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COMPARISON OF DEXMEDETOMIDINE AND MIDAZOLAM FOR SEDATION DURING REGIONAL ANAESTHESIA: A HOSPITAL BASED STUDY

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Abstract:

Background: Sedation during regional anaesthesia (RA) enhances patient comfort, reduces anxiety, and improves surgical conditions. Dexmedetomidine and midazolam are commonly used sedative agents; however, they differ significantly in their pharmacological profiles, onset, recovery characteristics, and side-effect profiles. This prospective, randomized study was conducted to compare the efficacy, safety, and recovery profiles of dexmedetomidine and midazolam when used for intraoperative sedation in patients undergoing surgery under regional anaesthesia.

Methods: A total of 112 adult patients undergoing elective lower abdominal or lower limb surgeries under regional anaesthesia were enrolled and randomized into two equal groups. Group D received a loading dose of dexmedetomidine (1 µg/kg over 10 minutes) followed by an infusion of 0.2–0.7 µg/kg/h. Group M received midazolam at 0.03–0.07 mg/kg IV bolus followed by intermittent doses. Sedation levels were assessed using the Ramsay Sedation Scale (RSS), and vital parameters including heart rate, blood pressure, and oxygen saturation were monitored throughout. Time to reach target sedation, recovery time, patient satisfaction scores, and adverse events were recorded.

Results: Dexmedetomidine resulted in significantly higher sedation scores (mean RSS 3.6 ± 0.4) compared to midazolam (RSS 3.1 ± 0.5, $p<0.001$). The mean time to achieve sedation was slightly longer with dexmedetomidine (8.1 ± 2.2 min) than with midazolam (6.2 ± 1.8 min), but recovery was significantly faster in the dexmedetomidine group (14.8 ± 3.5 min vs. 21.3 ± 4.2 min, $p<0.001$). Patient satisfaction scores were higher in the dexmedetomidine group (mean VAS 8.6 ± 1.1 vs. 7.2 ± 1.3). Hemodynamic fluctuations such as bradycardia and hypotension were more common with dexmedetomidine but were mild and manageable. Oxygen desaturation occurred only in the midazolam group (5.4%).

Conclusion: Dexmedetomidine is superior to midazolam for sedation during regional anaesthesia, offering better sedation depth, faster recovery, and higher patient satisfaction, with minimal

respiratory compromise. It should be considered the preferred agent for intraoperative sedation, especially in patients where respiratory preservation and rapid postoperative recovery are crucial.

Keywords: Dexmedetomidine, Midazolam, Sedation, Regional anaesthesia, Ramsay Sedation Score, Recovery time etc.

Introduction:

Regional anaesthesia (RA) has become an increasingly preferred technique for a wide range of surgical procedures due to its advantages in intraoperative hemodynamic stability, postoperative analgesia, and early recovery.[1] However, patient anxiety and discomfort during RA can affect both patient satisfaction and surgical outcomes, necessitating the use of effective and safe sedative agents.[2]

Midazolam, a short-acting benzodiazepine, has been widely used for procedural sedation due to its anxiolytic, amnestic, and sedative properties.[3] Despite its effectiveness, midazolam may cause dose-dependent respiratory depression, oversedation, and prolonged recovery times.[4] These drawbacks have prompted a search for alternatives that provide reliable sedation with minimal side effects.

Dexmedetomidine, a highly selective α2-adrenergic agonist, has emerged as a promising alternative for procedural sedation. It provides cooperative sedation, analgesia, and anxiolysis without significant respiratory depression, making it particularly suitable for patients undergoing RA.[5] Its unique pharmacologic profile allows for arousable sedation and maintains hemodynamic stability, although bradycardia and hypotension may occur.[6] Several clinical studies have compared dexmedetomidine and midazolam in various anaesthetic settings, suggesting that dexmedetomidine may offer better sedation quality and patient satisfaction.[7,8]

Given the clinical relevance of choosing an optimal sedative agent during RA, this study aims to compare the efficacy, safety, and patient outcomes of dexmedetomidine and midazolam when used for sedation in adult patients undergoing surgery under regional anaesthesia. By evaluating parameters such as sedation scores, hemodynamic variables, intraoperative complications, and recovery profiles, this hospital-based study seeks to provide evidence-based guidance on sedative choice during RA in the Indian clinical context.

Material and Methods:

A prospective, randomized, hospital-based comparative study was conducted in the Department of Anaesthesiology, ICARE Institute of Medical Sciences and Research & Dr. B. C. Roy Hospital, Haldia, West Bengal, over a period of 1 year, from 2nd July 2023 to 1st July 2024**.** Prior to commencement, ethical clearance was obtained from the Institutional Ethics Committee. Written informed consent was obtained from all participants included in the study.

A total of 112 adult patients**,** aged between 18 and 65 years, of either sex, classified as American Society of Anesthesiologists (ASA) physical status I or II, and scheduled for elective lower abdominal or lower limb surgeries under regional anaesthesia (either spinal or epidural), who provided written informed consent, were included in the study. Patients with hypersensitivity to either study drug, significant cardiovascular, hepatic or renal disorders, neurological or psychiatric illness, pregnant or lactating women, and those with contraindications to regional anaesthesia were excluded.

Patients were randomized into two groups using a computer-generated randomization list:

- Group D (Dexmedetomidine Group): 56 patients received a loading dose of dexmedetomidine 1 µg/kg IV over 10 minutes, followed by a maintenance infusion of 0.5 µg/kg/hr.
- Group M (Midazolam Group): 56 patients received a loading dose of midazolam 0.05 mg/kg IV, followed by a maintenance infusion titrated between 0.02–0.05 mg/kg/hr.

All patients were monitored with standard intraoperative devices including non-invasive blood pressure (NIBP), electrocardiography (ECG), and pulse oximetry (SpO_2). Regional anaesthesia was administered under strict aseptic conditions, either spinal or epidural depending on surgical indication. The sedation protocol commenced after confirming an adequate sensory level of block. Sedation depth was assessed using the Ramsay Sedation Scale (RSS) every 10 minutes intraoperatively. Hemodynamic parameters (heart rate, systolic and diastolic blood pressure, mean arterial pressure,

and SpO_2) were recorded at 5-minute intervals throughout the surgery. The primary outcome measures of the study included the adequacy of sedation, assessed using the Ramsay Sedation Scale with a target score of 3 to 4, intraoperative hemodynamic stability evaluated through continuous monitoring of heart rate, blood pressure, and oxygen saturation, and overall patient comfort and cooperation during the procedure. Secondary outcomes included the recovery profile, defined as the time taken from cessation of the sedative infusion to achieving a Ramsay Sedation Scale score of 2, and the incidence of adverse events such as bradycardia, hypotension, oxygen desaturation, nausea, and vomiting during or immediately after the procedure. Bradycardia (HR <50 bpm) was managed with IV atropine 0.6 mg. Hypotension (MAP <60 mmHg or >20% drop from baseline) was treated with IV fluids and/or mephentermine 6 mg boluses. Supplemental oxygen (2–4 L/min) was administered by nasal cannula if SpO_2 dropped below 94%.

Collected data were entered into Microsoft Excel and analyzed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Quantitative variables were expressed as mean ± standard deviation (SD) and compared using the Student's unpaired t-test**.** Categorical variables were analyzed using the Chi-square test or Fisher's exact test, where applicable. A *p*-value <0.05 was considered statistically significant.

Results:

A total of 112 patients were enrolled in the study and successfully completed the intervention—56 in Group D (Dexmedetomidine) and 56 in Group M (Midazolam). Both groups were comparable in terms of baseline demographic and clinical characteristics.

As shown in Table 1, the mean age of patients in Group D was 42.6 ± 11.5 years, while in Group M it was 43.2 ± 10.9 years ($p = 0.72$). The male-to-female distribution was similar between groups (30/26 in Group D vs. 32/24 in Group M; $p = 0.69$). Average body weight and ASA physical status were also statistically similar ($p > 0.05$), ensuring that demographic factors did not confound the study outcomes. The average duration of surgery was approximately 72 minutes in both groups.

Table 1: Demographic and Baseline Parameters

Parameter	Group D (n = 56)	Group M (n = 56)	*p*-value
Age (years)	42.6 ± 11.5	43.2 ± 10.9	0.72
Sex (M/F)	30 / 26	32 / 24	0.69
Weight (kg)	65.4 ± 8.2	66.1 ± 9.0	0.61
ASA I / II	36 / 20	34 / 22	0.68
Duration of surgery (min)	73.5 ± 12.8	71.2 ± 11.4	0.34

Table 2 summarizes key sedation-related outcomes. The mean Ramsay Sedation Score (RSS) during surgery was significantly higher in the Dexmedetomidine group (3.6 ± 0.4) compared to the Midazolam group (3.1 ± 0.5), indicating deeper and more consistent sedation ($p < 0.001$). Although dexmedetomidine took slightly longer to reach target sedation (8.1 ± 2.2 min vs. 6.2 ± 1.8 min in midazolam), the difference was statistically significant ($p < 0.001$) but clinically acceptable.

However, the recovery profile favored Dexmedetomidine; patients in Group D returned to an RSS of 2 significantly faster (14.8 ± 3.5 minutes) than those in Group M (21.3 ± 4.2 minutes), indicating quicker postoperative recovery and reduced sedation hangover ($p < 0.001$).

Additionally, patient satisfaction measured on a 10-point visual analogue scale (VAS) was significantly higher in Group D (8.7 ± 0.9) than in Group M (7.4 ± 1.1), suggesting that patients found the Dexmedetomidine experience more pleasant and comfortable.

Table 2: Sedation and Recovery Profile

Parameter	Group D (n = 56)	Group M (n = 56)	*p*-value
Mean RSS during surgery	3.6 ± 0.4	3.1 ± 0.5	<0.001*
Time to reach RSS 3 (min)	8.1 ± 2.2	6.2 ± 1.8	<0.001*
Time to recovery (RSS = 2) (min)	14.8 ± 3.5	21.3 ± 4.2	<0.001*
Patient satisfaction (VAS 0–10)	8.7 ± 0.9	7.4 ± 1.1	<0.001*

Figure 1 illustrates that sedation depth, measured by the Ramsay Sedation Score, increased steadily in the dexmedetomidine group, reaching a stable and consistent level (RSS ~3.6) throughout the procedure, whereas the midazolam group showed an earlier but lower peak (RSS ~3.1) with a slight decline over time, indicating less sustained sedation.

Hemodynamic trends during surgery are shown in Table 3. While baseline heart rate and blood pressure were comparable, patients in the Dexmedetomidine group experienced a more pronounced decrease in heart rate and mean arterial pressure (MAP) at 15, 30, and 45 minutes intraoperatively. For instance, the heart rate at 30 minutes was 69.1 ± 6.7 bpm in Group D vs. 75.6 ± 6.0 bpm in Group M, and the MAP was 86.9 ± 6.1 mmHg vs. 90.8 ± 5.5 mmHg, respectively ($p < 0.05$ at each time point).

These findings are consistent with the known α2-agonist properties of dexmedetomidine**,** which can cause bradycardia and hypotension through central sympatholytic action. Importantly, despite these changes, no patient in either group required discontinuation of the sedative infusion for hemodynamic instability, and all changes were managed conservatively.

Table 3: Hemodynamic Parameters During Surgery

Time Point	HR (bpm) Group D	HR (bpm) Group M	MAP (mmHg) Group D	MAP (mmHg) Group M
Baseline	81.2 ± 7.5	80.4 ± 6.8	94.6 ± 8.1	95.2 ± 7.6
15 min	73.4 ± 6.2	77.8 ± 5.9	88.3 ± 6.4	92.1 ± 5.8
30 min	69.1 ± 6.7	75.6 ± 6.0	86.9 ± 6.1	90.8 ± 5.5
45 min	68.2 ± 5.9	74.3 ± 5.7	85.2 ± 5.7	89.6 ± 6.0

As detailed in Table 4**,** adverse events were slightly more frequent in Group D, although the differences were not statistically significant. Bradycardia was observed in 6 patients (10.7%) in Group D versus 2 patients (3.6%) in Group M ($p = 0.14$). Hypotension occurred in 5 patients in Group D compared to 3 in Group M ($p = 0.46$). Oxygen desaturation was seen only in the Midazolam group (3 patients, 5.4%) and none in Group D. Nausea and vomiting were reported in both groups without statistical significance.

All adverse events were mild to moderate in intensity and were easily managed with standard interventions such as atropine for bradycardia, IV fluids and mephentermine for hypotension, and oxygen supplementation when required.

Table 4: Adverse Events

Adverse Event	Group D (n = 56)	Group M (n = 56)	*p*-value
Bradycardia	6 (10.7%)	2 (3.6%)	0.14
Hypotension	5 (8.9%)	3 (5.4%)	0.46
Oxygen desaturation	0 (0%)	3 (5.4%)	0.08
Nausea/Vomiting	2 (3.6%)	4 (7.1%)	0.40
Total adverse events	13 (23.2%)	12 (21.4%)	0.82

Although dexmedetomidine was associated with a higher incidence of bradycardia and hypotension, these differences were not statistically significant. No serious adverse events occurred in either group.

Discussion

This randomized, prospective study evaluated and compared the efficacy, safety, and recovery characteristics of dexmedetomidine and midazolam for sedation during regional anaesthesia (RA). The findings affirm that dexmedetomidine provides superior sedation depth, quicker recovery, better patient satisfaction, and fewer respiratory complications compared to midazolam, albeit with mild, manageable hemodynamic effects.

The significantly higher intraoperative Ramsay Sedation Scores (RSS) in the dexmedetomidine group (mean 3.6 ± 0.4 vs. 3.1 ± 0.5) reflect more effective sedation. Dexmedetomidine's unique property of "cooperative sedation," where patients are easily arousable yet calm, has been well-documented in prior studies.[5,7,9] This type of sedation is particularly suitable for RA, where communication with the patient is beneficial during the procedure.[10]

Although midazolam acted faster in reaching the desired RSS, the slightly longer onset with dexmedetomidine was clinically acceptable and expected due to its pharmacodynamics.[2,11] More importantly, the dexmedetomidine group demonstrated a significantly faster recovery time to RSS = 2, indicating faster emergence from sedation. This contradicts the common assumption that midazolam allows quicker recovery due to its short half-life but is supported by newer evidence demonstrating that dexmedetomidine causes less cognitive and psychomotor impairment in the postoperative period.[12,13]

Patient satisfaction was markedly higher with dexmedetomidine, likely due to its analgesic and anxiolytic effects, lack of respiratory depression, and smoother sedation experience [5,8,14]. In contrast, midazolam, while providing effective anxiolysis and amnesia, has been associated with disorientation, oversedation, and delayed psychomotor recovery.[4,15]

Hemodynamically, patients in the dexmedetomidine group exhibited a predictable reduction in heart rate and mean arterial pressure, especially between 15 to 45 minutes intraoperatively. These effects are attributed to central sympatholytic action via α2-adrenoceptor stimulation.[6] Though bradycardia (10.7%) and hypotension (8.9%) were more frequent in this group compared to midazolam, all cases were mild and resolved with conservative management. No cases required termination of sedation, which aligns with findings from other prospective trials.[9,16]

A notable advantage of dexmedetomidine is its preservation of respiratory function. In our study, oxygen desaturation occurred only in the midazolam group (5.4%) and none in the dexmedetomidine group. This reinforces prior literature showing that even at higher doses, dexmedetomidine does not cause significant respiratory depression [5,17], making it particularly safe in elderly or high-risk populations undergoing RA.[18]

Adverse events such as nausea and vomiting were minimal and comparable between groups. No serious complications or delayed recovery outcomes were noted in either group, supporting the overall safety of both agents in well-monitored settings.

Thus, in adult patients undergoing surgeries under regional anaesthesia, dexmedetomidine offers a more favorable sedation profile compared to midazolam. It ensures better sedation stability, improved patient satisfaction, and quicker postoperative recovery without significant respiratory compromise. However, clinicians should remain vigilant for mild bradycardia or hypotension, especially in patients with preexisting cardiovascular concerns.

Limitations of our study include its single-center design and limited sample size. Moreover, the cost-effectiveness of dexmedetomidine—an important consideration in resource-limited settings—was not evaluated. Further multicenter studies are warranted to assess long-term outcomes, especially in geriatric and high-risk groups.

Conclusion: This hospital-based, prospective, randomized study demonstrated that dexmedetomidine is a more effective and safer alternative to midazolam for sedation during regional anaesthesia. Dexmedetomidine provided superior sedation quality, higher patient satisfaction, and faster recovery with minimal respiratory depression. Although it was associated with a higher incidence of bradycardia and hypotension, these hemodynamic changes were mild, transient, and easily manageable. Midazolam, while effective, showed limitations in sedation consistency and recovery profile, and was associated with a higher risk of oxygen desaturation. Based on these findings, dexmedetomidine appears to be a preferred sedative agent during regional anaesthesia, especially in patients where maintaining respiratory stability and early postoperative recovery are priorities.

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