

## Comparison of Dexmedetomidine and Midazolam for Sedation during Regional Anaesthesia: A Prospective Comparative Study

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### Abstract

**Background:** Sedation during regional anaesthesia is an integral component of perioperative care, as it alleviates patient anxiety, enhances comfort, and improves surgical conditions while allowing patients to remain cooperative. Midazolam has long been used for procedural sedation; however, dexmedetomidine has gained increasing attention because of its unique sedative and analgesic properties with minimal respiratory depression. The present study was undertaken to compare the efficacy and safety of dexmedetomidine and midazolam for sedation during regional anaesthesia.

**Materials and Methods:** This prospective comparative study was conducted in the Department of Anaesthesiology at Gouri Devi Institute of Medical Sciences and Hospital, Durgapur, West Bengal, from April 2025 to April 2026. A total of 124 adult patients (ASA physical status I–II) undergoing elective lower abdominal or lower limb surgeries under regional anaesthesia were equally allocated into two groups. Group D (n = 62) received intravenous dexmedetomidine (loading dose 1 µg/kg followed by infusion of 0.2–0.7 µg/kg/h), while Group M (n = 62) received intravenous midazolam (loading dose 0.05 mg/kg with supplemental doses as required). Sedation quality was assessed using the Ramsay Sedation Scale (RSS). Recovery time, hemodynamic parameters, patient satisfaction, and adverse events were also evaluated. Statistical analysis was performed using SPSS version 26.0, and a p-value <0.05 was considered statistically significant.

**Results:** Baseline demographic characteristics were comparable between the two groups. The mean RSS score was significantly higher in Group D than in Group M ( $3.8 \pm 0.5$  vs.  $3.3 \pm 0.4$ ,  $p < 0.001$ ), and adequate sedation (RSS 3–4) was achieved more frequently with dexmedetomidine (93.5% vs. 79.0%,  $p = 0.02$ ). Although the time to achieve target sedation was longer in Group D ( $8.7 \pm 2.3$  vs.  $6.8 \pm 1.9$  minutes,  $p < 0.001$ ), recovery time was significantly shorter ( $14.6 \pm 3.4$  vs.  $21.8 \pm 4.1$  minutes,  $p < 0.001$ ). Patient satisfaction scores were significantly higher with dexmedetomidine ( $8.9 \pm 0.8$  vs.  $7.4 \pm 1.2$ ,  $p < 0.001$ ). Intraoperative heart rate and mean arterial pressure were lower in the dexmedetomidine group while remaining clinically acceptable. Oxygen desaturation occurred only in the midazolam group (8.1% vs. 0%,  $p = 0.02$ ), whereas the incidences of bradycardia and hypotension were higher with dexmedetomidine but were not statistically significant.

**Conclusion:** Dexmedetomidine provided superior sedation quality, faster recovery, greater patient satisfaction, and better preservation of respiratory function with minimal respiratory compromise than midazolam during regional anaesthesia. Despite a slightly longer onset of sedation and a higher incidence of manageable bradycardia and hypotension, dexmedetomidine demonstrated an overall superior safety and efficacy profile and may be considered the preferred sedative adjunct for patients undergoing regional anaesthesia.

**Keywords:** Dexmedetomidine, Midazolam, Regional anaesthesia, Sedation, Ramsay Sedation Scale, Patient satisfaction, Hemodynamic stability, Recovery time.

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### Introduction

Regional anaesthesia (RA) is widely used for a variety of surgical procedures because it provides excellent intraoperative analgesia, reduces postoperative pain, minimizes airway manipulation, and facilitates early recovery compared to general anaesthesia.[1] Despite these advantages, many

patients experience anxiety, fear, and discomfort while remaining conscious during surgery. Therefore, the use of sedative agents during RA has become an important component of perioperative care to enhance patient comfort, improve cooperation, and optimize surgical conditions. [2]

An ideal sedative for use during regional anaesthesia should provide adequate anxiolysis and sedation while preserving spontaneous respiration and hemodynamic stability. It should also allow rapid recovery and easy communication with the patient when required.[3] Various sedative agents have been employed for this purpose; among them, midazolam and dexmedetomidine are commonly used because of their favorable sedative and anxiolytic properties.[4]

Midazolam is a short-acting benzodiazepine that produces sedation, anxiolysis, hypnosis, and anterograde amnesia through modulation of gamma-aminobutyric acid (GABA) receptors.[5] It has been widely accepted for procedural and intraoperative sedation because of its rapid onset and predictable clinical effects. However, its use may be associated with respiratory depression, prolonged recovery, oversedation, and postoperative cognitive impairment, particularly in elderly patients and when higher doses are administered.[6]

Dexmedetomidine is a highly selective  $\alpha_2$ -adrenergic receptor agonist that provides sedation, analgesia, and anxiolysis without causing significant respiratory depression.[7] Unlike conventional sedatives, dexmedetomidine induces a state of cooperative sedation in which patients remain calm, comfortable, and easily arousable. This characteristic makes it particularly suitable for patients undergoing surgery under regional anaesthesia.[8] In addition, dexmedetomidine possesses analgesic-sparing properties and has been shown to improve perioperative patient satisfaction and recovery profiles.[9] Several studies have compared dexmedetomidine and midazolam for sedation during regional anaesthesia and other procedural settings. Available evidence suggests that dexmedetomidine provides superior sedation quality, greater patient satisfaction, improved analgesia, and a lower incidence of respiratory complications compared with midazolam.[10] However, dexmedetomidine may be associated with bradycardia and hypotension owing to its sympatholytic effects, necessitating careful monitoring during administration.[7,11]

In view of the advantages and limitations of both agents, the present prospective comparative study was designed to evaluate dexmedetomidine and midazolam as sedative adjuncts during regional anaesthesia.

The primary objective was to compare the quality of sedation and recovery profile, while secondary objectives included assessment of hemodynamic stability, patient satisfaction, and adverse effects associated with each sedative regimen.

## Materials and Methods

This prospective comparative study was conducted in the Department of Anaesthesiology, Gouri Devi Institute of Medical Sciences and Hospital, Durgapur, West Bengal, over a period of one year from April 2025 to April 2026. Ethical approval was obtained from the Institutional Ethics Committee prior to commencement of the study, and written informed consent was obtained from all participants. A total of 124 adult patients scheduled to undergo elective lower abdominal or lower limb surgeries under regional anaesthesia were enrolled in the study. Patients aged between 18 and 65 years, belonging to the American Society of Anesthesiologists (ASA) physical status I or II, and willing to provide informed consent were included. Patients with known hypersensitivity to dexmedetomidine or midazolam, significant cardiovascular, hepatic, renal, respiratory, neurological, or psychiatric disorders, pregnant or lactating women, patients receiving chronic sedative therapy, and those with contraindications to regional anaesthesia were excluded from the study.

The enrolled patients were allocated into two groups of 62 patients each. Patients in Group D received dexmedetomidine as a loading dose of 1  $\mu\text{g/kg}$  administered intravenously over 10 minutes, followed by a maintenance infusion of 0.2–0.7  $\mu\text{g/kg/hour}$  titrated according to the desired level of sedation. Patients in Group M received midazolam at a loading dose of 0.05 mg/kg intravenously followed by supplemental doses of 0.01–0.02 mg/kg as required to maintain adequate sedation throughout the procedure.

All patients underwent a thorough pre-anaesthetic evaluation before surgery. In the operating room, standard monitoring including electrocardiography (ECG), non-invasive blood pressure (NIBP), pulse oximetry ( $\text{SpO}_2$ ), and heart rate monitoring was instituted. Regional anaesthesia was administered under strict aseptic precautions according to institutional protocols.

Following confirmation of an adequate sensory block level, the study drugs were administered. Sedation depth was assessed intraoperatively using the Ramsay Sedation Scale (RSS) [3], and a target sedation score of 3–4 was maintained. Adequate sedation was defined as a Ramsay Sedation Scale score of 3–4. Sedation scores were recorded at regular intervals during the procedure. Hemodynamic parameters including heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation were monitored and documented at baseline and at predetermined intervals throughout surgery.

The primary outcome measures included adequacy of sedation assessed using the Ramsay Sedation Scale and patient satisfaction scores. Secondary outcome measures included time taken to achieve target sedation, recovery time, hemodynamic stability, and the incidence of adverse events such as bradycardia, hypotension, oxygen desaturation, nausea, vomiting, and excessive sedation. Recovery time was defined as the interval between discontinuation of the sedative agent and attainment of a Ramsay Sedation Scale score of 2.

Patient satisfaction was assessed postoperatively using a 10-point Visual Analogue Scale (VAS), with higher scores indicating greater satisfaction. Bradycardia was defined as a heart rate below 50 beats per minute and was treated with intravenous atropine.

Hypotension was defined as a reduction in mean arterial pressure greater than 20% from baseline or a mean arterial pressure below 60 mmHg and was managed with intravenous fluids and vasopressor support when required. Oxygen desaturation was defined as SpO<sub>2</sub> below 94% and was managed with supplemental oxygen administration.

The collected data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 26.0. Continuous variables were expressed as mean  $\pm$  standard deviation, while categorical variables were presented as frequencies and percentages. Continuous variables between the two groups were compared using the unpaired Student's t-test,

whereas categorical variables were analyzed using the Chi-square test or Fisher's exact test as appropriate. A p-value of less than 0.05 was considered statistically significant.

## Results

A total of 124 patients undergoing elective lower abdominal or lower limb surgeries under regional anaesthesia were enrolled in the study and completed follow-up. Patients were equally distributed into two groups: Group D (Dexmedetomidine, n = 62) and Group M (Midazolam, n = 62). Table 1 shows the baseline demographic characteristics of the study participants.

Both groups were comparable with respect to baseline demographic and clinical characteristics. The majority of patients in both groups belonged to the 46–60 years age group (37.1% in Group D and 33.9% in Group M), followed by the 31–45 years age group (33.9% and 32.3%, respectively). Patients aged 18–30 years constituted 16.1% in Group D and 19.4% in Group M, while those older than 60 years accounted for 12.9% and 14.5%, respectively. Male participants were slightly more common than female participants in both groups (56.5% vs. 43.5% in Group D and 59.7% vs. 40.3% in Group M). There were no statistically significant differences between the two groups with respect to age distribution (p = 0.88) or gender distribution (p = 0.72), indicating that the groups were comparable at baseline.

**Table 1: Age Group and Gender Distribution**

| Variable    | Group D (n=62) | Group M (n=62) | p-value |
|-------------|----------------|----------------|---------|
| 18–30 years | 10 (16.1%)     | 12 (19.4%)     | 0.88    |
| 31–45 years | 21 (33.9%)     | 20 (32.3%)     |         |
| 46–60 years | 23 (37.1%)     | 21 (33.9%)     |         |
| >60 years   | 8 (12.9%)      | 9 (14.5%)      |         |
| Male        | 35 (56.5%)     | 37 (59.7%)     | 0.72    |
| Female      | 27 (43.5%)     | 25 (40.3%)     |         |

Table 2 compares the sedation quality and recovery characteristics between the dexmedetomidine and midazolam groups.

The mean Ramsay Sedation Scale (RSS) score was significantly higher in Group D than in Group M ( $3.8 \pm 0.5$  vs.  $3.3 \pm 0.4$ ,  $p < 0.001$ ). Adequate sedation (RSS score 3–4) was achieved in a significantly greater proportion of patients in Group D compared to Group M (93.5% vs. 79.0%,  $p = 0.02$ ). Although the time required to achieve the

target level of sedation was significantly longer in the dexmedetomidine group ( $8.7 \pm 2.3$  minutes) than in the midazolam group ( $6.8 \pm 1.9$  minutes,  $p < 0.001$ ), recovery time was significantly shorter with dexmedetomidine ( $14.6 \pm 3.4$  minutes vs.  $21.8 \pm 4.1$  minutes,  $p < 0.001$ ).

Furthermore, postoperative patient satisfaction, assessed using the Visual Analogue Scale (VAS), was significantly higher in Group D than in Group M ( $8.9 \pm 0.8$  vs.  $7.4 \pm 1.2$ ,  $p < 0.001$ ).

**Table 2: Sedation Quality and Recovery Characteristics**

| Parameter                      | Group D    | Group M    | p-value |
|--------------------------------|------------|------------|---------|
| Mean RSS Score                 | 3.8 ± 0.5  | 3.3 ± 0.4  | <0.001  |
| Adequate Sedation (RSS 3–4)    | 58 (93.5%) | 49 (79.0%) | 0.02    |
| Time to Achieve Sedation (min) | 8.7 ± 2.3  | 6.8 ± 1.9  | <0.001  |
| Recovery Time (min)            | 14.6 ± 3.4 | 21.8 ± 4.1 | <0.001  |
| Satisfaction Score (VAS)       | 8.9 ± 0.8  | 7.4 ± 1.2  | <0.001  |

The intraoperative hemodynamic parameters of patients in the dexmedetomidine and midazolam groups are presented in Table 3. The mean intraoperative heart rate was significantly lower in the dexmedetomidine group compared with the midazolam group ( $71.8 \pm 6.4$  bpm vs.  $77.6 \pm 6.8$  bpm,  $p < 0.001$ ). Similarly, the mean arterial pressure (MAP) during surgery was significantly

lower in Group D than in Group M ( $87.4 \pm 5.9$  mmHg vs.  $91.2 \pm 6.1$  mmHg,  $p = 0.001$ ). Despite these differences, the proportion of patients who maintained stable hemodynamics throughout the procedure was comparable between the two groups, with 88.7% in Group D and 80.6% in Group M ( $p = 0.21$ ). The difference was not statistically significant.

**Table 3: Hemodynamic Stability**

| Parameter                      | Group D    | Group M    | p-value |
|--------------------------------|------------|------------|---------|
| Mean HR during surgery (bpm)   | 71.8 ± 6.4 | 77.6 ± 6.8 | <0.001  |
| Mean MAP during surgery (mmHg) | 87.4 ± 5.9 | 91.2 ± 6.1 | 0.001   |
| Stable Hemodynamics            | 55 (88.7%) | 50 (80.6%) | 0.21    |

Table 4 compares the incidence of adverse events between the two study groups. Bradycardia was observed more frequently in the dexmedetomidine group than in the midazolam group (11.3% vs. 3.2%); however, the difference was not statistically significant ( $p = 0.08$ ). Similarly, hypotension occurred in 8.1% of patients in Group D and 4.8% in Group M, with no significant difference between

the groups ( $p = 0.46$ ). In contrast, oxygen desaturation was observed only in the midazolam group (8.1%) and was absent in the dexmedetomidine group, representing a statistically significant difference ( $p = 0.02$ ). The incidence of nausea and vomiting was low in both groups (3.2% in Group D vs. 6.5% in Group M) and did not differ significantly ( $p = 0.40$ ).

**Table 4: Adverse Events**

| Adverse Event       | Group D (n=62) | Group M (n=62) | p-value |
|---------------------|----------------|----------------|---------|
| Bradycardia         | 7 (11.3%)      | 2 (3.2%)       | 0.08    |
| Hypotension         | 5 (8.1%)       | 3 (4.8%)       | 0.46    |
| Oxygen Desaturation | 0 (0%)         | 5 (8.1%)       | 0.02    |
| Nausea/Vomiting     | 2 (3.2%)       | 4 (6.5%)       | 0.40    |

Table 5 compares the overall outcome assessment between the dexmedetomidine and midazolam groups. An excellent outcome was observed in a significantly higher proportion of patients in Group D than in Group M (64.5% vs. 38.7%). Conversely, a good outcome was more frequently reported in the midazolam group (43.5%) than in the

dexmedetomidine group (29.0%). Fair outcomes were recorded in 6.5% of patients receiving dexmedetomidine and 17.8% of those receiving midazolam, while no patient in either group had a poor outcome. The overall distribution of outcome categories differed significantly between the two groups (Chi-square = 8.92,  $p = 0.012$ ).

**Table 5: Overall Outcome Assessment**

| Outcome   | Group D (n=62) | Group M (n=62) | Chi-square | p-value |
|-----------|----------------|----------------|------------|---------|
| Excellent | 40 (64.5%)     | 24 (38.7%)     | 8.92       | 0.012   |
| Good      | 18 (29.0%)     | 27 (43.5%)     |            |         |
| Fair      | 4 (6.5%)       | 11 (17.8%)     |            |         |
| Poor      | 0              | 0              |            |         |

## Discussion

The present prospective comparative study evaluated the efficacy and safety of dexmedetomidine and midazolam for sedation during regional anaesthesia in patients undergoing elective lower abdominal and lower limb surgeries.

The findings demonstrated that dexmedetomidine provided superior sedation quality, faster recovery, greater patient satisfaction, and fewer respiratory adverse events than midazolam. Although dexmedetomidine was associated with a slightly longer onset of sedation and a higher incidence of

bradycardia and hypotension, these adverse events were mild and manageable without affecting the overall clinical outcome. The baseline demographic characteristics of both groups were comparable with respect to age and gender distribution, indicating that the study groups were well matched before intervention. This minimizes the influence of confounding variables on the observed outcomes and strengthens the validity of the comparison. Similar baseline comparability has been reported by Chinnappa et al.[4] and Korkmaz et al., who observed no significant demographic differences between patients receiving dexmedetomidine and midazolam during regional anaesthesia.[12] One of the major findings of the present study was the significantly better sedation quality achieved with dexmedetomidine. Patients receiving dexmedetomidine attained higher Ramsay Sedation Scale scores, and a significantly greater proportion achieved the desired level of sedation than those receiving midazolam. These findings are consistent with the pharmacological properties of dexmedetomidine, which produces cooperative sedation while preserving spontaneous respiration and allowing patients to remain easily arousable.[7] Hall et al.[8] also demonstrated that dexmedetomidine provides effective sedation with minimal respiratory depression and excellent patient cooperation. Similarly, Korkmaz et al.[12] reported superior sedation quality and improved patient comfort with dexmedetomidine during regional anaesthesia. A systematic review by Barends et al.[13] further confirmed that dexmedetomidine provides more effective procedural sedation with greater patient and operator satisfaction than midazolam across different clinical settings.

Although patients in the dexmedetomidine group required a slightly longer time to achieve the target level of sedation, recovery following discontinuation of sedation was significantly faster than in the midazolam group. Early recovery facilitates postoperative neurological assessment, earlier mobilization, and improved operating room efficiency. Similar observations were reported by Korkmaz et al., who found that dexmedetomidine was associated with a favourable recovery profile despite its relatively slower onset of action.[12] Barends et al.[13] also concluded that dexmedetomidine offers improved recovery characteristics compared with midazolam while maintaining effective sedation.

Patient satisfaction was significantly higher among patients receiving dexmedetomidine in the present study. This may be attributed to better anxiolysis, stable intraoperative sedation, improved comfort, and rapid postoperative recovery. Harsoor and Rani highlighted that dexmedetomidine improves the overall perioperative experience because of its

sedative, anxiolytic, and analgesic-sparing effects.[9] Similar findings were reported in the systematic review by Barends et al., which demonstrated significantly higher patient and clinician satisfaction with dexmedetomidine than with midazolam during procedural sedation.[13]

The present study demonstrated significantly lower intraoperative heart rate and mean arterial pressure in patients receiving dexmedetomidine. These findings are expected because dexmedetomidine decreases sympathetic outflow through stimulation of central  $\alpha_2$ -adrenergic receptors. Ebert et al.[14] demonstrated dose-dependent reductions in heart rate and blood pressure with increasing plasma concentrations of dexmedetomidine while maintaining adequate sedation. Belleville et al.[15] also reported predictable reductions in cardiovascular parameters with minimal respiratory depression following dexmedetomidine administration. These observations support the hemodynamic findings of the present study, where despite lower heart rate and mean arterial pressure, most patients maintained stable intraoperative hemodynamics without major clinical consequences.

Regarding adverse events, bradycardia and hypotension occurred more frequently in the dexmedetomidine group, although these differences were not statistically significant. Conversely, oxygen desaturation occurred only in the midazolam group and represented the only statistically significant adverse event observed between the two groups. Candiotti et al.[16] demonstrated that dexmedetomidine provides effective monitored anaesthesia care with a favourable safety profile and minimal respiratory compromise compared with conventional sedative regimens. Similarly, Frolich et al.[17] reported that dexmedetomidine maintains better respiratory stability despite producing predictable reductions in heart rate and blood pressure. These findings are consistent with the present study, in which respiratory complications were observed only among patients receiving midazolam.

The overall outcome assessment significantly favoured dexmedetomidine, with a greater proportion of patients achieving excellent outcomes than those receiving midazolam. These findings probably reflect the combined advantages of better sedation quality, earlier recovery, greater patient satisfaction, and fewer respiratory complications. Joshi et al.[18] similarly demonstrated that dexmedetomidine produced superior overall procedural conditions and higher patient satisfaction compared with midazolam during monitored anaesthesia care. Weerink et al.[19] explained that the favourable pharmacokinetic and pharmacodynamic profile of dexmedetomidine contributes to reliable sedation and predictable

recovery across various clinical settings. Likewise, Sethi et al.[20] reported that dexmedetomidine offered better procedural sedation with fewer respiratory complications than midazolam, supporting the findings of the present study.

The present study has certain limitations. It was conducted at a single tertiary care centre with a relatively small sample size, which may limit the generalizability of the findings. Furthermore, only ASA physical status I and II patients undergoing elective lower abdominal and lower limb surgeries were included. Long-term postoperative recovery, cognitive outcomes, and cost-effectiveness were not evaluated. Future multicentre randomized controlled trials involving larger and more diverse patient populations are required to further validate these findings.

Overall, the findings of the present study suggest that dexmedetomidine is a safe and effective sedative for patients undergoing regional anaesthesia. Compared with midazolam, it provides superior sedation quality, faster recovery, greater patient satisfaction, and better preservation of respiratory function while maintaining acceptable hemodynamic stability under appropriate monitoring.

### Conclusion:

Dexmedetomidine proved to be a safe and effective sedative agent for patients undergoing surgery under regional anaesthesia. Compared with midazolam, it provided significantly better sedation quality, higher patient satisfaction, and faster postoperative recovery while preserving respiratory function and reducing the incidence of oxygen desaturation.

Although dexmedetomidine was associated with a slightly longer time to achieve the target level of sedation and a higher frequency of bradycardia and hypotension, these adverse events were mild, predictable, and readily managed with appropriate intraoperative monitoring. Overall, dexmedetomidine demonstrated superior clinical performance and may be considered a preferable sedative adjunct to midazolam for regional anaesthesia, particularly in patients in whom respiratory safety and rapid recovery are important. Larger multicentre randomized controlled trials are warranted to further validate these findings and establish standardized sedation protocols for routine clinical practice.

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