

Preoperative Use of Midazolam vs Dexmedetomidine for Anxiolysis in Day-Care Surgery

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Abstract

Surgical procedures trigger significant fear and anxiety that can adversely affect physiological responses and recovery outcomes. This prospective, randomized, double-blinded clinical trial compared the anxiolytic efficacy and safety of intravenous midazolam and dexmedetomidine in 60 patients undergoing day-care surgery. Primary outcomes included anxiety scores measured by STAI and sedation assessed by the OAA/S scale at multiple perioperative time points. Secondary outcomes assessed in the study included detailed evaluation of hemodynamic parameters, such as heart rate, systolic, and diastolic blood pressure, mean arterial pressure, and overall cardiovascular stability, along with the incidence and nature of drug-related side effects. Both dexmedetomidine and midazolam were found to be effective in achieving adequate anxiolysis and improving patient comfort during the procedure. However, notable differences were observed in their safety profiles. Dexmedetomidine was more frequently associated with hemodynamic alterations, particularly episodes of bradycardia and hypotension, likely attributable to its central sympatholytic action. In contrast, patients receiving midazolam demonstrated a comparatively stable cardiovascular profile but experienced a higher incidence of adverse effects, such as nausea and vomiting. These findings indicate that while both agents are clinically effective for anxiety reduction, the selection of an appropriate sedative should be individualized, taking into consideration the patient's baseline cardiovascular status, susceptibility to adverse effects, procedural requirements, and overall risk profile to optimize safety and therapeutic outcomes.

Keywords: Anxiety, anxiolysis, day-care surgery, dexmedetomidine, midazolam, sedation

INTRODUCTION

Surgical procedures are among the most intense and challenging events a person can experience. The fear and anxiety that often accompany them can trigger significant stress in the body, leading to stimulated neuroendocrine responses [1]. This surge in stress hormones not only affects overall body functions but may also influence recovery outcomes and, in severe cases, impact the chances of survival.

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Recent evidence suggests that between 50% and 75% of pediatric patients undergoing surgery exhibit significantly greater preoperative anxiety than adults. This heightened anxiety in children may be attributed to developmental factors, reduced understanding of the surgical process, all of which can adversely affect perioperative outcomes and thus delaying their postoperative recovery [2, 3]. The physiological effects of anxiety before surgery include increased neuroendocrine stress responses, which can raise heart rate, blood pressure, and inflammatory markers, potentially complicating anesthesia and recovery. Furthermore, patients with intense preoperative anxiety may require larger doses of anesthetics and analgesics and often experience longer recovery times [4].

In day-care surgery, where the goal is rapid patient turnover and quick recovery, managing preoperative anxiety effectively is crucial. Anxiety can delay times and prolong discharge times, and increase postoperative complications, such as agitation and pain [5].

Pharmacological premedication using anxiolytic drugs is a common approach to alleviate this stress. Midazolam, a benzodiazepine, has traditionally been used due to its rapid onset and effective sedation. It helps patients feel calmer and more comfortable before surgery.

However, midazolam may cause side effects like residual sedation, respiratory depression, and paradoxical reactions, which limit its use in some cases [6].

Dexmedetomidine, an alpha-2 adrenergic agonist, has gained attention as an alternative premedication. It provides sedation without significant respiratory depression and also has analgesic and anxiolytic properties. Studies indicate that dexmedetomidine may lead to more stable hemodynamics, reduced postoperative agitation, and better overall patient cooperation during surgical procedures [7].

Comparative clinical trials and meta-analyses reveal that dexmedetomidine often outperforms midazolam in controlling preoperative anxiety, particularly in pediatric patients undergoing day-care surgery. While both drugs reduce anxiety effectively, dexmedetomidine may reduce emergence delirium and facilitate smoother recoveries [8].

Despite these advantages, dexmedetomidine can cause bradycardia and hypotension, so its administration requires careful monitoring. Studies also suggest that the choice between midazolam and dexmedetomidine depends on patient-specific factors, surgery type, and anesthesia plans [9].

With increasing day-care surgical procedures worldwide, optimizing anxiolytic strategies holds significant value for improving patient comfort and surgical outcomes. Therefore, ongoing research comparing midazolam and dexmedetomidine remains essential to guide clinicians towards the safest and most effective preoperative care [10].

METHODOLOGY

Study Design and Population

A prospective, randomized, double-blinded trial was approved by the institutional review board. Markandeshwar Institute of Medical Sciences and Research (MMIMSR). Sixty patients aged 18–65 years, ASA I-II, scheduled for elective day-care surgical procedures were included. Exclusion criteria encompassed allergies to study drugs, psychiatric or systemic illnesses, and recent CNS depressant use [11].

Randomization and Interventions

Patients were randomly assigned into two groups of 30 each, receiving either intravenous midazolam (loading dose 0.08 mg/kg over 10 min, maintenance 0.05 mg/kg/hr) or dexmedetomidine (loading dose 1 µg/kg over 10 min, maintenance 0.5 µg/kg/hr). Identical volumes were prepared by an independent pharmacist. Blinding was maintained for patients, clinicians, and assessors [12].

Outcome Measures

Anxiety was measured using the State-Trait Anxiety Inventory (STAI) at baseline, 30 min after start, end of operation, 30 min post-op, and one-week post-op. Sedation was monitored intraoperatively using the Observers Assessment of Alertness Scale every 5 minutes.

Hemodynamic variables (HR, MAP), respiratory rate, oxygen saturation, and adverse events (e.g., bradycardia, hypotension, nausea) were continuously monitored and managed per standard protocols.

STATISTICAL ANALYSIS

Data were analyzed using appropriate statistical software. Normality of continuous variables was tested using the Shapiro–Wilk test. Parametric data were compared with independent t-tests, while non-parametric data utilized Mann-Whitney U or Wilcoxon signed-rank tests as appropriate. Categorical variables were analyzed using chi-square or Fisher’s exact tests. A p-value less than 0.05 was considered statistically significant.

DATA COLLECTION

Eighty ASA I-II patients scheduled for elective extremity surgery under regional anesthesia were randomly assigned to two groups of 40 each to receive either intravenous dexmedetomidine or midazolam. Baseline demographic and clinical variables, such as age, weight, height, gender, and duration of surgery were recorded.

The State-Trait Anxiety Inventory (STAI-1) was used to assess anxiety levels at baseline, 30 minutes after the start of the operation, at the end of surgery, 30 minutes postoperatively, and on the seventh postoperative day. Sedation was monitored intraoperatively every 5 minutes using the Observers Assessment of Alertness Scale (OAAS).

Hemodynamic parameters including heart rate, mean arterial pressure, oxygen saturation, and potential side effects, such as hypotension, bradycardia, nausea, vomiting, and headache were continuously recorded during the perioperative and postoperative periods.

Both drug infusions were titrated to maintain a target sedation level corresponding to an OAAS score of approximately 4. Vital signs and adverse events were managed per standard protocols.

RESULTS

Study Population and Baseline Characteristics

All enrolled participants completed the study protocol, and there were no withdrawals or protocol deviations. The baseline characteristics of both groups were comparable, supporting successful randomization. The mean age of patients in the dexmedetomidine group was 40.1 ± 12.6 years, while in the midazolam group it was 39.8 ± 11.4 years. The gender distribution was balanced with 18 males and 22 females in Group D and 20 males and 20 females in Group M. Other demographic features, including mean weight, height, and duration of surgery, showed no statistically significant differences between groups, as summarized (Table 1).

Table 1. Baseline characteristics of Dexmedetomidine and Midazolam groups.

Variable	Dexmedetomidine (D)	Midazolam (M)
Age (years)	40.1 ± 12.6	39.8 ± 11.4
Weight (kg)	75.3 ± 14.1	79.1 ± 13.2
Height (cm)	168.4 ± 9.8	170.1 ± 10.5
Gender (M/F)	18 / 22	20 / 20
Surgery Duration (min)	74.0 ± 17.0	83.0 ± 23.0

Sedation Scores (OAAS)

Figure 1 provides a detailed representation of the OAAS scores, highlighting the differences in recovery levels among the study groups. Sedation levels, as measured by the Observers Assessment of Alertness Scale (OAAS), were recorded at 15, 30, 45, 60, and 90 minutes post-administration of study drugs. Both groups showed a similar trend of light to moderate sedation during the intraoperative period, with no significant difference in OAAS scores at all measured time points. All patients in both groups reached adequate sedation by the start of surgery and remained stable throughout the procedure.

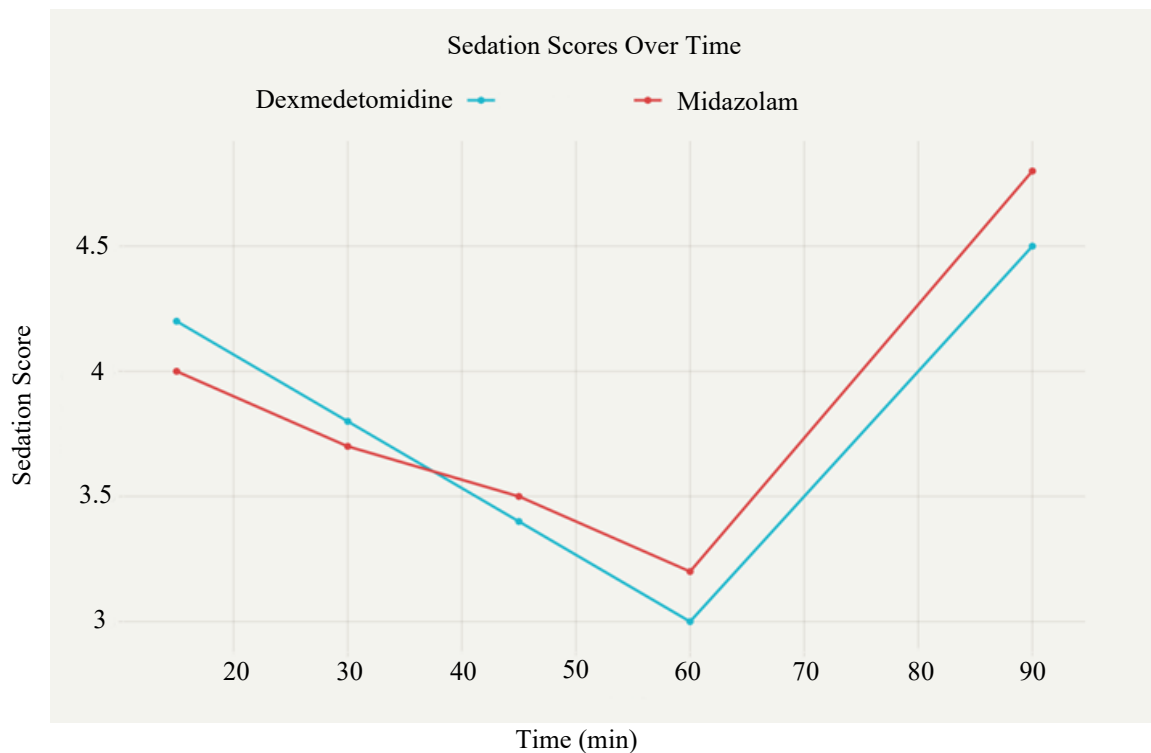


Figure 1. Sedation scores over time.

Anxiety Scores (STAI)

Assessment of preoperative and postoperative anxiety was performed using the State-Trait Anxiety Inventory (STAI). Anxiety scores declined progressively after premedication and remained consistently lower in both groups during and after surgery. The changes were similar between groups at all time points, indicating that both drugs were effective in reducing perioperative anxiety. The time-related anxiety score data is summarized (Table 2).

Table 2. Mean anxiety scores at various time points in dexmedetomidine and midazolam groups.

Timepoint	Dexmedetomidine	Midazolam
Baseline	45	44
30 min after start	42	41
End of Operation	40	39
30 min Post-op	39	38
7 Days Post-op	38	36

Midazolam Groups

The comparison of hemodynamic parameters showed stable heart rate and mean arterial pressure across both groups. At baseline, both groups had closely matched heart rates and MAP values. During surgery, the dexmedetomidine group demonstrated a slightly lower heart rate (70 vs. 74) and MAP (85 vs. 87) compared to the midazolam group. These small differences reflect dexmedetomidine's known effect of mild bradycardia and reduced sympathetic tone.

No clinically significant hypotension or tachycardia was observed in either group, or values remained within safe ranges throughout the perioperative period. Overall, both drugs provided reliable hemodynamic control, but dexmedetomidine was associated with more pronounced, yet well-tolerated, decreases in heart rate and blood pressure. This supports its utility when intraoperative cardiovascular stability is a priority for short procedures (Figure 2).

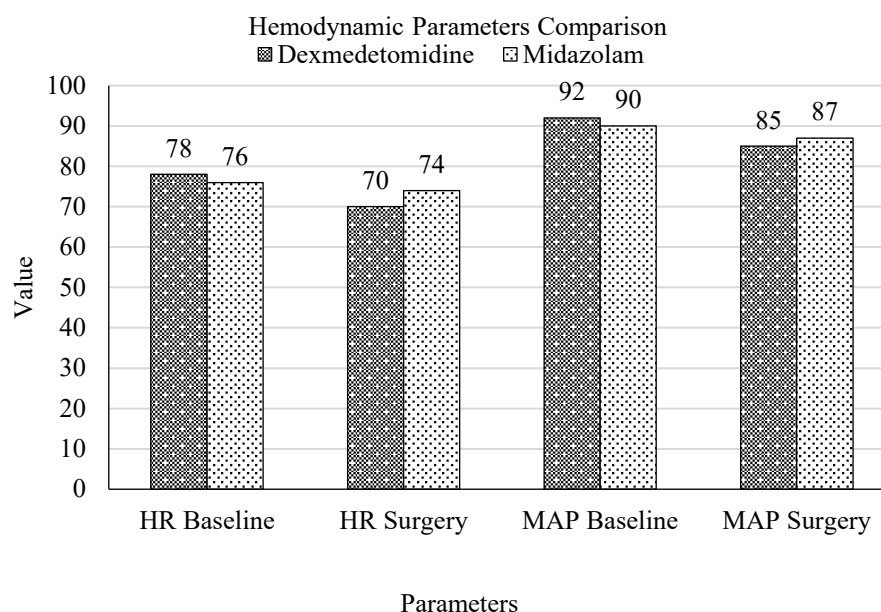


Figure 2. Hemodynamic parameters comparison.

Adverse Events

All patients were carefully monitored for adverse events. While most tolerated the study medications without major complications, the dexmedetomidine group showed a greater incidence of bradycardia ($n = 10$, 25%) and hypotension ($n = 4$, 10%), compared to the midazolam group (1 patient each, 2.5%). Conversely, the midazolam group had more reports of nausea ($n = 4$, 10%) and vomiting ($n = 1$, 2.5%), while these were rare or absent with dexmedetomidine. These events were transient and managed with standard supportive therapies, and no patient required withdrawal from the study due to adverse effects. See Table 3 for details.

Table 3. Comparison of side effects between dexmedetomidine and midazolam groups.

Side effect	Dexmedetomidine	Midazolam
Hypotension	4	1
Bradycardia	10	1
Nausea	1	4
Vomiting	0	1
Headache	2	0

DISCUSSION

This study confirms both midazolam and dexmedetomidine effectively reduce preoperative anxiety in day-care surgery patients. Dexmedetomidine showed more favorable sedation profiles but with increased bradycardia and hypotension cases, necessitating vigilant monitoring. Midazolam was associated with higher nausea and vomiting incidence [13–15].

Sedation levels and anxiety scores declined progressively in both groups, reflecting effective anxiolysis and recovery facilitation. Dexmedetomidine's unique action on alpha-2 receptors may offer advantages for maintaining hemodynamic stability and reducing emergence delirium, corroborating findings from meta-analyses [16].

Choice of agent should consider patient health status, surgical procedure, and risk tolerance. Further studies with larger samples could refine dosing strategies and safety protocols for broader populations [17].

CONCLUSION

Both midazolam and dexmedetomidine are viable options for preoperative anxiolysis in day-care surgery. Dexmedetomidine provides effective sedation with cardiovascular considerations, while midazolam remains a trusted, widely used anxiolytic with known side effects. Personalized use guided by clinical context optimizes patient comfort and outcomes.

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