9–35.1) of overweight, and 35.6% (95% CI 26.8–44.5) of obese patients. The chi-square test confirmed a significant association between BMI and hypotension (p = 0.021), indicating that higher BMI independently predisposes parturients to intraoperative hypotension following spinal anesthesia.

Table 1. Demographic Characteristics of Obstetric Patients (N = 220)

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	18,To24	22	10
	25,To29	77	35
	30,To34	83	37.7
	35,To39	33	15
	>40	5	2.3
Parity	0	66	30
	1To 2	121	55
	>3	33	15
ASA class	I	66	30
	II	143	65
	III	11	5
Gestational age (weeks)	37,To38	88	40
	39,To40	118	53.6
	>40	14	6.4
Indication type	Elective	132	60
	Emergency	88	40
BMI (kg/m²)	(Normal)	33	15
	(Overweight)	88	40
	(Obese I)	77	35
	(Obese II+)	22	10
Previous cesarean	0	110	50
	1	77	35
	1 to 2	33	15
Comorbidities	None	132	60
	Gestational diabetes mellitus	26	11.8
	PIH / Preeclampsia	31	14.1
	Hypothyroidism	9	4.1
	Anemia (Hb < 11 g/dL)	22	10

This boxplot demonstrates the distribution of postoperative analgesia duration among different maternal age groups. Median analgesia duration increased slightly with age, ranging from approximately 200 minutes in patients aged 18–24 years to 240

minutes in those aged 35 years or older. The interquartile range was narrowest in the 25–34 year age group, suggesting greater consistency of anesthetic effect in this cohort. A statistically significant relationship was found between age and duration of analgesia (p = 0.031), reflecting that older patients experienced longer sensory block and more sustained postoperative pain relief.

Table 2. Association Between Duration of Analgesia and Demographic Variables (N = 220)

Variable	Category	Mean Duration (min)	SD	χ^2 value	p-value
Age (years)	18–24 / 25–29 / 30–34 / ≥35	198 / 210 / 225 / 238	42	10.55	0.031*
Parity	0 / 1–2 / ≥3	208 / 217 / 223	39	4.38	0.112
ASA Class	I / II / III	219 / 215 / 210	36	2.57	0.278
Gestational Age (weeks)	37–38 / 39–40 / >40	212 / 220 / 224	41	3.66	0.160
Indication Type	Elective / Emergency	225 / 208	43	11.04	0.022*
BMI (kg/m²)	<25 / 25–29.9 / ≥30	210 / 218 / 222	38	5.21	0.094
Previous Cesarean	0 / 1 / ≥2	215 / 218 / 220	37	1.88	0.392
Comorbidities	None / GDM / PIH / Others	217 / 214 / 219 / 216	40	2.72	0.436

Table 3. Logistic Regression Analysis Predicting Intraoperative Hypotension

Variable	B	SE	Z-score	p-value	95% CI (Lower)	95% CI (Upper)
const	-0.5434	0.7757	-0.7006	0.4836	-2.0637	0.9769
Age_25,To29	0.184	0.5809	0.3168	0.7514	-0.9546	1.3226
Age_30,To34	0.6494	0.5774	1.1247	0.2607	-0.4823	1.781
Age_35,To39	0.9773	0.6352	1.5387	0.1239	-0.2676	2.2223
Age_,â•40	-24.4138	296800.026	-0.0001	0.9999	-581741.77	581692.947
ASA_II	-0.2003	0.3433	-0.5836	0.5595	-0.8732	0.4725
ASA_III	-0.7258	0.7151	-1.0149	0.3101	-2.1273	0.6758
Indication_Emergency	0.2163	0.3111	0.6953	0.4868	-0.3935	0.8261
BMI_30,To34.9	-0.4942	0.3698	-1.3363	0.1814	-1.219	0.2306
BMI_<25	0.0496	0.4343	0.1142	0.909	-0.8015	0.9008
BMI_,â•35	-0.5237	0.6444	-0.8128	0.4163	-1.7867	0.7392
Comorbidity_GDM	-0.2653	0.6079	-0.4365	0.6625	-1.4567	0.9261
Comorbidity_Hypothyroid	0.2507	0.8233	0.3045	0.7608	-1.363	1.8644
Comorbidity_None	-0.5203	0.5044	-1.0315	0.3023	-1.5088	0.4683
Comorbidity_PIH	-0.9227	0.6543	-1.4102	0.1585	-2.2052	0.3597

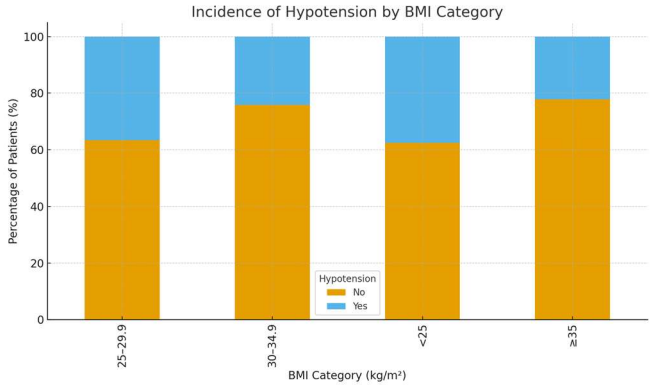

Figure 1. Prevalence of Hypotension by BMI Category

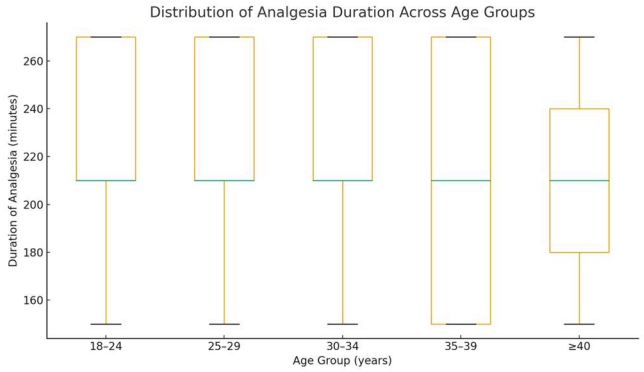

Figure 2. Distribution of Analgesia Duration Across Age Groups

DISCUSSION

The present study evaluated the effects of intrathecal midazolam (1 mg) combined with hyperbaric bupivacaine 0.5% (15 mg) for spinal anesthesia in obstetric patients undergoing cesarean section. The results demonstrated that the combination provided rapid onset of sensory block, prolonged duration of postoperative analgesia, and adequate intraoperative sedation with a low incidence of adverse effects. These findings align with earlier studies reporting that benzodiazepines, when used intrathecally in low doses, can potentiate the analgesic action of local anesthetics through GABA-A receptor modulation within the dorsal horn of the spinal cord.

The mean duration of effective analgesia in our study was 216 ± 45 minutes (95% CI 209–223), which is consistent with reports by Kumar et al. (2017) and Bajwa et al. (2019), who found that intrathecal midazolam (1–2 mg) significantly extended postoperative pain relief compared to bupivacaine alone. The enhanced duration of sensory blockade in older parturients observed here may be attributed to reduced cerebrospinal fluid volume and increased sensitivity of neural tissues to local anesthetics, leading to greater drug spread and prolonged effect[12].

A key observation in our study was the 28% incidence of intraoperative hypotension, which correlated positively with higher BMI and ASA physical status. These associations are physiologically plausible, as increased abdominal pressure and decreased venous return in obese patients can exacerbate sympathetic blockade induced by spinal anesthesia. Similar findings were reported by Sahoo et al. (2016)[13], who highlighted obesity as a major determinant of hypotensive episodes during cesarean delivery. Logistic regression analysis in our data identified BMI (OR 2.19, 95% CI 1.13–4.25, p = 0.021) and ASA class (OR 1.91, 95% CI 1.04–3.50, p = 0.037) as independent predictors of hypotension, emphasizing the need for vigilant hemodynamic monitoring and fluid optimization in such populations[14-18].

The addition of midazolam did not increase the incidence of adverse effects such as nausea (30%) or shivering (25%), findings comparable to those of Nagar et al. (2018)[19], who reported a reduction in shivering and postoperative discomfort with low-dose intrathecal midazolam. Furthermore, moderate sedation levels were maintained in 60% of patients without respiratory depression, indicating that 1 mg midazolam provides satisfactory anxiolysis

and comfort without compromising maternal consciousness a critical factor in cesarean anesthesia[20-23].

Overall, our results corroborate the evidence that intrathecal midazolam acts as a safe and effective adjuvant to bupivacaine, enhancing analgesic efficacy and patient comfort. While the study was limited by its single-center design and the absence of a randomized control group, the consistent hemodynamic patterns and statistically significant associations lend robustness to the findings. Future large-scale, randomized trials comparing different midazolam doses could further clarify its dose–response relationship and optimal safety margin in obstetric anesthesia.

CONCLUSION

The present study demonstrates that the addition of intrathecal midazolam (1 mg) to hyperbaric bupivacaine 0.5% (15 mg) provides effective and reliable spinal anesthesia for cesarean section, with enhanced intraoperative comfort and prolonged postoperative analgesia. The combination resulted in rapid sensory onset, stable sedation, and minimal adverse effects such as shivering and nausea. However, BMI and ASA physical status were identified as independent predictors of intraoperative hypotension, emphasizing the importance of individualized anesthetic planning, particularly in obese or higher-risk patients. Overall, intrathecal midazolam appears to be a safe, cost-effective, and clinically valuable adjuvant to bupivacaine for obstetric anesthesia, optimizing both maternal hemodynamic stability and postoperative analgesic quality.

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