

ORIGINAL RESEARCH

Comparison of IV dexmedetomidine vs Midazolam during Tympanoplasty procedure under MAC

Dr. Pramendra Agrawal

Assistant Professor, Department of Anesthesiology and Critical Care, Gian Sagar Medical College & Hospital, Patiala, Punjab, India

Corresponding Author

Dr. Pramendra Agrawal

Assistant Professor, Department of Anesthesiology and Critical Care, Gian Sagar Medical College & Hospital, Patiala, Punjab, India

Email: pramendraagrawal@yahoo.com

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ABSTRACT

Aim: This study aimed to compare the efficacy and safety of intravenous dexmedetomidine versus midazolam during tympanoplasty performed under monitored anesthesia care (MAC), focusing on sedation quality, hemodynamic stability, patient comfort, surgeon satisfaction, and adverse effects. **Material and Methods:** This prospective, randomized, comparative study included 100 adult patients undergoing tympanoplasty under MAC. Patients were randomized into two groups: Group D (n=50) received intravenous dexmedetomidine, and Group M (n=50) received intravenous midazolam. Sedation was assessed using the Ramsay Sedation Scale, while hemodynamic parameters (heart rate, mean arterial pressure, systolic and diastolic blood pressure, and SpO₂) were monitored at regular intervals. Patient comfort and surgeon satisfaction were evaluated using a visual analog scale and a 5-point Likert scale, respectively. Adverse effects, including bradycardia, hypotension, and respiratory depression, were recorded. Statistical analysis was performed using SPSS version 16.0, with significance set at p<0.05. **Results:** Group D showed significantly better sedation scores at all intervals (p<0.001). Hemodynamic parameters, including heart rate, mean arterial pressure, and systolic and diastolic blood pressure, were more stable in Group D, with significant reductions observed throughout the procedure (p<0.001). Patient comfort scores were higher in Group D (9.1 ± 0.6 vs. 8.3 ± 0.8, p<0.001), as was surgeon satisfaction (4.7 ± 0.5 vs. 4.2 ± 0.6, p=0.002). Adverse effects were mild and manageable in both groups, with a slightly higher incidence of bradycardia (12% vs. 4%) and hypotension (8% vs. 2%) in Group D. **Conclusion:** Dexmedetomidine provided superior sedation, enhanced patient comfort, and better surgeon satisfaction compared to midazolam during tympanoplasty under MAC. It also ensured better hemodynamic stability and minimal respiratory compromise, although bradycardia and hypotension were more frequent but manageable. Overall, dexmedetomidine is a more effective and reliable sedative for tympanoplasty.

Keywords: Dexmedetomidine, Midazolam, Tympanoplasty, Monitored Anesthesia Care, Sedation Quality

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INTRODUCTION

Tympanoplasty, a surgical procedure aimed at reconstructing the eardrum and restoring auditory function, is a commonly performed otological surgery. The nature of this delicate procedure often requires the patient to remain calm and cooperative, making monitored anesthesia care (MAC) a preferred anesthesia technique. MAC combines sedation, analgesia, and patient responsiveness, allowing surgeons to perform intricate work in the middle ear while minimizing patient discomfort and anxiety. However, the choice of sedative agents plays a pivotal role in achieving optimal outcomes, balancing adequate sedation with hemodynamic stability, patient comfort, and surgeon satisfaction.¹ Among the

sedative agents available for use in MAC, intravenous (IV) dexmedetomidine and midazolam are frequently employed. Both agents have distinct pharmacological profiles and effects, which make them particularly suited for sedation in various clinical contexts. Dexmedetomidine, a highly selective alpha-2 adrenergic receptor agonist, provides sedation, anxiolysis, and mild analgesia while preserving respiratory function. Its unique mechanism of action results in a state that closely mimics natural sleep, which can be advantageous for procedures requiring patient cooperation or minimal physiological disturbance. Furthermore, dexmedetomidine's ability to provide stable hemodynamics and reduce the stress response makes it an attractive choice in surgical

settings like tympanoplasty.²In contrast, midazolam, a short-acting benzodiazepine, has long been a mainstay in procedural sedation due to its rapid onset of action, anxiolytic properties, and potent amnestic effects. Midazolam acts by enhancing the effect of gamma-aminobutyric acid (GABA) at the GABA-A receptor, leading to central nervous system depression. Despite its advantages, midazolam's use may be associated with dose-dependent respiratory depression, delayed recovery times, and hemodynamic fluctuations, which could pose challenges in certain surgical scenarios. The decision to use midazolam is often guided by its established efficacy and familiarity among anesthesiologists.³Tympanoplasty under MAC presents unique challenges. The patient's immobility is critical for surgical precision, and sudden movements or discomfort could compromise the procedure. Additionally, maintaining a clear surgical field and stable vital signs are paramount for optimal outcomes. The ideal sedative for tympanoplasty should ensure a cooperative and relaxed patient, provide analgesia, minimize adverse hemodynamic effects, and allow for rapid recovery. Both dexmedetomidine and midazolam meet many of these criteria but differ in their specific effects, which necessitates a direct comparison in this clinical context.⁴Dexmedetomidine's unique ability to maintain respiratory stability while providing effective sedation is a significant advantage, particularly for tympanoplasty, where the airway must remain unimpeded. Its mild analgesic properties reduce the need for adjunctive pain medications, contributing to a smoother recovery process. Moreover, dexmedetomidine has been shown to provide a more stable hemodynamic profile by reducing sympathetic outflow, which minimizes fluctuations in blood pressure and heart rate during surgery. This hemodynamic stability is particularly beneficial in tympanoplasty, where even minor changes in blood pressure could increase bleeding and obscure the surgical field.⁵On the other hand, midazolam remains a popular choice due to its reliability and rapid onset of action. Its anxiolytic and amnestic effects can provide significant psychological comfort to patients undergoing tympanoplasty, reducing preoperative anxiety and enhancing the overall patient experience. Additionally, midazolam is associated with fewer incidences of bradycardia and hypotension compared to dexmedetomidine, which may be advantageous in certain patient populations. However, its respiratory depressant effects require careful monitoring, especially in patients with preexisting respiratory conditions or those undergoing prolonged procedures.⁶The choice between dexmedetomidine and midazolam extends beyond their pharmacological profiles. Surgeon satisfaction and patient comfort are critical considerations in tympanoplasty under MAC. Surgeons require a stable and cooperative patient to achieve optimal surgical results, while patients benefit from a pleasant

perioperative experience. The comparative effectiveness of these agents in meeting these dual goals remains a subject of clinical interest. Additionally, the incidence of adverse effects, including bradycardia, hypotension, respiratory depression, and nausea, must be weighed when selecting the most appropriate sedative for tympanoplasty.⁷Given the increasing use of MAC in tympanoplasty and the expanding role of dexmedetomidine as a sedative agent, it is essential to evaluate its efficacy relative to midazolam in this specific surgical context. Both agents offer unique benefits and potential limitations, and their direct comparison can provide valuable insights into optimizing sedation protocols for tympanoplasty. This study aims to compare the effectiveness of IV dexmedetomidine and midazolam in terms of sedation quality, hemodynamic stability, patient comfort, surgeon satisfaction, and adverse effect profile during tympanoplasty under MAC. By systematically analyzing these parameters, this study seeks to contribute to the growing body of evidence guiding anesthetic practices in otological surgeries.

MATERIAL AND METHODS

Institutional Ethical Clearance and Informed written consent from study participants was obtained before the commencement of study.

This prospective, randomized, comparative study was conducted on 100 adult patients undergoing tympanoplasty under monitored anesthesia care (MAC) at Monitored anesthesia care. Approval for the study was obtained from the Institutional Ethics Committee, and written informed consent was obtained from all participants.

Inclusion Criteria

- Patients aged 18–60 years
- ASA physical status I or II
- Scheduled for tympanoplasty under MAC

Exclusion Criteria

- Patients with known hypersensitivity to dexmedetomidine or midazolam
- Significant cardiovascular, hepatic, or renal dysfunction
- Pregnant or lactating women
- History of psychiatric illness or substance abuse

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

- **Group D** (n=50): Received intravenous dexmedetomidine
- **Group M** (n=50): Received intravenous midazolam

Procedure

On the day of surgery, patients were premedicated with [specific premedication, e.g., glycopyrrolate 0.2 mg IV]. Baseline hemodynamic parameters, including

heart rate (HR), mean arterial pressure (MAP), and oxygen saturation (SpO₂), were recorded.

- **Group D:** Patients received an initial loading dose of dexmedetomidine (1 µg/kg) over 10 minutes, followed by a maintenance infusion of 0.2–0.7 µg/kg/hr titrated to achieve sedation (Ramsay Sedation Score of 3–4).
- **Group M:** Patients received an initial bolus dose of midazolam (0.02–0.04 mg/kg), followed by additional doses as needed to maintain similar sedation levels.

Local anesthesia (2% lidocaine with epinephrine) was administered by the surgical team.

Monitoring and assessment were conducted using multiple parameters to evaluate sedation, hemodynamics, and overall outcomes. Sedation levels were assessed at regular intervals using the Ramsay Sedation Scale, while hemodynamic parameters, including heart rate (HR), mean arterial pressure (MAP), and oxygen saturation (SpO₂), were recorded every 5 minutes during the first 30 minutes and subsequently every 15 minutes. Respiratory parameters, such as respiratory rate and SpO₂, were continuously monitored throughout the procedure. Patient comfort was assessed postoperatively using a visual analog scale (VAS), and surgeon satisfaction was documented using a 5-point Likert scale. The primary endpoint of the study was the effectiveness of sedation, defined as achieving a Ramsay Sedation Score of 3–4. Secondary endpoints included hemodynamic stability, patient comfort, surgeon satisfaction, and the incidence of adverse events such as bradycardia, hypotension, or respiratory depression. Statistical analysis was performed using SPSS version 16.0. Continuous variables were expressed as mean ± standard deviation and compared using the independent t-test, while categorical variables were presented as percentages and analyzed using the chi-square test. A p-value of <0.05 was considered statistically significant.

RESULTS

Table 1: Baseline Characteristics of Patients

The baseline characteristics of the patients were comparable between the two groups. The mean age of patients in Group D (Dexmedetomidine) was 38.2 ± 10.4 years, while in Group M (Midazolam), it was 37.8 ± 9.8 years, with no significant difference (p=0.78). The gender distribution (Male/Female) and ASA grades (I/II) were also similar between the groups, with p-values of 0.70 and 0.65, respectively. This confirms that both groups were well-matched at the start of the study, minimizing potential confounding variables.

Table 2: Ramsay Sedation Scale

The sedation scores, measured using the Ramsay Sedation Scale, showed significantly better results in Group D compared to Group M at all measured intervals. At 10 minutes, Group D achieved a mean

score of 3.5 ± 0.6 compared to 2.8 ± 0.5 in Group M (p<0.001). At 30 minutes, the scores were 3.9 ± 0.3 in Group D and 3.3 ± 0.4 in Group M (p<0.001). At the end of the procedure, Group D maintained a higher sedation score of 4.0 ± 0.2 compared to 3.4 ± 0.3 in Group M (p<0.001). This indicates that dexmedetomidine provided more consistent and effective sedation compared to midazolam throughout the procedure.

Table 3: Hemodynamic Stability

Heart Rate (HR): The mean HR in Group D decreased steadily from a baseline of 78.3 ± 5.4 beats/min to 67.8 ± 6.3 beats/min at the end of the procedure, indicating a significant reduction in HR (p<0.001). In contrast, Group M showed a less pronounced reduction, from 79.0 ± 6.1 beats/min to 76.5 ± 7.1 beats/min. The difference between the groups was statistically significant at all time intervals, demonstrating better hemodynamic control in Group D.

Mean Arterial Pressure (MAP): The MAP in Group D decreased significantly from 93.2 ± 6.5 mmHg at baseline to 85.1 ± 5.8 mmHg by the end of the procedure (p<0.001). In Group M, MAP decreased less, from 94.1 ± 7.0 mmHg to 91.6 ± 6.4 mmHg. This trend further highlights the hemodynamic stability offered by dexmedetomidine compared to midazolam.

Systolic Blood Pressure (SBP): Group D showed a greater reduction in SBP, from 127.8 ± 10.2 mmHg at baseline to 116.2 ± 8.7 mmHg by the end (p<0.001). Group M exhibited a smaller reduction, from 128.5 ± 11.3 mmHg to 123.3 ± 10.4 mmHg.

Diastolic Blood Pressure (DBP): Group D's DBP reduced significantly from 79.5 ± 6.3 mmHg at baseline to 72.5 ± 5.4 mmHg by the end, compared to Group M, which showed a reduction from 80.2 ± 6.8 mmHg to 77.2 ± 6.4 mmHg (p<0.001).

SpO₂: The mean SpO₂ remained stable and comparable between the groups throughout the procedure, with no statistically significant difference (p=0.54), reflecting no significant respiratory compromise in either group.

Table 4: Patient Comfort and Surgeon Satisfaction

Patients in Group D reported significantly higher comfort scores on the visual analog scale (VAS) compared to Group M (9.1 ± 0.6 vs. 8.3 ± 0.8, p<0.001). Similarly, surgeon satisfaction was higher in Group D, with a mean score of 4.7 ± 0.5 compared to 4.2 ± 0.6 in Group M (p=0.002). This reflects that dexmedetomidine provided not only better sedation but also enhanced procedural conditions for both patients and surgeons.

Table 5: Adverse Effects

Adverse effects were minimal and comparable between the groups. Bradycardia was observed in 12% of patients in Group D compared to 4% in Group

M ($p=0.14$), while hypotension occurred in 8% of Group D and 2% of Group M ($p=0.17$). Respiratory depression was not observed in Group D but occurred in 4% of Group M patients ($p=0.49$). Nausea and vomiting were more common in Group M (10%) compared to Group D (4%), though the difference was not statistically significant ($p=0.24$). Overall, the adverse effects were mild and manageable in both groups.

Table 1: Baseline Characteristics of Patients

Variable	Group D (Dexmedetomidine) (n=50)	Group M (Midazolam) (n=50)	p-value
Age (years)	38.2 ± 10.4	37.8 ± 9.8	0.78
Gender (Male/Female)	30/20	28/22	0.70
ASA Grade I/II	35/15	33/17	0.65

Table 2: Ramsay Sedation Scale

Time Interval	Group D (Mean ± SD)	Group M (Mean ± SD)	p-value
10 minutes	3.5 ± 0.6	2.8 ± 0.5	<0.001
30 minutes	3.9 ± 0.3	3.3 ± 0.4	<0.001
End of procedure	4.0 ± 0.2	3.4 ± 0.3	<0.001

Table 3: Hemodynamic Stability

Parameter	Baseline	5 min	10 min	20 min	30 min	45 min	60 min	End of Procedure	p-value
Mean HR (beats/min)	Group D:	72.5 ± 4.8	68.9 ± 5.3	67.8 ± 6.1	67.3 ± 6.0	68.1 ± 5.7	68.3 ± 5.5	67.8 ± 6.3	<0.001
	Group M:	77.4 ± 5.9	76.8 ± 5.7	76.5 ± 7.3	76.2 ± 6.8	76.0 ± 6.2	75.9 ± 6.4	76.5 ± 7.1	
Mean MAP (mmHg)	Group D:	89.3 ± 5.6	87.5 ± 5.2	86.4 ± 5.1	85.1 ± 5.8	85.3 ± 5.7	85.7 ± 5.9	85.1 ± 5.8	<0.001
	Group M:	92.6 ± 6.4	91.8 ± 6.3	91.7 ± 6.2	91.6 ± 6.1	91.4 ± 6.2	91.3 ± 6.4	91.6 ± 6.4	
SBP (mmHg)	Group D:	127.8 ± 10.2	119.1 ± 9.4	117.8 ± 8.8	117.0 ± 8.6	116.9 ± 8.4	116.5 ± 8.5	116.2 ± 8.7	<0.001
	Group M:	128.5 ± 11.3	124.8 ± 10.2	124.1 ± 10.0	123.7 ± 9.9	123.5 ± 10.0	123.4 ± 10.2	123.3 ± 10.4	
DBP (mmHg)	Group D:	75.8 ± 5.9	74.3 ± 5.6	73.5 ± 5.5	73.0 ± 5.4	72.8 ± 5.2	72.7 ± 5.3	72.5 ± 5.4	<0.001
	Group M:	80.2 ± 6.8	78.6 ± 6.5	78.1 ± 6.3	77.8 ± 6.2	77.5 ± 6.1	77.4 ± 6.2	77.2 ± 6.4	
Mean SpO2 (%)	Group D:	98.0 ± 0.7	97.9 ± 0.8	97.9 ± 0.7	97.8 ± 0.8	97.9 ± 0.7	97.9 ± 0.7	97.9 ± 0.7	0.54
	Group M:	98.0 ± 0.8	97.9 ± 0.8	97.8 ± 0.7	97.8 ± 0.8	97.8 ± 0.8	97.8 ± 0.7	97.8 ± 0.8	

Table 4: Patient Comfort and Surgeon Satisfaction

Outcome	Group D (Dexmedetomidine)	Group M (Midazolam)	p-value
Patient Comfort (VAS)	9.1 ± 0.6	8.3 ± 0.8	<0.001
Surgeon Satisfaction	4.7 ± 0.5	4.2 ± 0.6	0.002

Table 5: Adverse Effects

Adverse Effect	Group D (Dexmedetomidine) (n=50)	Group M (Midazolam) (n=50)	p-value
Bradycardia	6 (12%)	2 (4%)	0.14
Hypotension	4 (8%)	1 (2%)	0.17
Respiratory Depression	0 (0%)	2 (4%)	0.49
Nausea/Vomiting	2 (4%)	5 (10%)	0.24

DISCUSSION

The findings of this study comparing intravenous dexmedetomidine and midazolam for tympanoplasty

under monitored anesthesia care (MAC) are consistent with existing literature and provide further evidence supporting the advantages of dexmedetomidine in this

context. The baseline characteristics of both groups were comparable, with no significant differences in age, gender distribution, or ASA grades. This is in line with other studies that ensured randomization effectively balanced patient demographics, minimizing confounding variables. For example, study designs by Aantaa et al. (1997) and Ramsay et al. (2004) similarly showed comparable baseline characteristics when comparing sedative agents in randomized trials, ensuring validity in the observed outcomes.^{8,9} Dexmedetomidine provided significantly better sedation scores compared to midazolam at all measured intervals. At 10 minutes, Group D achieved a sedation score of 3.5 ± 0.6 versus 2.8 ± 0.5 in Group M, with a similar trend persisting throughout the procedure ($p < 0.001$). This supports findings by Guler et al. (2005), who demonstrated that dexmedetomidine provided deeper and more stable sedation compared to midazolam during minor surgical procedures.¹⁰ Similarly, Venn et al. (2002) found that dexmedetomidine maintained sedation more effectively without requiring frequent dose adjustments, a finding echoed in this study.¹¹ The significant reduction in HR observed in Group D (from 78.3 ± 5.4 to 67.8 ± 6.3 beats/min) reflects the known bradycardic effect of dexmedetomidine, as previously reported by Belleville et al. (1992). In contrast, midazolam caused only a mild reduction in HR, consistent with its weaker sympatholytic effects.¹² The MAP decreased more significantly in Group D (93.2 ± 6.5 to 85.1 ± 5.8 mmHg, $p < 0.001$) compared to Group M, which is consistent with studies by Guler et al. (2005) and Jaakola et al. (1992). Dexmedetomidine's reduction in MAP is attributed to its central sympatholytic action and vasodilatory effects.^{10,13} The reductions in SBP and DBP in Group D were more pronounced than in Group M, demonstrating better hemodynamic control during the procedure. These findings are similar to those of Lawrence and De Lange (1997), who found that dexmedetomidine provided superior attenuation of hemodynamic responses compared to midazolam during surgical procedures.¹⁴ Oxygen saturation levels remained stable and comparable in both groups, reflecting the safety of both sedative agents in maintaining respiratory function, as corroborated by the findings of Hall et al. (2000).¹⁵ Patient comfort scores were significantly higher in Group D (9.1 ± 0.6 vs. 8.3 ± 0.8 , $p < 0.001$), which is consistent with the findings of Gertler et al. (2001), who highlighted the anxiolytic and analgesic properties of dexmedetomidine.¹⁶ Higher surgeon satisfaction scores in Group D (4.7 ± 0.5 vs. 4.2 ± 0.6 , $p = 0.002$) align with studies by Venn et al. (2002), where dexmedetomidine improved operating conditions by providing stable sedation and hemodynamics.¹¹ Bradycardia occurred in 12% of patients in Group D, which, although higher than the 4% in Group M, was consistent with studies such as Belleville et al. (1992) and Gertler et al. (2001). The

incidence of hypotension (8% in Group D vs. 2% in Group M) was similarly mild and manageable.¹⁶ Respiratory depression was absent in Group D but occurred in 4% of Group M, reflecting dexmedetomidine's advantage in maintaining respiratory stability. The lower incidence of nausea and vomiting in Group D (4% vs. 10%) aligns with studies by Aantaa et al. (1997), which suggested that dexmedetomidine may reduce postoperative nausea and vomiting due to its antiemetic properties.⁸

CONCLUSION

In conclusion, this study demonstrated that IV dexmedetomidine provided superior sedation quality, enhanced patient comfort, and better surgeon satisfaction compared to midazolam during tympanoplasty under monitored anesthesia care. Dexmedetomidine also ensured greater hemodynamic stability, with significant reductions in heart rate and blood pressure, while maintaining respiratory function. Although bradycardia and hypotension were slightly more frequent with dexmedetomidine, these events were mild and manageable. Midazolam, while effective, showed comparatively less stable hemodynamics and a higher incidence of nausea and vomiting. Overall, dexmedetomidine proved to be a more effective and reliable sedative for tympanoplasty procedures.

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