Original Research Paper

Volume - 15 | Issue - 11 | November - 2025 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Anaesthesiology

A COMPARATIVE STUDY BETWEEN DEXMEDETOMIDINE/NALBUPHINE AND MIDAZOLAM/NALBUPHINE IN MONITORED ANESTHESIA CARE DURING EAR SURGERY

Dr. Denishgiri Manojgiri Meghanathi*	Senior Resident, Department of Anaesthesiology, Shri M. P. Shah Govt. Medical College & Guru Gobind Singh Govt. Hospital, Jamnagar, Gujarat, India. *Corresponding Author
Dr. Ravali Kammari	Senior Resident, Department of Anaesthesiology, Shri M. P. Shah Govt. Medical College & Guru Gobind Singh Govt. Hospital, Jamnagar, Gujarat, India.
Dr. Sachin Patel	Resident, Department of Anaesthesiology, Shri M. P. Shah Govt. Medical College & Guru Gobind Singh Govt. Hospital, Jamnagar, Gujarat, India.
Dr. Jaydev Dave	Professor, Department of Anaesthesiology, Shri M. P. Shah Govt. Medical College & Guru Gobind Singh Govt. Hospital, Jamnagar, Gujarat, India.
Dr. Prashant Sorathiya	Assistant Professor, Department of Anaesthesiology, Shri M. P. Shah Govt. Medical College & Guru Gobind Singh Govt. Hospital, Jamnagar, Gujarat, India.

ABSTRACT **Background:** Tympanoplasty performed under Monitored Anesthesia Care (MAC) allows patient comfort and intraoperative hearing assessment. The optimal sedative–analgesic combination should provide stable hemodynamics, adequate sedation, and rapid recovery. This study compared the efficacy and safety of dexmedetomidine–nalbuphine with midazolam–nalbuphine during tympanoplasty. **Methods:** Sixty ASA I–III patients aged 18–65 years scheduled for tympanoplasty under local anesthesia with MAC were randomly allocated into two equal groups. Group D received intravenous dexmedetomidine (loading 1 µg/kg over 10 min, then 0.7 µg/kg/h) plus nalbuphine (100 µg/kg). Group M received intravenous midazolam (20 µg/kg over 10 min, then 20 µg/kg/h) plus nalbuphine (100 µg/kg). Heart rate, blood pressure, sedation score (Ramsay), pain score (VAS), and surgeon satisfaction were recorded. Adverse events were also noted. **Results:** Baseline demographics were comparable between groups. Group D showed significantly lower intraoperative heart rate and mean arterial pressure yet remained within clinically acceptable limits. Sedation was deeper and more consistent in Group D ($p < 0.001$), with lower pain scores and a longer duration of effective analgesia (131.7 ± 7.9 min vs 105.5 ± 4.8 min, $p < 0.001$). Fewer patients in Group D required rescue analgesia. Surgeon satisfaction was higher with dexmedetomidine–nalbuphine ($p < 0.001$). No significant respiratory depression or major complications occurred in either group. **Conclusion:** Dexmedetomidine combined with nalbuphine provides superior sedation and analgesia compared with midazolam–nalbuphine during tympanoplasty under MAC. The regimen maintains hemodynamic stability, reduces rescue drug requirements, and enhances surgeon satisfaction, making it a reliable alternative for middle-ear procedures.

KEYWORDS : Dexmedetomidine, Midazolam, Nalbuphine, Tympanoplasty, Monitored Anesthesia Care, Sedation, Analgesia

INTRODUCTION

Effective perioperative pain and sedation management are vital for optimizing surgical conditions and patient comfort. Tympanoplasty, one of the most frequently performed middle-ear surgeries, can be carried out either under general anesthesia or under local anesthesia supplemented with sedation—commonly known as Monitored Anesthesia Care (MAC). MAC provides anxiolysis, analgesia, and cooperative sedation while maintaining spontaneous ventilation and protective airway reflexes.

The major advantages of MAC in ear surgery include minimal airway manipulation, reduced bleeding in the surgical field, faster recovery, and the ability to evaluate hearing intraoperatively. Achieving these benefits requires selecting sedative and analgesic agents that produce adequate comfort and stable hemodynamics without excessive respiratory depression.

Benzodiazepines such as midazolam have been widely used for MAC because of their sedative, anxiolytic, and amnestic properties. However, they can occasionally cause respiratory depression and delayed recovery, especially when combined with opioids. Nalbuphine, a mixed κ-agonist and µ-antagonist opioid, provides effective analgesia with a lower risk of respiratory compromise compared to pure µ-agonists, making it a suitable component of MAC regimens.

Dexmedetomidine, a highly selective α_2-adrenergic receptor agonist, offers both sedative and analgesic properties along with sympatholytic and anxiolytic effects. It produces a state of calm wakefulness—often termed "cooperative sedation"—that allows patients to remain responsive while relaxed. Importantly, it exerts minimal respiratory depression, an advantage in procedures performed under local anesthesia.

Considering these pharmacologic characteristics, dexmedetomidine may provide superior intraoperative comfort and hemodynamic stability compared with midazolam when both are combined with nalbuphine. The present study was designed to compare the efficacy and safety of dexmedetomidine–nalbuphine versus midazolam–nalbuphine combinations for sedation and analgesia during tympanoplasty performed under monitored anesthesia care.

AIMS AND OBJECTIVES

To study and Compare

- Safety and efficacy of dexmedetomidine / nalbuphine and midazolam / nalbuphine.
- Need for Rescue Sedation/Analgesia intraoperatively
- Side effects and Sedative effects of the drugs and to Study patient's satisfaction
- Study operative condition (surgeon's satisfaction) and Time to discharge

MATERIAL AND METHODS

Study Design and Ethical Approval

This prospective, randomized, and double-blinded comparative study was carried out after obtaining clearance from the Institutional Ethics Committee. All participants provided written informed consent before enrolment. The research was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Selection

Sixty adult patients, aged between 18 and 65 years, belonging to the American Society of Anesthesiologists (ASA) physical status I–III, scheduled to undergo elective tympanoplasty under local anesthesia with monitored anesthesia care, were included.

Patients were excluded if they refused participation, had a known allergy to study drugs, were classified as ASA IV or V, or presented with significant cardiovascular, hepatic, or renal dysfunction, uncontrolled hypertension, or bradycardia.

Randomization and Blinding
Participants were randomly assigned into two equal groups (n = 30 each) using a chit-in-box method. Drug preparations were performed by an independent anesthesiologist not involved in patient monitoring or data collection, ensuring both the attending anesthesiologist and observer remained blinded to group allocation.

Anesthetic Technique
All patients received standard preoperative fasting and medication guidelines. In the operating room, baseline vital parameters were recorded, and intravenous access was secured. Premedication included ondansetron 0.08 mg/kg IV and glycopyrrolate 0.004 mg/kg IV.
Group D: Dexmedetomidine 1 µg/kg IV was infused slowly over 10 minutes, followed by a maintenance infusion of 0.7 µg/kg/h. Nalbuphine 100 µg/kg IV was administered as a single dose.
Group M: Midazolam 20 µg/kg IV was infused over 10 minutes, followed by a maintenance infusion of 20 µg/kg/h, along with nalbuphine 100 µg/kg IV as a single dose.

Following sedation, the operating surgeon—blinded to group assignment—performed local infiltration of 1% lidocaine with adrenaline (1:200,000). All patients also received intravenous paracetamol 1 g as supplemental analgesia.

Monitoring and Data Collection
Continuous monitoring included ECG, non-invasive blood pressure (NIBP), pulse oximetry, and respiratory rate. Data were recorded at baseline and at fixed intraoperative intervals.

Primary Parameters
Sedation Level: Assessed using the Ramsay Sedation Score (RSS), targeting a score of ≥3. If RSS dropped below 3, propofol (100–200 µg/kg/h IV) was administered as rescue sedation.

Pain Assessment: Measured with the 10-point Visual Analogue Scale (VAS).

Secondary Parameters
Hemodynamics: Heart rate (HR), systolic, diastolic, and mean arterial pressures were observed throughout the procedure.
Rescue Analgesia: The number of patients requiring additional analgesia and the time to first rescue dose were recorded.
Satisfaction Scores: Surgeon satisfaction with operating conditions was rated on a 10-point numerical scale, and patient satisfaction in the recovery room was rated on a 5-point scale.
Adverse Effects: Incidences of bradycardia, hypotension, desaturation, nausea, vomiting, or other complications were documented.

Statistical Analysis
Quantitative data were presented as mean ± standard deviation (SD) and analyzed using the Student's t-test. Categorical data were compared using the Chi-square test. A p-value < 0.05 was considered statistically significant.

OBSERVATION AND RESULTS

Demographic Characteristics
Both groups were comparable in baseline demographic variables, as summarized in Table 1. The mean age was slightly higher in Group D (38.6 ± 12.6 years) than in Group M (32.2 ± 10.4 years), a difference that was statistically significant (p = 0.036) but not clinically relevant. There were no significant differences between groups regarding sex distribution, weight, or height (p > 0.05).

Table 1: Baseline Patient Demographics

PARAMETERS		GROUP M (n=30)	GROUP D (n=30)	P VALUE
AGE (IN YEARS)		32.17 ± 10.36	38.57 ± 12.58	0.036
WEIGHT (IN KG)		62.03 ± 8.54	61.27 ± 7.38	0.711
HEIGHT (IN CMS)		162.83 8.25	158.93 6.83	0.051
SEX	Male	13	15	
	Female	17	15	

Intraoperative Parameters
Mean heart rate, systolic and diastolic blood pressures, and mean arterial pressure were significantly lower in Group D throughout the intraoperative period compared with Group M (p < 0.05), indicating superior hemodynamic stability with dexmedetomidine–nalbuphine. Despite these statistical differences, no patient developed clinically significant hypotension or bradycardia requiring intervention.

Oxygen saturation remained above 98% in both groups at all times, and no respiratory depression was observed.

Sedation depth, assessed using the Ramsay Sedation Score, was consistently higher in Group D at each intraoperative time point (p < 0.001). Pain scores (VAS) were significantly lower in Group D than in Group M, reflecting enhanced intraoperative comfort.

The requirement for rescue analgesia was minimal in the dexmedetomidine group—only two patients needed additional medication—whereas several patients in the midazolam group required supplemental doses (p < 0.001).

The mean duration of effective analgesia was markedly longer with dexmedetomidine–nalbuphine (131.7 ± 7.9 minutes) than with midazolam–nalbuphine (105.5 ± 4.8 minutes, p < 0.001).

Table 2: Intraoperative Parameters

PARAMETERS	GROUP M (n=30)	GROUP D (n=30)	P VALUE	Remark
Mean HR (bpm)	79.20 5.24	71.80 5.81	<0.0001	Significant
Mean MAP (mmHg)	89.51 3.75	85.89 3.91	<0.0001	Significant
SpO_2(%)	98.50 0.68	98.97 0.18	<0.0001	Significant
Total duration of effective analgesia	105.53 4.83	131.67 7.88	<0.0001	Significant
Rescue sedation / Analgesia	0.73 0.73	0.03 0.18	<0.0001	Significant
Surgeon satisfaction score	7.60 0.93	8.67 0.47	<0.0001	Significant
VAS Score	0.50 0.51	0.13 0.35	0.002	Significant
Ramsay Score	3.43 0.50	3.93 0.52	<0.0001	Significant

Postoperative Outcomes
Postoperative evaluation demonstrated significantly lower pain scores in Group D (VAS 0.07 ± 0.25) compared with Group M (VAS 0.30 ± 0.47; p = 0.019). Patient satisfaction scores were higher in the dexmedetomidine group (4.6 ± 0.4 vs 3.9 ± 0.7; p < 0.05). Recovery times were comparable between groups (p = 0.44).

Table 3: Postoperative Outcomes

PARAMETERS	GROUP M (n=30)	GROUP D (n=30)	P VALUE	Remark
Postoperative VAS score	0.30 0.47	0.07 0.25	0.019	Significant
Recovery time (min)	13.2 2.9	12.6 3.1	0.44	Not significant
Patient satisfaction score (1-5)	3.9 0.7	4.6 0.4	<0.05	Significant

Adverse Events
No major adverse effects were recorded. Occasional mild nausea and vomiting occurred in both groups with similar incidence. No patient experienced significant bradycardia, hypotension, or desaturation requiring clinical intervention.

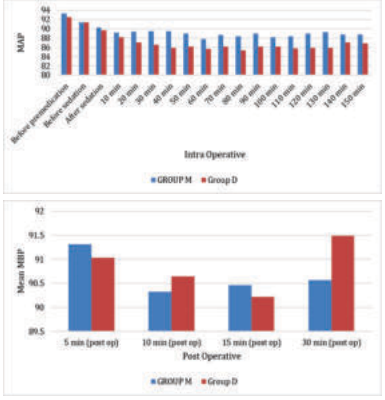

Figure 1: Mean Arterial Pressure Trend

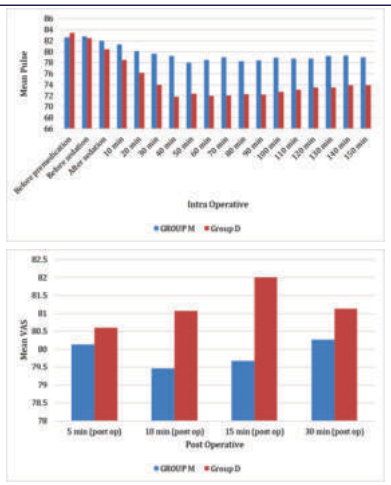

Figure 2: Heart Rate Trend

DISCUSSION

The present study compared the sedative, analgesic, and hemodynamic effects of two drug combinations—dexmedetomidine with nalbuphine versus midazolam with nalbuphine—during tympanoplasty performed under monitored anesthesia care (MAC). The results demonstrated that dexmedetomidine–nalbuphine provided deeper sedation, better analgesia, and greater surgeon satisfaction without compromising respiratory stability or prolonging recovery.

Sedation Quality and Analgesic Profile

Dexmedetomidine acts as a highly selective α_2-adrenergic agonist, producing dose-dependent sedation and analgesia through inhibition of central sympathetic outflow and modulation of nociceptive pathways. This "cooperative sedation" allows patients to remain calm yet easily arousable, an effect that is particularly desirable during procedures conducted under local anesthesia.

In the present study, the dexmedetomidine group achieved significantly higher Ramsay Sedation Scores and lower VAS pain scores than the midazolam group, confirming superior sedative and analgesic effects. The prolonged duration of effective analgesia and reduced requirement for rescue medication further highlight dexmedetomidine's ability to enhance perioperative comfort.

These findings are consistent with previous clinical trials in ENT and minor surgical procedures, where dexmedetomidine-based regimens produced deeper sedation and better pain control compared to benzodiazepine-based combinations. The addition of nalbuphine, a mixed κ-agonist and μ-antagonist opioid, likely contributed to sustained analgesia while minimizing opioid-related respiratory depression.

Hemodynamic Stability

Patients receiving dexmedetomidine exhibited lower heart rate and mean arterial pressure throughout surgery. This controlled reduction in hemodynamics results from the drug's sympatholytic properties, which attenuate catecholamine release. Such an effect is often advantageous in otologic surgery, where a relatively bloodless surgical field facilitates precision and reduces intraoperative bleeding. Importantly, none of the patients in the dexmedetomidine group developed clinically significant hypotension or bradycardia, indicating that the regimen maintained cardiovascular safety within acceptable limits.

Respiratory Safety

A major concern with sedative-analgesic techniques is the potential for respiratory depression, particularly when combining benzodiazepines with opioids. In this study, neither group demonstrated desaturation or significant respiratory compromise; however, dexmedetomidine offered an additional safety margin by maintaining spontaneous ventilation throughout the procedure. This observation aligns with existing evidence suggesting that α_2-agonists exert minimal depressive effects on respiratory drive compared with GABA-ergic sedatives.

Satisfaction and Recovery

Surgeon satisfaction scores were significantly higher in the dexmedetomidine group, reflecting better intraoperative conditions, patient immobility, and overall ease of surgery. Patient satisfaction was also superior, with most participants reporting comfort and early recovery without agitation. Recovery times were similar in both groups, suggesting that dexmedetomidine's sedative profile does not delay postoperative discharge when used in appropriate doses.

Clinical Implications

For procedures requiring patient cooperation, such as tympanoplasty, the dexmedetomidine–nalbuphine combination appears to offer a balanced approach to sedation and analgesia. It provides stable hemodynamics, excellent operating conditions, and reduced need for supplemental medication—all while preserving airway reflexes.

Limitations

The present study was limited by its single-center design and relatively small sample size. Serum catecholamine levels and bispectral index monitoring were not performed, which could have provided additional insight into sedation depth and sympathetic activity. Future research involving larger multicentric populations and dose-optimization studies would further validate these findings.

CONCLUSION

For patients undergoing tympanoplasty with Monitored Anesthesia Care, an intravenous regimen of dexmedetomidine and nalbuphine offers superior sedation and analgesia compared to a midazolam and nalbuphine combination. The dexmedetomidine group experienced a longer duration of effective analgesia, had a significantly lower requirement for rescue medication, and received higher surgeon satisfaction ratings. These benefits were achieved while maintaining hemodynamic stability and a robust safety profile, with no instances of respiratory depression. Consequently, the dexmedetomidine-nalbuphine combination stands out as a highly effective and safe option for MAC in the context of ear surgery.

REFERENCES

1. Mohamed MH, Hakim KYK. Comparative study between dexmedetomidine/nalbuphine and midazolam/nalbuphine in monitored anesthesia care during ear surgery. Egypt J Anaesth. 2014 Jan 1;30(1):7–12.
2. Nallam SR, Chiruvella S, Reddy A. Monitored anaesthesia care – Comparison of nalbuphine/dexmedetomidine versus nalbuphine/propofol for middle ear surgeries: A double-blind randomised trial. Indian J Anaesth. 2017 Jan;61(1):61–7.
3. Karaaslan K, Yilmaz F, Gulcu N, Colak C, Sereflican M, Kocoglu H. Comparison of dexmedetomidine and midazolam for monitored anesthesia care combined with tramadol via patient-controlled analgesia in endoscopic nasal surgery: A prospective, randomized, double-blind, clinical study. Curr Ther Res Clin Exp. 2007 Mar;68(2):69–81.
4. Busick T, Kussman M, Scheidt T, Tobias JD. Preliminary experience with dexmedetomidine for monitored anesthesia care during ENT surgical procedures. Am J Ther. 2008 Dec;15(6):520–7.
5. Giovannitti JA, Thoms SM, Crawford JJ. Alpha-2 Adrenergic Receptor Agonists: A Review of Current Clinical Applications. Anesth Prog. 2015;62(1):31–8.
6. Das S, Ghosh S. Monitored anesthesia care: An overview. J Anaesthesiol Clin Pharmacol. 2015;31(1):27–9.
7. Stoelting's Pharmacology and Physiology in Anesthetic Practice, 5th Edition | Anesthesiology | ASA Publications.
8. Preemptive Analgesia | Anesthesiology | ASA Publications
9. Ronald D. Miller. Textbook of Anaesthesia; 7th edition.
10. Goodman & Gilman's: The Pharmacological Basis of Therapeutics, 12e | AccessMedicine | McGraw-Hill Medical.