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Original Research Article

A Randomized Controlled Study to Evaluate the Anxiolytic Effect of Midazolam in Patients of Cesarean Section at SMS Medical College, Jaipur

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Abstract:

Background: Preoperative anxiety is highly prevalent in obstetric patients undergoing cesarean section and has significant implications for both maternal and neonatal outcomes. Midazolam, a short-acting benzodiazepine, has been proposed as an effective anxiolytic agent; however, concerns regarding neonatal safety have limited its widespread use in obstetric anesthesia.

Objective: To evaluate the anxiolytic efficacy of low-dose intravenous midazolam administered preoperatively in patients undergoing lower segment cesarean section (LSCS) under spinal anesthesia, and to determine its impact on neonatal vitality, maternal consciousness, and recall of the moment of birth.

Methods: This randomized, double-blind, placebo-controlled trial was conducted at S.M.S. Medical College and Attached Group of Hospitals, Jaipur. A total of 160 ASA II pregnant women aged 18-40 years scheduled for elective LSCS were randomly allocated into two groups: Group A (n=80) received midazolam 0.0125 mg/kg IV, while Group B (n=80) received an identical volume of 0.9% normal saline before spinal anesthesia. Anxiety was assessed using the Visual Facial Anxiety Scale (VFAS) at baseline and at 05, 15, and 60 minutes post-intervention. Sedation was evaluated using the Ramsay Sedation Scale at 10 minutes post-administration of solution. Neonatal outcomes were assessed using Apgar scores at 01 and 05 minutes. Hemodynamic parameters and maternal recall of childbirth were also documented.

Results: The midazolam group demonstrated significantly greater reduction in VFAS scores compared to the control group at all post-intervention time points ($p<0.001$). Mean VFAS scores decreased from 6.11±0.69 at baseline to 1.80±0.43 at 60 minutes in Group A, compared to 6.83±0.76 to 5.40±0.49 in Group B. Ramsay sedation scores were significantly higher in the midazolam group (2.27±0.45 vs 1.00±0.00, $p<0.001$). Neonatal Apgar scores at 01 minute (8.47±0.50 vs 8.40±0.49, $p=0.342$) and 05 minutes (9.00 in both groups) showed no significant difference. Hemodynamic parameters demonstrated greater stability in the midazolam group. Maternal complications including nausea, shivering, and vomiting were more frequent in the control group.

Conclusion: Low-dose intravenous midazolam (0.0125 mg/kg) provides effective anxiolysis and improved hemodynamic stability in parturients undergoing cesarean section under spinal anesthesia without adverse effects on neonatal outcomes.

Keywords: Midazolam; Cesarean section; Preoperative anxiety; Spinal anesthesia; Visual Facial Anxiety Scale; Apgar score; Neonatal outcomes.

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Introduction

Lower segment cesarean section (LSCS) is one of the most frequently performed surgical procedures worldwide and constitutes a major proportion of obstetric practice. [1] Advances in surgical technique, anesthesia, and perinatal care have made cesarean section a relatively safe procedure; however, it remains a source of considerable psychological distress for many parturients. [2] Preoperative anxiety is a universal phenomenon, but in obstetric patients it assumes special significance because of its dual impact on both mother and fetus. [3] Several studies have reported that nearly two-thirds of women scheduled for cesarean section experience moderate to severe preoperative anxiety. [4] This anxiety is multifactorial, encompassing fear of surgical complications, concern for fetal well-being, anticipation of intraoperative pain or discomfort, and the prospect of being conscious during surgery in an unfamiliar operating environment. [5]

Preoperative anxiety is not merely a psychological issue but a pathophysiological state that can adversely affect perioperative outcomes. [6] Anxiety stimulates the hypothalamic-pituitary-adrenal (HPA) axis and the sympathetic nervous system, resulting in elevated circulating catecholamines and cortisol. [7] These stress responses lead to tachycardia, hypertension, altered immune responses, and hypercoagulability. [8] In pregnant women, excessive anxiety has been correlated with higher maternal plasma cortisol levels, which are transferred to the fetus, as evidenced by elevated cortisol in umbilical cord blood samples.[9] Maternal stress and anxiety have been linked to increased risk of preterm labor, low birth weight, impaired fetal growth, and potential long-term neurodevelopmental consequences for the child. [10]

Lower segment cesarean section under regional anesthesia, particularly spinal anesthesia, is considered the gold standard due to its safety, rapid onset, and avoidance of airway manipulation. [11,12] However, the requirement for maternal wakefulness during surgery may exacerbate anxiety and distress.[13] Some patients express a preference for general anesthesia to avoid awareness of the surgical process, despite its higher risks, underscoring the importance of effective preoperative anxiolysis.[5] Moreover, heightened maternal anxiety has been shown to influence the degree of spinal anesthesia-induced hypotension, thereby increasing the need for vasopressor therapy and raising the risk of compromised uteroplacental perfusion and neonatal acidemia.[14]

Benzodiazepines are among the most widely used pharmacological agents for anxiolysis in surgical patients.[15,16] They act through potentiation of gamma-aminobutyric acid (GABA) neurotransmission, leading to anxiolytic, sedative, muscle-relaxant, and amnestic effects.[17,18] Despite their efficacy, the use of benzodiazepines in obstetric anesthesia has been controversial, largely due to concerns regarding maternal over-sedation, respiratory depression, impaired cooperation during LSCS, and potential neonatal depression if the drug crosses the placenta prior to delivery.

Midazolam, a short-acting, water-soluble benzodiazepine, has several properties that make it a suitable candidate for obstetric use. [19,20] It exhibits rapid onset of action, short elimination half-life (1.5-2.5 hours), and predictable clearance, reducing the risk of prolonged sedation. [21] Unlike diazepam, midazolam does not accumulate extensively in maternal tissues, and its water solubility minimizes pain on injection. In addition to its anxiolytic action, midazolam produces anterograde amnesia, thereby attenuating maternal recall of distressing intraoperative events without impairing cooperation. [20] Importantly, multiple studies have demonstrated that low-dose intravenous midazolam, administered either before or during LSCS, is not associated with adverse neonatal outcomes as measured by Apgar score or umbilical cord blood gas analysis. [19,22,23]

Given the paucity of robust, context-specific evidence, there is a clear need to systematically evaluate the anxiolytic efficacy and safety of low-dose midazolam in Indian obstetric patients undergoing LSCS under spinal anesthesia. The present randomized controlled trial was designed to evaluate the anxiolytic effect of low-dose midazolam administered preoperatively in women undergoing LSCS, assessing maternal anxiety levels, hemodynamic stability, maternal awareness and recall of the birth event, and neonatal outcomes as measured by Apgar score.

Materials and Methods

Study Design and Setting: This prospective, randomized, double-blind, placebo-controlled interventional trial was conducted in the Department of Anaesthesiology, S.M.S. Medical College and Attached Group of Hospitals, Jaipur, Rajasthan, India. The study was initiated after obtaining approval from the Institutional Research Review Board and Ethics Committee. Written informed consent was obtained from all participants prior to enrollment.

Sample Size Calculation: Based on a reference study (2022; 72(4): 450-456), sample size was calculated at a 95% confidence level with an alpha error of 0.05. The observed mean difference in anxiety score using the Visual Facial Anxiety Scale (VFAS) before and after administration of low-dose midazolam versus placebo was -1.3 versus 0.0, with a standard deviation of 2.8. At a study power of 80%, the required sample size was calculated as 74 cases in each group. Considering a 10% attrition rate, 80 subjects were enrolled in each group, yielding a final sample size of 160 patients.

Inclusion Criteria: Adult female patients aged 18-40 years, scheduled for elective LSCS, belonging to American Society of Anaesthesiologists (ASA) physical status II, and consenting to participate in the study were included.

Exclusion Criteria: Patients with underdeveloped fetus or congenital malformations, acute fetal distress, multiple pregnancies, cardiac disorders, moderate to severe lung disorders, moderate to severe psychiatric illness, pregnancy-induced hypertension, coagulopathies, drug allergy, local infection at injection site, or spinal deformities were excluded from the study.

Randomization and Blinding: Eligible patients were randomly allocated into two groups using the sealed-envelope method. Double blinding was

ensured, with neither the anesthesiologist nor the patient aware of group assignment, as identical volumes of solutions were used for both groups.

Group Allocation: Group A (Midazolam group, n=80) received a single intravenous bolus of midazolam 0.0125 mg/kg before spinal anesthesia. Group B (Control group, n=80) received an identical volume of 0.9% normal saline placebo solution before spinal anesthesia.

Study Procedure: All patients were received in the operating theatre where patient identification, pre-anesthetic check-up, informed consent, and fasting status were confirmed. Baseline demographic data including age, weight, height, parity, gestational age, and indication for LSCS were recorded. Preoperative vital signs (HR, SBP, DBP, MAP, SpO_2) were documented. An 18G IV cannula was inserted in the upper limb and Ringer Lactate infusion was started. Preoperative anxiety was assessed using the Visual Facial Anxiety Scale (VFAS).

Spinal Anesthesia Technique: Spinal anesthesia was performed with the patient in a sitting position under full aseptic precautions. The L3-L4 interspace was identified using the midline approach, and a 25G Quincke-type spinal needle was inserted. Injection of 0.5% hyperbaric bupivacaine (02 ml) was given intrathecally, and the patient was placed in the supine position after injection.

Intraoperative Monitoring: Continuous monitoring of HR, SBP, DBP, MAP, and SpO_2 was performed throughout the procedure. VFAS was re-evaluated at 05, 15, and 60 minutes post-intervention. Sedation was assessed at 10 minutes post-administration of solution using the Ramsay Sedation Scale. Neonatal Apgar scores were recorded at 01 and 05 minutes after delivery. Hemodynamic parameters were recorded at 05-minute intervals. Any intraoperative or postoperative complications were documented.

Maternal Recall Assessment: Maternal recall of the moment of birth was assessed at two time points: at presentation of the newborn and again at 90 minutes post-delivery.

Statistical Analysis: All collected data were entered into Microsoft Excel and analyzed using standard statistical software. Continuous variables were expressed as mean ± standard deviation (SD). Categorical variables were expressed as frequency and percentage. Comparisons of continuous variables between groups were performed using the Independent Samples t-test. Associations between categorical variables were analyzed using the Chi-square test, and Fisher's exact test was applied when expected cell counts in contingency tables were small. A p-value <0.05 was considered statistically significant.

Results

A total of 160 patients were enrolled in this study and randomly allocated into two equal groups of 80 each. All patients completed the study protocol, and there were no dropouts or exclusions during the study period.

Table 1: Baseline Demographics of Study Population

Parameter	Group A (Midazolam)	Group B (Control)	p-value
Age (years)	29.68 ± 01.96	29.59 ± 01.95	0.777
Weight (kg)	62.23 ± 02.94	61.95 ± 03.09	0.565
Nulliparous	36 (45.00%)	40 (50.00%)	0.742
Multiparous	44 (55.00%)	40 (50.00%)	

The mean age of patients in Group A was 29.68 ± 01.96 years compared to 29.59 ± 01.95 years in Group B (p=0.777). The mean weight was 62.23 ± 02.94 kg in Group A and 61.95 ± 03.09 kg in Group B (p=0.565). The proportion of nulliparous patients was 45.00% in Group A versus 50.00% in Group B. These differences were not statistically significant, indicating that both groups were comparable with respect to baseline demographic characteristics (Table 01).

Table 2: Comparison of Visual Facial Anxiety Scale Scores at Different Time Intervals

Time Point	Group A	Change	Group B	Change	p-value
Baseline	6.11 ± 0.69	---	6.83 ± 0.76	---	---
05 min	2.95 ± 0.61	-3.16	6.39 ± 0.52	-0.14	<0.001
15 min	2.17 ± 0.38	-3.94	6.28 ± 0.50	-0.18	<0.001
60 min	1.80 ± 0.43	-4.31	5.40 ± 0.49	-1.13	<0.001

The Visual Facial Anxiety Scale scores demonstrated a marked and sustained reduction in the midazolam group compared to the control group. In Group A, anxiety scores decreased from 6.11 ± 0.69 at baseline to 2.95 ± 0.61 at 05 minutes (-3.16 points), 2.17 ± 0.38 at 15 minutes (-3.94 points), and 1.80 ± 0.43 at 60 minutes (-4.31 points). In contrast, Group B showed only minimal decreases. The

differences between groups were highly significant at all post-intervention time points (p<0.001) (Table 02).

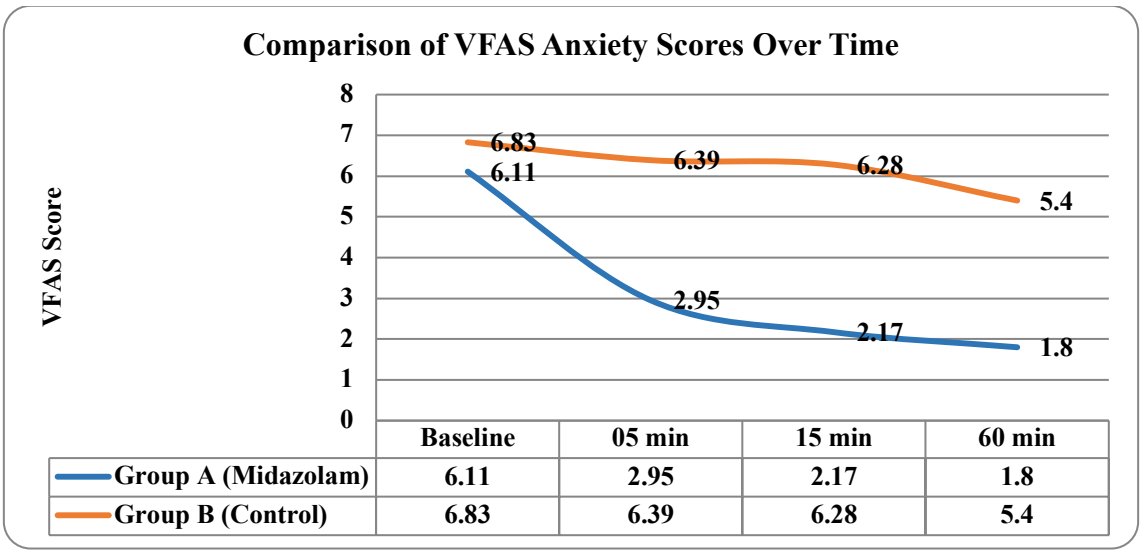

Figure 1: Comparison of VFAS Anxiety Scores Over Time

Table 3: Comparison of Ramsay Sedation Score at 10 Minutes Post-Administration of Solution

Group	Mean ± SD	p-value
Group A (Midazolam)	2.27 ± 0.45	<0.001
Group B (Control)	1.00 ± 0.00	

The Ramsay sedation score at 10 minutes post-administration of solution was significantly higher in the midazolam group (2.27 ± 0.45) compared to the control group (1.00 ± 0.00), with a highly significant difference (p<0.001). This demonstrates that midazolam produced meaningful sedation while all patients in the control group remained fully alert and anxious (Table 03).

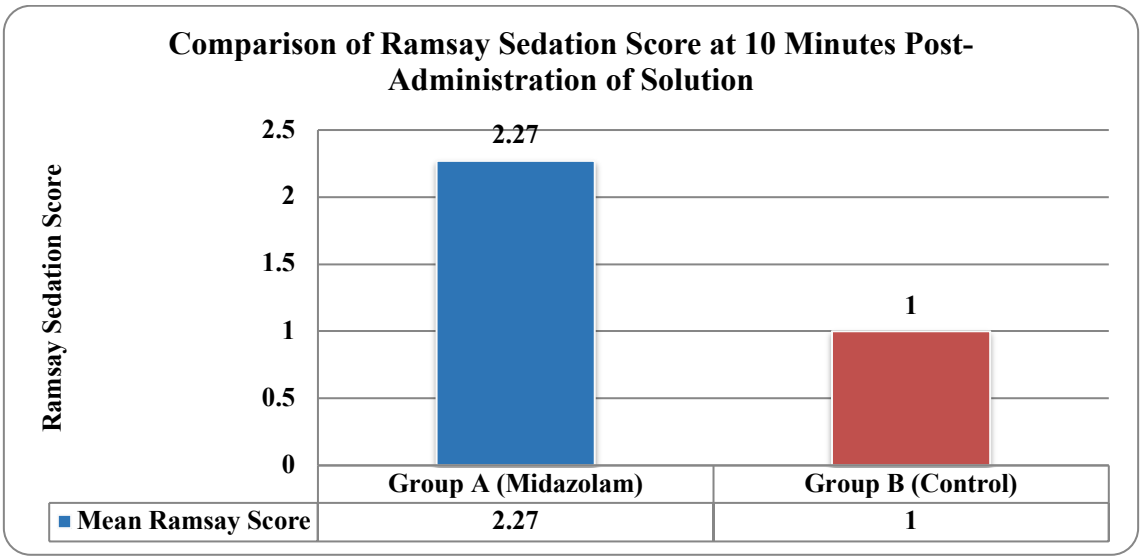

Figure 2: Comparison of Ramsay Sedation Score at 10 Minutes Post-Administration of Solution

Table 4: Comparison of Memory Response Outcomes Between Study Groups

Time Point	Response	Group A	Group B	p-value
At Presentation	Memory Present	74 (92.50%)	78 (97.50%)	0.147
	Memory Absent	06 (07.50%)	02 (02.50%)	
At 90 Minutes	Memory Present	70 (94.60%)	78 (100.00%)	0.040
	Memory Absent	04 (05.40%)	00 (00.00%)	

Memory of intraoperative events at presentation was present in 74 patients (92.50%) in Group A and 78 patients (97.50%) in Group B. This difference was not statistically significant (p=0.147). At 90 minutes, memory retention was 94.60% in Group A compared to 100.00% in Group B, and this difference was statistically significant (p=0.040) (Table 04).

Table 5: Comparison of Neonatal Apgar Scores at 01 and 05 Minutes

Time Point	Group A (Midazolam)	Group B (Control)	p-value
01 min	8.47 ± 0.50	8.40 ± 0.49	0.342
05 min	9.00 ± 0.00	9.00 ± 0.00	---

Neonatal Apgar scores at 01 minute were 8.47 ± 0.50 in Group A and 8.40 ± 0.49 in Group B, with no significant difference (p=0.342). At 05 minutes, both groups achieved a uniform Apgar score of 9.00. These results demonstrate that low-dose midazolam did not adversely affect neonatal outcomes (Table 05).

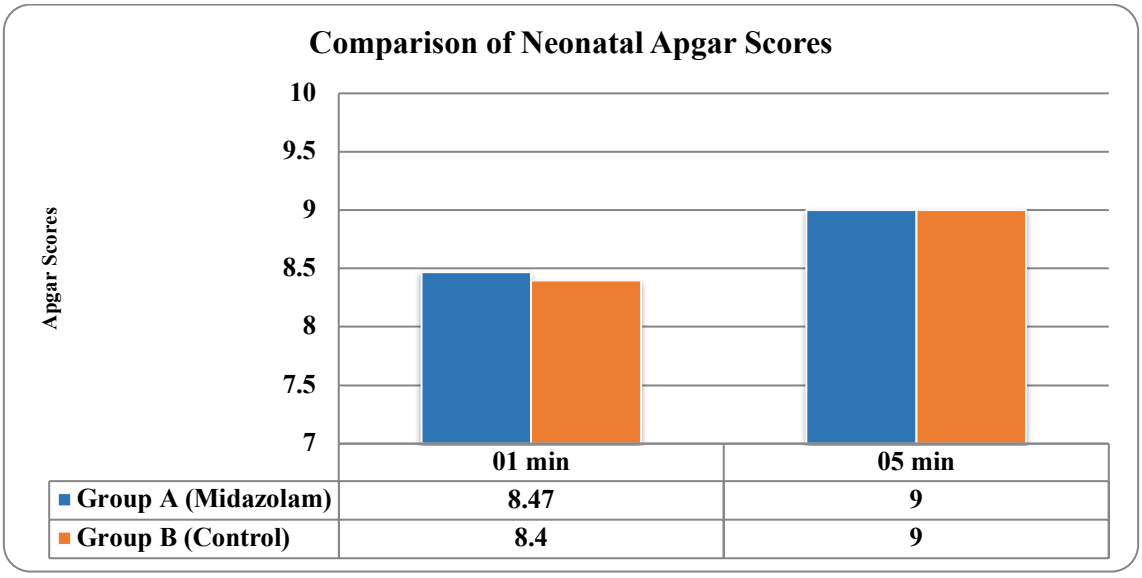

Figure 3: Comparison of Neonatal Apgar Scores

Table 6: Comparison of Mean Heart Rate at Different Time Intervals

Time Point	Group A (Midazolam)	Group B (Control)	p-value
Baseline	72.9 ± 11.68	74.8 ± 11.52	0.281
00 min	78.6 ± 12.28	78.5 ± 12.18	0.990
02 min	78.4 ± 14.49	81.9 ± 11.51	0.088
05 min	77.0 ± 14.84	83.5 ± 12.66	0.003
10 min	72.7 ± 11.78	77.7 ± 13.20	0.012
15 min	73.0 ± 08.82	77.4 ± 10.08	0.004
30 min	75.3 ± 11.19	77.7 ± 10.79	0.165
45 min	75.2 ± 10.50	77.9 ± 10.39	0.107
60 min	72.8 ± 08.20	77.2 ± 10.46	0.008

Heart rate was monitored throughout the procedure. Baseline values were comparable between groups. Significant reductions in heart rate were observed in Group A at 05 minutes (p=0.003), 10 minutes (p=0.012), 15 minutes (p=0.004), and 60 minutes (p=0.008). These findings indicate that midazolam was associated with greater heart rate stability (Table 06).

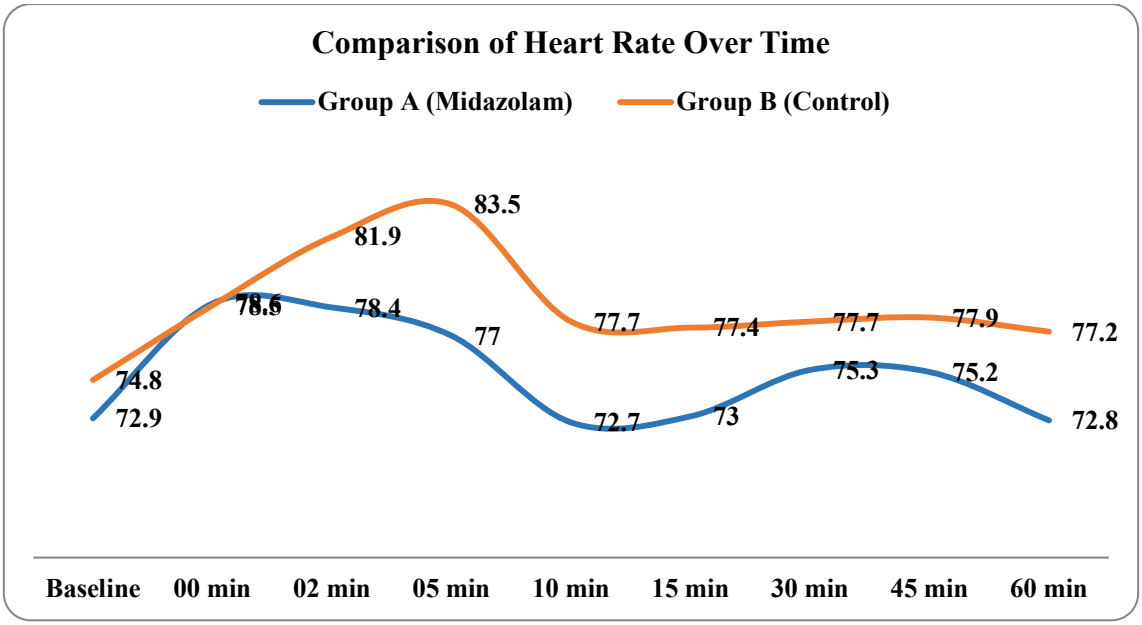

Figure 4: Comparison of Heart Rate Over Time

Table 7: Comparison of Mean Blood Pressure Parameters at Different Time Intervals

Time	SBP(A)	SBP(B)	p	DBP(A)	DBP(B)	p	MAP(A)	MAP(B)	p
Baseline	131.2	133.6	0.087	83.9	86.3	0.075	99.8	102.1	0.061
00 min	124.7	131.6	<0.001	76.2	82.7	<0.001	92.4	99.0	<0.001
02 min	119.2	130.6	<0.001	71.4	78.7	<0.001	87.3	94.7	<0.001
05 min	117.8	125.2	<0.001	69.3	76.4	<0.001	85.4	92.8	<0.001
10 min	119.9	123.9	0.047	72.1	74.7	0.154	88.0	91.2	0.081
60 min	120.2	123.5	0.052	74.4	73.5	0.608	89.7	90.1	0.788

Blood pressure parameters (SBP, DBP, MAP) were comparable at baseline. Immediately after spinal anesthesia and at 02 and 05 minutes, all three parameters were significantly lower in the midazolam group ($p<0.001$). At later intervals, differences diminished and stabilized. These findings demonstrate that midazolam attenuated the early stress-related elevation in blood pressure following spinal anesthesia (Table 07).

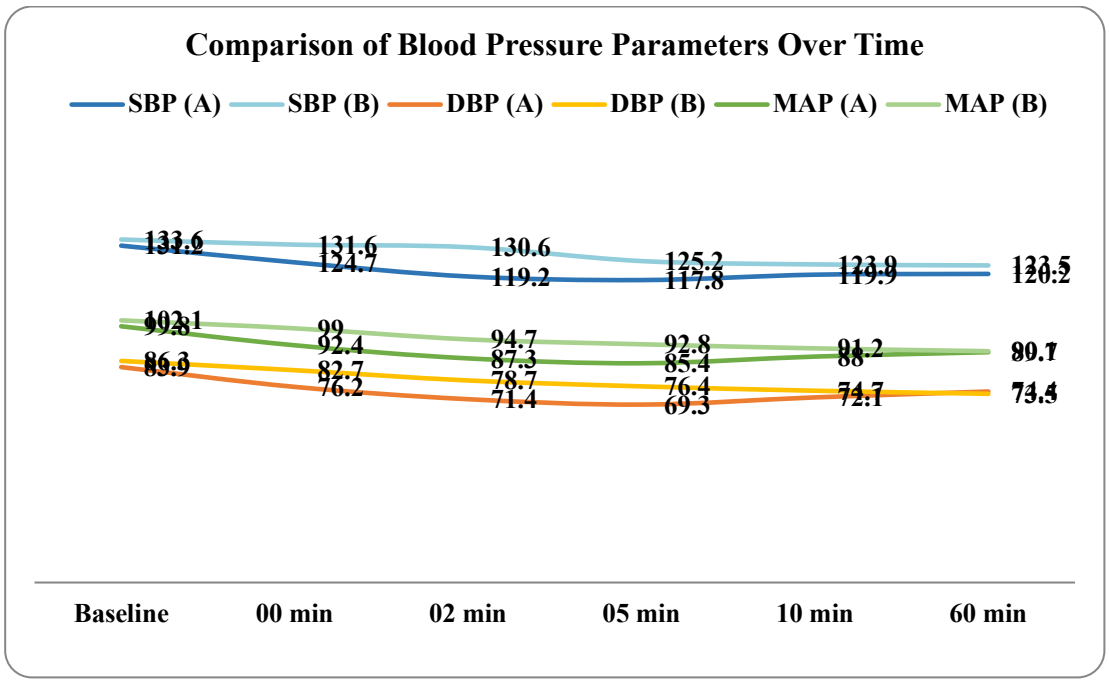

Figure 5: Comparison of Blood Pressure Parameters Over Time

Table 8: Distribution of Maternal Complications in Both Study Groups

Complication	Group A (Midazolam)	Group B (Control)
Nausea	10 (12.50%)	17 (21.25%)
Shivering	00 (00.00%)	16 (20.00%)
Vomiting	00 (00.00%)	08 (10.00%)
Drowsiness	05 (06.25%)	00 (00.00%)
Dizziness	08 (10.00%)	00 (00.00%)
None	57 (71.25%)	39 (48.75%)

Maternal complications differed between groups. Nausea occurred in 10 patients (12.50%) in Group A versus 17 patients (21.25%) in Group B. Shivering was present in 16 patients (20.00%) in Group B but absent in Group A. Vomiting was reported in 08 patients (10.00%) in Group B and none in Group A. Mild drowsiness occurred in 05 patients (06.25%) and dizziness in 08 patients (10.00%) in Group A only (Table 08).

Discussion

The present study was undertaken to evaluate the anxiolytic efficacy, sedative profile, hemodynamic stability, recall, and neonatal outcomes of low-dose midazolam premedication in women undergoing cesarean section under spinal anesthesia. A total of 160 patients were studied, divided equally into a midazolam group and a control group. The findings of our study demonstrate that low-dose intravenous midazolam (0.0125 mg/kg) provides effective anxiolysis with favorable hemodynamic stability and without adverse neonatal effects.

The demographic characteristics of both groups were comparable with respect to age, weight, and parity, ensuring that observed differences in outcomes could be attributed to the intervention rather than baseline variations. This comparability is consistent with previous randomized controlled trials investigating midazolam in obstetric populations. [19,23,24]

The primary finding of this study is the significant and sustained reduction in anxiety scores achieved with low-dose midazolam. The Visual Facial Anxiety Scale scores decreased from 6.11 ± 0.69 at baseline to 1.80 ± 0.43 at 60 minutes in the midazolam group, representing a reduction of 4.31 points. In contrast, the control group showed only a modest decline of 1.13 points over the same period. These results are consistent with Senel and Mergan (2014), [19] who reported significantly lower anxiety scores in women receiving 0.025 mg/kg midazolam prior to cesarean section. Similarly, Oliveira et al. (2021, 2022) [25,26] and Silva et al. (2022) [27] demonstrated that low-dose midazolam (0.0125 mg/kg) effectively reduced anxiety without affecting maternal or neonatal outcomes.

The Ramsay sedation scores in our study confirmed that midazolam produced meaningful sedation (2.27 ± 0.45 vs 1.00 ± 0.00, $p<0.001$) without causing excessive drowsiness or impaired cooperation. This level of sedation corresponds to a calm, cooperative patient who responds to commands, which is ideal for cesarean section under regional anesthesia. Deka et al. (2016) [28] reported similar sedation profiles with sub-hypnotic doses of midazolam, noting improved intraoperative stability without significant adverse effects.

Memory response outcomes in our study revealed that immediate recall at presentation was comparable between groups (92.50% vs 97.50%, p=0.147), but at 90 minutes, the midazolam group showed significantly lower memory retention (94.60% vs 100.00%, p=0.040). This delayed amnestic effect is consistent with the pharmacological profile of midazolam, which produces anterograde amnesia through its action on GABA-A receptors in the hippocampus. [17,18] Kanto et al. (1984) [29] similarly reported short-term amnesia lasting 30-60 minutes after midazolam administration in cesarean patients.

Importantly, neonatal Apgar scores in our study were comparable between groups at both 01 minute (8.47 ± 0.50 vs 8.40 ± 0.49, p=0.342) and 05 minutes (9.00 in both groups). These findings align with multiple studies demonstrating the neonatal safety of low-dose midazolam in obstetric anesthesia. Mokhtar et al. (2016) [23] found no differences in neonatal Apgar scores or neurologic adaptation in preeclamptic women receiving midazolam premedication. Frölich et al. (2006) [22] demonstrated that combined fentanyl and midazolam prior to anesthesia produced no adverse neonatal effects as assessed by Apgar scores, neurobehavioral evaluation, and continuous oxygen saturation monitoring.

Hemodynamic parameters in our study showed that patients in the midazolam group maintained significantly lower heart rate and blood pressure values at 05, 10, and 15 minutes compared to the control group. This hemodynamic stability is clinically important as it suggests that midazolam attenuated the stress response to spinal anesthesia and surgical stimuli. Dodawad et al. (2016) [30] reported that intrathecal midazolam reduced the incidence of hypotension and contributed to greater hemodynamic stability in hypertensive pregnant women. The mechanism underlying this effect likely involves the anxiolytic and sedative properties of

midazolam, which reduce sympathetic activation and catecholamine release associated with preoperative stress.

Maternal complications in our study differed between groups. Nausea, vomiting, and shivering were more frequent in the control group, while mild drowsiness and dizziness occurred only in the midazolam group. This finding is consistent with Deka et al. (2016) [28] who reported a significantly lower incidence of nausea and vomiting in midazolam-treated patients. Mohammed et al. (2024) [31] also demonstrated that anxiolytic doses of midazolam significantly reduced intraoperative nausea and vomiting during cesarean section.

The limitations of this study include its single-center design, which may limit generalizability. The sample size, while adequate for detecting differences in primary outcomes, may be insufficient to identify rare adverse events. Assessment of sedation and anxiety involves some subjectivity, which could introduce observer bias. Finally, long-term neonatal follow-up was not performed.

Conclusion

The present study demonstrates that intravenous administration of low-dose midazolam (0.0125 mg/kg) in parturients undergoing cesarean section under spinal anesthesia significantly reduces anxiety while providing better sedation and hemodynamic stability compared to the control group. Memory of intraoperative events immediately at presentation did not differ significantly between groups; however, memory retention declined over the subsequent 90 minutes in the midazolam group, indicating a delayed amnestic effect. Neonatal outcomes, as assessed by Apgar scores, remained unaffected. Maternal side effects were fewer in the midazolam group, limited to mild drowsiness and dizziness, whereas nausea, vomiting, and shivering were more common in the control group. Overall, low-dose intravenous midazolam proved to be a safe and effective adjuvant for improving maternal comfort without compromising neonatal well-being.

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Conflict of Interest: The authors declare no conflict of interest.

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