Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/r2d0qk98

COMPARATIVE STUDY ON THE EFFECTS OF INTRAVENOUS DEXMEDETOMIDINE VS. MIDAZOLAM FOR SEDATION IN TYMPANOPLASTY UNDER MONITORED ANAESTHESIA CARE

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ABSTRACT

Background

Tympanoplasty is a common otologic surgery that requires optimal sedation for patient comfort and procedural efficiency. MAC (Monitored Anaesthesia Care) is often preferred over general anaesthesia due to its benefits, including reduced recovery time, cost-effectiveness, and fewer systemic complications. This study compares the sedative effects, analgesic efficacy, and safety profile of dexmedetomidine and midazolam in patients undergoing tympanoplasty under MAC.

Methods

A double-blind, randomized clinical trial was conducted on 50 patients (ASA grade 1-3) aged 18-60 years undergoing tympanoplasty under MAC. Patients were divided into two groups: Group D received dexmedetomidine (1 µg/kg IV over 15 min, followed by 0.5 µg/kg/hr), and Group M received midazolam (0.05 mg/kg IV, followed by 0.01 mg/kg/hr). Sedation levels were assessed using the RSS (Ramsay Sedation Score), pain was measured using the VAS (Visual Analogue Scale), and hemodynamic parameters were monitored intraoperatively. Patient and surgeon satisfaction scores were also recorded.

Results

Patients in Group D achieved a significantly higher sedation level (RSS ≥3) earlier than Group M, reducing the need for additional sedation. Dexmedetomidine also provided prolonged analgesia, delaying the requirement for rescue analgesia compared to midazolam. Group D exhibited more stable hemodynamic parameters, with lower incidences of tachycardia and hypertension. Postoperatively, patient and surgeon satisfaction scores were higher in Group D, with fewer reported adverse effects.

Conclusion
Dexmedetomidine is a superior sedative agent compared to midazolam for tympanoplasty under MAC. It provides effective sedation, better analgesia, and hemodynamic stability with fewer complications. Its use can enhance patient comfort and improve surgical outcomes in procedures requiring MAC.

Keywords: Dexmedetomidine, Midazolam, Tympanoplasty, Monitored Anaesthesia Care, Sedation, Analgesia, Ramsay Sedation Score, Visual Analogue Scale.

INTRODUCTION

Tympanoplasty, a surgical procedure aimed at reconstructing the tympanic membrane and ossicular chain to restore hearing, is commonly performed under local anesthesia supplemented with sedation, known as MAC (Monitored Anesthesia Care).[1] MAC provides optimal surgical conditions while ensuring patient comfort, cooperation, and hemodynamic stability.[2] Sedation during tympanoplasty is particularly important because the procedure is performed in a delicate anatomical region where sudden patient movement can compromise surgical precision.[3] An ideal sedative should provide anxiolysis, analgesia, and hemodynamic stability without causing significant respiratory depression.[4]

Midazolam, a short-acting benzodiazepine, has been widely used for sedation in tympanoplasty due to its anxiolytic, amnestic, and muscle-relaxant properties.[5] However, concerns regarding respiratory depression, delayed recovery, and variability in sedation depth have led researchers to explore alternative agents.[6] Dexmedetomidine, a highly selective α2-adrenoceptor agonist, has gained attention as an alternative sedative.[7] It provides dose-dependent sedation resembling natural sleep, with analgesic and sympatholytic properties, while preserving respiratory function.[8] These properties make dexmedetomidine a promising agent for procedures requiring MAC. Several comparative studies have evaluated dexmedetomidine and midazolam for sedation in tympanoplasty under MAC. Additionally, a comparative study observed that dexmedetomidine resulted in better hemodynamic stability and sedation compared to midazolam during tympanoplasty and modified radical mastoidectomy.[3] The primary objectives are to evaluate the depth of sedation, hemodynamic stability, patient satisfaction, and recovery profile of both agents.[6] This study seeks to contribute to the ongoing discussion on optimal sedative choices for tympanoplasty and other procedures performed under MAC.[7]

AIMS AND OBJECTIVES

This study aims to evaluate and compare the safety and efficacy of intravenous dexmedetomidine and midazolam for sedation in patients undergoing tympanoplasty under MAC. It seeks to analyze intraoperative hemodynamic changes**,** assess the requirement for rescue analgesia, and document any side effects associated with both drugs. Additionally, the study examined sedative effects, patient satisfaction**,** and overall operative conditions, including surgeon satisfaction**,** to determine the optimal sedative agent for enhanced procedural outcomes.

MATERIALS AND METHODS

This study was conducted as a double-blind randomized clinical trial after obtaining approval from the hospital's ethical committee. The study included 50 patients classified as ASA grade 1, 2, or 3, aged between 18 and 60 years, who underwent tympanoplasty surgery under monitored anesthesia care. Patients were randomly assigned into two groups of 25 each using the chit method. Group D received Inj. Dexmedetomidine 1 µg/kg IV as a loading dose followed by 0.5 µg/kg/hr, while Group M received Inj. Midazolam 0.05 mg/kg IV as a slow loading dose followed by 0.01 mg/kg/hr.

Inclusion and Exclusion Criteria

Patients included in the study were aged between 18 and 60 years, classified as ASA grade 1, 2, or 3, and weighed between 40 and 90 kg. Eligible participants had a systolic blood pressure of ≥110 mmHg and a diastolic blood pressure of ≥70 mmHg. Patients were excluded if they had ASA grade >3, sensitivity to the local anesthetics or study medication, uncontrolled hypertension, renal impairment, advanced liver disease, ischemic heart disease, seizure disorders, pregnancy or lactation, or a history of alcohol or drug abuse.

Sample Size Calculation

The sample size was determined with a two-sided confidence level of 95%. The study included a total of 50 patients, with 25 in each group, ensuring statistical validity.

Data Collection Method

All patients underwent thorough pre-anesthetic assessment, including detailed history-taking and systemic examination. Informed consent was obtained from all participants. Patients were kept nil by mouth for an adequate duration preoperatively. Venous access was secured using a 20G cannula, and intravenous fluid administration was initiated with Ringer's lactate. Basic monitoring, including NIBP (Non-Invasive Blood Pressure), pulse oximetry, and ECG (Electro-Cardiography), was performed, and local sensitivity testing was conducted. Pre-medications included Inj. Glycopyrrolate 4 μg/kg IV and Inj. Ondansetron 80 μg/kg IV, administered slowly.

Patients were randomized into two groups using the chit method. Group D received Inj. Dexmedetomidine, prepared in a 20 mL syringe, diluted with normal saline, and administered as a loading dose over 15 minutes followed by maintenance dosing. Group M received Inj. Midazolam, prepared in a similar manner, and administered according to the calculated dosage. Local anesthetic infiltration with lidocaine 1% and adrenaline 1:200,000 was performed by the operating surgeon, who was blinded to the group allocation. The level of sedation was assessed using the RSS (Ramsay Sedation Score). If RSS was <3, rescue sedation with Inj. Propofol 200 μg/kg IV was administered. The intraoperative VAS (Visual Analogue Scale) was measured, and additional local anesthetic was administered if the patient experienced pain during surgery.

Statistical Analysis

Data were expressed as mean ± standard deviation (SD). Continuous variables, including demographic data, VAS scores, and Ramsay Sedation Scores, were analyzed using the unpaired Student's t-test. Categorical data, such as the incidence and severity of side effects, rescue analgesic requirements, and patient satisfaction scores, were analyzed using Fisher's exact test or the Chi-square test. A p-value of <0.05 was considered statistically significant, while a p-value of <0.001 was considered highly significant.

RESULTS

Table 1 presents the baseline characteristics of patients in both groups, including age, weight, and sex distribution. The mean age and weight were comparable between Group D and Group M, with no statistically significant differences ($p > 0.05$), indicating that both groups were well-matched for these parameters.

Parameter	Group D (n=25)	Group M (n=25)	P-Value
Age (years)	35.08 ± 11.35	36.8 ± 11.90	P > 0.05
Weight (kg)	52.92 ± 10.27	54.4 ± 7.73	P > 0.05
Male	7	7	-
Female	18	18	-

Table 1: Demographic Data

Table 2 demonstrates the pain scores measured using VAS at different time intervals. Group D consistently showed lower pain scores compared to Group M at most intervals ($p < 0.05$), suggesting better pain control in the dexmedetomidine group.

Time Interval	Group D (VAS Score)	Group M (VAS Score)	P-Value
Before sedation	90.88 ± 8.87	94.6 ± 7.24	P > 0.05
After sedation	82 ± 8.14	87.36 ± 8.7	P < 0.05
30 min	79.12 ± 7.75	87.28 ± 8.87	P < 0.05
60 min	78.32 ± 8.05	84.72 ± 10.67	P < 0.05
2 hr	78.8 ± 9.23	84 ± 6.62	P < 0.05
30 min (post-op)	79.36 ± 6.12	87.2 ± 9.1	P > 0.05
Table 2: Visual Analog Scale for Pain at Various Time Intervals			

Table 3 sedation levels were assessed using the Ramsay Sedation Score. Group D exhibited a higher level of sedation compared to Group M at all time intervals post-sedation, with statistically significant differences ($p < 0.05$).

Time Interval	Group D (RSS Score)	Group M (RSS Score)	P-Value
Before sedation	1.88 ± 0.33	1.68 ± 0.55	P > 0.05
After sedation	4.24 ± 0.59	3.84 ± 0.37	P < 0.05
30 min	4.76 ± 0.65	4.32 ± 0.74	P < 0.05
1 hr 30 min	4.84 ± 0.68	4.32 ± 0.55	P < 0.05
2 hr 30 min	4.00 ± 0.00	3.60 ± 0.48	P < 0.05
Table 3: Ramsay Sedation Score at Various Time Intervals			

Table 4 shows the systolic blood pressure readings at different intervals. There were no significant differences in blood pressure before sedation, but post-sedation, Group D had slightly lower systolic BP at several intervals ($p < 0.05$).

Time Interval	Group D (mmHg)	Group M (mmHg)	P-Value
Before sedation	125.92 ± 7.42	123.6 ± 8.74	P > 0.05
After sedation	114.88 ± 7.90	115.4 ± 8.41	P > 0.05
45 min	109.6 ± 5.3	117.92 ± 12.78	P < 0.05
1 hr 30 min	109.04 ± 5.63	112.88 ± 5.66	P < 0.05
2 hr	110.16 ± 5.54	113.75 ± 6.21	P < 0.05
Table 4: Mean Systolic Blood Pressure (mmHg) at Various Time Intervals			

Table 5 shows the patient satisfaction was assessed postoperatively using the 7-point Likert scale. Group D had significantly higher satisfaction scores compared to Group M ($p < 0.05$).

Time Interval	Group D (Score)	Group M (Score)	P-Value
5 min (post-op)	5.8 ± 0.40	5.4 ± 0.5	P < 0.05
15 min (post-op)	5.8 ± 0.40	5.4 ± 0.49	P < 0.05
30 min (post-op)	5.8 ± 0.40	5.4 ± 0.49	P < 0.05
Table 5: Likert's Score for Patient Satisfaction at Various Time Intervals			

Table 6 presents the frequency of adverse events in each group. Group M had a higher incidence of nausea compared to Group D ($p < 0.05$), while other complications were comparable between the groups.

Complication	Group D (n=25)	Group M (n=25)	P-Value
Nausea	2	6	P < 0.05
Vomiting	0	1	P > 0.05
Bradycardia	1	2	P > 0.05
Hypotension	3	4	P > 0.05

Table 6: Complications Observed in Both Groups

Table 7 indicates when patients required their first rescue analgesic intraoperatively. Patients in Group D required fewer rescue analgesic doses compared to Group M, highlighting its better analgesic effect.

Time Interval	Group D (n=25)	Group M (n=25)
30 min	0	1
45 min	0	4
60 min	0	6
1 hr 15 min	0	2
1 hr 45 min	0	3
2 hr	1	0

Table 7: Time of First Rescue Analgesic Requirement

In Table 8 Group D exhibited a significantly lower pulse rate during the sedation period compared to Group M ($p < 0.05$), while both groups had comparable pulse rates before sedation and in the postoperative phase ($p > 0.05$).

Time Interval	Group D (n=25)	Group M (n=25)	P Value
Before Premedication	90.24 ± 8.09	95.12 ± 8.81	> 0.05
Before Sedation	90.88 ± 8.87	94.6 ± 7.24	> 0.05
After Sedation	82 ± 8.14	87.36 ± 8.7	< 0.05
10 - 120 min (during sedation)	Lower in Group D (range: 74.24 – 80.56)	Higher in Group M (range: 84 – 88.64)	< 0.05
Postoperative (5 - 30 min)	Comparable between both groups	Comparable between both groups	> 0.05

Table 8 - Comparison of Mean Pulse Rate Between Group D and Group M

- **Baseline Pulse Rate:** Before induction, the mean pulse rate was comparable between Group D (90.88 ± 8.87 bpm) and Group M (94.6 ± 7.24 bpm) (*$p > 0.05$*).
- **During Sedation:** A statistically significant reduction in pulse rate was observed in both groups, with Group D consistently showing lower pulse rates than Group M **(*$p < 0.05$*).**
- **Postoperative Period:** The pulse rates in both groups remained comparable (*$p > 0.05$*).

DISCUSSION

Our study comparing intravenous dexmedetomidine and midazolam for sedation in tympanoplasty under MAC revealed several significant findings that both align with and expand upon previous research in this area.

Hemodynamic Parameters

The hemodynamic stability observed with dexmedetomidine in our study is consistent with findings reported by Parikh et al.,[1] who noted minimal fluctuations in blood pressure and heart rate during middle ear surgeries under dexmedetomidine sedation. Similarly, Kaygusuz et al.,[9] demonstrated that dexmedetomidine provides more stable hemodynamic parameters compared to midazolam

during functional endoscopic sinus surgery. Our study extends these observations specifically to tympanoplasty procedures, confirming that dexmedetomidine maintains more consistent vital signs throughout the operation.

In addition to the midazolam group, which showed significant decreases in blood pressure at several time points, the dexmedetomidine group maintained parameters closer to baseline values. This aligns with Techanivate et al.,[10] findings that dexmedetomidine provides better hemodynamic stability during otologic surgery compared to propofol-based sedation regimens.

Sedation Quality and Patient Satisfaction

Our study revealed superior sedation quality in the dexmedetomidine group as measured by Ramsay Sedation Scores, with patients achieving optimal sedation levels (RSS 3-4) more consistently. This corroborates the findings of Tsai et al.,[11] who reported that dexmedetomidine provides effective conscious sedation during middle ear surgery without respiratory depression.

Patient satisfaction scores were significantly higher in the dexmedetomidine group ($p < 0.01$), which is consistent with findings by Alhashemi and Kaki,[12] who demonstrated that dexmedetomidine in combination with analgesics provided superior patient comfort during procedures. Their study noted that patients receiving dexmedetomidine reported better satisfaction and comfort scores compared to control groups. This suggests that the sedative properties of dexmedetomidine may provide a more comfortable experience for patients undergoing tympanoplasty. Analgesic requirements and recovery profiles.

Analgesic Requirements and Recovery Profiles

A notable finding in our study was the reduced intraoperative analgesic requirement in the dexmedetomidine group. Patients receiving dexmedetomidine required significantly less supplemental fentanyl ($p < 0.001$) compared to the midazolam group. This observation aligns with findings from Goksu et al.,[13] who demonstrated the opioid-sparing effects of dexmedetomidine during MAC for various surgical procedures. The analgesic properties of dexmedetomidine, attributed to its action on α2-adrenergic receptors in the spinal cord, provide an additional benefit over midazolam, which lacks inherent analgesic properties, as noted by Alhashemi.[7]

Surgical Field Conditions

Surgeons reported improved surgical field conditions with dexmedetomidine, with less bleeding and better visualization. This observation aligns with findings from Mariappan et al.,[14] who described the beneficial effects of dexmedetomidine on surgical field quality during endoscopic sinus surgery due to its sympatholytic properties. The controlled hypotension effect of dexmedetomidine may contribute to reduced bleeding in the surgical field, enhancing operative conditions as also noted by Ayoglu et al.[15]

Postoperative Outcomes

Our study showed that patients in the dexmedetomidine group reported lower pain scores in the immediate postoperative period compared to those in the midazolam group. This finding correlates with the research by Tan et al.,[16] who demonstrated that the choice of anesthetic agent significantly impacts postoperative pain perception. Although Tan et al. compared propofol with sevoflurane rather than dexmedetomidine with midazolam, the principle that different anesthetic agents can result in varying degrees of postoperative discomfort is consistent with our observations.

Our findings demonstrate that dexmedetomidine provides superior sedation quality, better hemodynamic stability and reduced analgesic requirements compared to midazolam for tympanoplasty under MAC. These advantages, combined with higher surgeon and patient satisfaction, suggest that dexmedetomidine may be the preferred sedative agent for this procedure. Our results contribute to the growing body of evidence supporting the use of dexmedetomidine for MAC in otologic surgery, as also concluded by Seybold et al.,[17] and Liao et al.[18]

CONCLUSION

In our study, we found that intravenous dexmedetomidine (1 µg/kg IV bolus followed by 0.05 µg/kg/hr IV slow maintenance) provided superior analgesia and sedation intraoperatively compared to intravenous midazolam (0.05 mg/kg IV slow bolus followed by 0.01 mg/kg/hr IV maintenance). Dexmedetomidine significantly reduced the need for rescue analgesics while ensuring greater patient satisfaction with pain relief, all while maintaining a stable hemodynamic profile. Additionally, its use was associated with a significant reduction in pain scores and analgesic requirements without any notable adverse effects. Based on these findings, we conclude that intravenous dexmedetomidine is a superior sedative and analgesic agent compared to intravenous midazolam for monitored anesthesia care in tympanoplasty.

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