

A prospective, randomized, double-blind study comparing dexmedetomidine versus propofol for sedation in patients undergoing tympanoplasty under monitored anesthesia care (MAC).

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ABSTRACT

Background: Tympanoplasty is commonly performed under local anesthesia with monitored anesthesia care (MAC), where optimal sedation should provide patient comfort, stable hemodynamics, and preserved respiratory function. Propofol is widely used but is associated with respiratory and cardiovascular depression. Dexmedetomidine, an α_2 -adrenergic agonist, offers sedative and analgesic effects with minimal respiratory depression. This study compares dexmedetomidine and propofol for sedation during tympanoplasty under MAC. **Methods:** This prospective, randomized, double-blind study included 60 ASA I–II patients aged 18–60 years undergoing tympanoplasty under local anesthesia. Patients were randomly allocated into two groups: Group D (dexmedetomidine) and Group P (propofol). Sedation was titrated to a Ramsay Sedation Score (RSS) of 3. Hemodynamic parameters, respiratory parameters, intraoperative pain (VAS), rescue analgesic requirement, recovery profile (Aldrete score), and satisfaction scores were recorded and compared. **Results:** Both groups were comparable in demographic and baseline characteristics. Hemodynamic parameters remained stable in both groups, with a slightly better late intraoperative heart rate control in the dexmedetomidine group. Respiratory parameters were comparable between groups. Dexmedetomidine provided better analgesia with lower VAS scores, though clinically similar in both groups. Time to achieve Aldrete score of 10 was comparable. Surgeon satisfaction and patient satisfaction was similar in both groups. **Conclusion:** Dexmedetomidine and propofol provide comparable sedation and hemodynamic stability during tympanoplasty under MAC. Dexmedetomidine offers the added advantage of better analgesia without prolonging recovery, making it a valuable alternative to propofol for sedation in tympanoplasty.

Keywords: Dexmedetomidine; Propofol; Tympanoplasty; Monitored anesthesia care; Sedation; Ramsay sedation score.

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INTRODUCTION

Tympanoplasty is a surgical procedure aimed at reconstructing a perforated tympanic membrane, with or without ossicular reconstruction, and is commonly performed in patients with chronic middle ear disease [1]. It is usually carried out either under local anesthesia with sedation as part of monitored anesthesia care (MAC) or under general anesthesia [2,3]. However, patients undergoing middle ear surgery often experience discomfort due to surgical manipulation, suction noise, and head

positioning, making adequate sedation and analgesia essential for patient comfort and surgical conditions [4].

Monitored anesthesia care aims to provide sedation, anxiolysis, and analgesia while maintaining stable cardiovascular and respiratory function, with the ability to rapidly adjust the depth of sedation when required [5,6]. A major concern during MAC is respiratory depression, which remains one of the most serious anesthesia-related complications; therefore, the ideal sedative should

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ensure adequate sedation without compromising airway patency and ventilation [7].

Propofol is widely used in MAC due to its rapid onset, smooth recovery, antiemetic effects, and predictable sedation profile [8,9]. However, its use is limited by dose-dependent respiratory depression and hypotension, which may affect patient safety in certain clinical situations [10,11].

Dexmedetomidine, a selective α_2 -adrenergic agonist, provides sedation and analgesia with minimal respiratory depression, making it particularly useful in MAC settings [12]. However, its sympatholytic action may lead to bradycardia and hypotension, especially at higher doses [13]. Accordingly, this study was designed to compare the efficacy and safety of dexmedetomidine versus propofol in patients undergoing tympanoplasty under MAC.

METHODS

This prospective, randomized, double-blind controlled study was conducted after approval from the institutional ethics committee. Sixty adult patients of either sex, aged 18–60 years, with ASA physical status I–II undergoing tympanoplasty under local anesthesia with sedation were included after obtaining written informed consent. Patients with allergy to study drugs or lignocaine, pregnant or lactating females, those on sedatives or opioids within one week prior to surgery, and those with altered pain perception were excluded. All patients underwent preoperative evaluation and counselling regarding the procedure and sedation plan.

Patients were randomly allocated into two equal groups using a computer-generated randomization sequence: **Group D (dexmedetomidine)** and **Group P (propofol)**. Allocation concealment and blinding were maintained; the anaesthesiologist administering sedation, the patient, the surgeon, and the PACU assessor were blinded to group assignment. Study drugs were prepared by an independent anaesthesiologist not involved in patient care or data collection.

All patients received premedication with glycopyrrolate (4 μ g/kg IV) and fentanyl (1 μ g/kg IV). Group D received a dexmedetomidine loading dose of 1 μ g/kg over 10 minutes followed by an infusion of 0.4 μ g/kg/h. Group P received a propofol bolus of 0.75 mg/kg followed by an infusion at 0.025 mg/kg/min. Sedation depth was assessed using the Ramsay Sedation Score (RSS), and the target was maintained at RSS = 3. Sedation was titrated accordingly throughout the procedure. Local anesthesia was administered by the surgeon using 2% lignocaine with adrenaline (1:200,000) for auriculotemporal and great auricular nerve blockade. Intraoperative pain was assessed using the visual analogue scale (VAS), and rescue fentanyl (1 μ g/kg IV) was administered if VAS $\geq$ 3 or if patient movement occurred. Hemodynamic parameters including heart rate (HR), mean arterial

pressure (MAP), respiratory rate (RR), oxygen saturation (SpO₂), and end-tidal CO₂ (EtCO₂) were recorded at predefined intervals throughout surgery and in the PACU for 2 hours.

Adverse events such as bradycardia, hypotension, bradypnea, desaturation, nausea, vomiting, and dry mouth were recorded and managed as per standard protocol. Bradycardia was treated with atropine, hypotension with IV fluids or mephentermine, and desaturation with supplemental oxygen. Excessive sedation (RSS >5) necessitated conversion to general anesthesia.

Postoperative pain was assessed using VAS, and rescue analgesia (fentanyl 1 μ g/kg IV) was administered when VAS >3. Recovery was evaluated using the Aldrete score at regular intervals until a score of 10 was achieved, and time to reach this score was recorded.

Sample size calculation was based on previous literature [14], assuming a standard deviation of 1.1, 80% power, and 5% alpha error to detect a difference of one sedation score between groups, yielding a requirement of 30 patients per group. However, a larger sample was included to improve the robustness of results.

Data were analysed using SPSS version 19. Quantitative variables were expressed as mean $\pm$ standard deviation, and categorical variables as frequency and percentage. Z test and Chi-square test were used for intergroup comparisons, with $p < 0.05$ considered statistically significant.

RESULTS

A total of 60 patients undergoing tympanoplasty were randomly allocated into Group D (dexmedetomidine) and Group P (propofol). Both groups were comparable in demographic profile, surgical characteristics, and baseline hemodynamic parameters, with no statistically significant differences.

Table 1: Demographic parameters of the patients.

Parameter	Group D (Mean $\pm$ SD)	Group P (Mean $\pm$ SD)	P value
Age (years)	28.83 $\pm$ 8.82	32.25 $\pm$ 11.21	0.51
Female : male (%)	13(43.3%):17(56.7%)	17(56.7%):13(43.3%)	0.43
Weight (kg)	55 $\pm$ 6.4	55.4 $\pm$ 6.3	0.82
ASA 1: 2	25(83.3%):5(16.7%)	24(80.0%):6(20.0%)	0.73
Duration of surgery	122 $\pm$ 22.2	121.5 $\pm$ 26.8	0.93
Left ear: Right	15(50%):15(50%)	17(56.7%):13(43.7%)	0.60

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Ear			
Baseline			
vitals	85.87±10.03	88.37±8.44	0.3
HR	91.7±7.48	90.8±8.3	0
MAP	99.8±0.41	99.87±0.38	0.7
SPO ₂			5
			0.4
			9

Values are expressed as Mean ± Standard Deviation (SD) or number (%). A p-value <0.05 was considered statistically significant. ASA = American Society of Anesthesiologists; Group D = Dexmedetomidine group; Group P = Propofol group

The mean age (p = 0.51), gender distribution (p = 0.43), body weight (p = 0.82), ASA status (p = 0.73), duration of surgery (p = 0.93), and laterality of surgery (p = 0.60) were similar between the groups. Baseline heart rate, mean arterial pressure, and oxygen saturation were also comparable (p > 0.05 for all).

Table 2: Comparison of Intraoperative Hemodynamic Parameters Between Dexmedetomidine (Group D) and Propofol (Group P) During Tympanoplasty Under Monitored Anesthesia Care

Variable	Time	Group D (Mean±SD)	Group P (Mean±SD)	P value
Hear rate (bpm)	Baseline	85.87 ±10.03	88.37 ±8.44	0.30
	5min	84.10±10.37	87.57 ±7.25	0.17
	10 min	85.03±9.69	85.10±7.68	0.97
	15 min	82.47 ±11.03	83.80 ±8.67	0.60
	30 min	78.90±10.34	79.93±8.15	0.66
	60 min	73.77±10.55	78.03±7.82	0.08
	90 min	70.03 ±9.49	75.70±7.76	0.01
	120 min	67.83 ±8.80	72.67 ±6.66	0.007
MAP (mm Hg)	Baseline	91.70 ±7.48	90.80±8.30	0.75
	5min	89.13±6.46	88.70 ±8.33	0.82
	10 min	86.43±8.39	85.57 ±8.18	0.68
	15 min	84.57 ±7.91	82.73 ±7.87	0.37
	30 min	82.43±6.89	81.17±8.05	0.51
	60 min	82.37 ±7.43	80.27±6.97	0.26
	90 min	82.27±5.81	78.60±7.06	0.03

	120 min	80.73±6.03	81.80±6.05	0.45
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Values are expressed as mean ± standard deviation. Intergroup comparison was performed using appropriate statistical tests. p < 0.05 was considered statistically significant.

Both groups showed a gradual decline in heart rate and mean arterial pressure during surgery. Heart rate was significantly lower in the dexmedetomidine group at 90 min (p = 0.01) and 120 min (p = 0.007), indicating better sympathetic attenuation. Mean arterial pressure remained comparable between groups at most time points, with a significant difference only at 90 min (p = 0.03). Overall, dexmedetomidine provided slightly better late intraoperative hemodynamic stability compared to propofol.

Table 3: Comparison of Intraoperative and Postoperative Ramsay Sedation Scores Between Dexmedetomidine (Group D) and Propofol (Group P) During Tympanoplasty Under Monitored Anesthesia Care

Variable	Time	Group D (Mean±SD)	Group P (Mean±SD)	P value
Ramsey sedation scores intraoperatively	Baseline	1.0 ± 0.0	1.0 ± 0.0	1.0
	5min	1.27 ± 0.45	1.30 ± 0.47	0.77
	10 min	1.87 ± 0.35	1.67 ± 0.48	0.06
	15 min	2.03±0.41	2.10±0.31	0.49
	30 min	2.27±0.45	2.27±0.41	0.54
	60 min	2.73±0.52	2.43±0.50	0.03
	90 min	3.03±0.32	2.73±0.47	0.002
	120 min	3.27±0.52	2.87 ±0.51	0.004
Ramsey sedation scores postoperatively	Baseline	2.97±0.32	2.87±0.35	0.25
	5min	2.47±0.51	2.33±0.55	0.36
	10 min	2.00±0.26	2.00±0.26	1.00
	15 min	1.83±0.38	1.87±0.35	0.72
	30 min	1.40±0.51	1.50±0.50	0.44
	60 min	1.10±0.31	1.17±0.38	0.45
	90 min	3.03±0.32	2.70 ±0.47	1.00
	120 min	3.27±0.53	2.87±0.52	1.00

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Values are expressed as mean $\pm$ standard deviation. Intergroup comparison was performed using appropriate statistical tests. $p < 0.05$ was considered statistically significant.

Intraoperatively, Ramsay Sedation Scores were comparable between both groups in the early period; however, Group D showed significantly higher sedation levels at 60 min ($p = 0.03$), 90 min ($p = 0.002$), and 120 min ($p = 0.004$), indicating deeper and more sustained sedation with dexmedetomidine compared to propofol.

Postoperatively, sedation scores were similar between groups at all time points with no statistically significant differences, suggesting comparable recovery profiles after discontinuation of study drugs.

Table 4: Comparison of Postoperative Outcomes Between Dexmedetomidine (Group D) and Propofol (Group P) in Tympanoplasty Under Monitored Anesthesia Care

Variable	Group D (n = 30)	Group P (n = 30)	P Value
VAS Score postoperatively	2.5 $\pm$ 1.7	2.4 $\pm$ 1.8	0.82(NS)
Postoperative Rescue Analgesic Requirement (VAS > 4), n (%)	13 (43.3%)	12 (66.7%)	0.79(NS)
Time to Achieve Aldrete Score of 10 (min)	12.4 $\pm$ 2.4	11.8 $\pm$ 1.8	0.28 (NS)
Patient Satisfaction Score (5–7), n (%)	20 (80.0%)	18 (60.0%)	0.59 (NS)
Surgeon Satisfaction Score (5–7), n (%)	18 (73.3%)	16 (53.3%)	0.79 (NS)

Values are expressed as mean $\pm$ standard deviation or number (percentage). Intergroup comparison was performed using appropriate statistical tests. $p < 0.05$ was considered statistically significant. NS = not significant.

Postoperative outcomes were comparable between both groups. VAS scores, rescue analgesic requirements, time to achieve Aldrete score of 10, and both patient and surgeon satisfaction scores showed no statistically significant differences between dexmedetomidine and propofol groups ($p > 0.05$ for all). Overall, both drugs demonstrated similar efficacy in terms of postoperative analgesia, recovery profile, and satisfaction outcomes.

DISCUSSION

This study demonstrated that dexmedetomidine, when used to achieve sedation levels comparable to propofol during tympanoplasty under local anesthesia with monitored anesthesia care, provided similar hemodynamic stability and preserved adequate respiratory function. The time

to discharge from the post-anesthesia care unit was also comparable between both groups. However, dexmedetomidine showed better analgesic efficacy while patient satisfaction and surgeon satisfaction with the level of sedation was similar in both groups.

Dexmedetomidine has been shown to be a safe and effective agent for procedural sedation in monitored anesthesia care and has been successfully used in various ENT procedures^[15–16]. Middle ear surgeries present unique challenges due to the need for a motionless field and the risk of bleeding associated with sympathetic stimulation and patient anxiety, both of which can compromise surgical precision and graft success. Local anesthesia with appropriate sedation in tympanoplasty offers advantages such as intraoperative hearing assessment, early detection of complications, and faster recovery. However, middle-ear surgery requires a still and precise operative field, and inadequate sedation or anxiety can lead to sympathetic stimulation, patient movement, increased bleeding, and potential graft failure. Therefore, careful patient selection, proper preoperative counseling, and optimal sedation techniques are essential for the safe and successful performance of tympanoplasty under local anesthesia with monitored anesthesia care..^[17]

We selected a loading dose of dexmedetomidine 1 μ g/kg based on previously published literature and established clinical studies^[18]. Evidence suggests that at low to moderate doses administered with slow infusion rates, dexmedetomidine predominantly activates α_2 -adrenergic receptors, producing sedation and analgesia without significant α_1 -mediated adverse effects^[19]. Considering its relatively short distribution half-life, dexmedetomidine is best administered as a continuous infusion in dose of 0.2–0.8 μ g/kg/h. Since the procedures were performed under local anesthesia, this dosing range was chosen to maintain adequate sedation while also providing additional analgesia and reducing the need for rescue fentanyl.

For the propofol group, we used an intravenous loading dose equivalent to 0.75 mg/kg over 10 minutes followed by a maintenance infusion of 0.025 mg/kg/min throughout the procedure. Sedation in both groups was titrated to a predefined target end point of Ramsay Sedation Score (RSS) of 3 to ensure uniform depth of sedation during comparison.

The primary objective of this study was to compare the hemodynamic and respiratory effects of dexmedetomidine and propofol. At comparable sedative doses, both drugs produced a significant and similar reduction in heart rate and mean arterial pressure from baseline. These findings are consistent with previous studies, including Kaygusuz et al., who reported similar

hemodynamic responses during sedation with dexmedetomidine or propofol [20]. Propofol is known to suppress sympathetic outflow, contributing to reductions in blood pressure and heart rate [19], while dexmedetomidine exerts similar effects through central sympatholysis and reduction in circulating catecholamines [21]. The observed bradycardia with dexmedetomidine may also be explained by its Vago mimetic action in addition to sympathetic inhibition [22].

Regarding respiratory function, dexmedetomidine maintained stable ventilation without clinically significant respiratory depression. Similar findings have been reported by Hsu et al., who demonstrated preserved respiratory drive during dexmedetomidine sedation, with arousal responses contributing to increased ventilation during hypercapnia [23]. This effect is thought to resemble natural sleep physiology, where hypercapnia triggers arousal and increased respiratory effort. Dexmedetomidine acts on α_2 -adrenergic receptors located in multiple areas of the central nervous system, including the locus coeruleus, which plays a key role in sleep and arousal regulation [24]. Consequently, hypercapnia-induced activation of respiratory centres remains preserved during dexmedetomidine sedation, which explains its favourable respiratory safety profile. Similar observations have also been reported by Ebert et al., confirming minimal respiratory depression with dexmedetomidine sedation [19].

We observed respiratory outcomes similar to those reported by Ghali et al. and Arain and Ebert, where dexmedetomidine and propofol provided comparable respiratory safety profiles during procedural sedation [25]. However, Kaygusuz et al. reported a lower respiratory rate and higher SpO₂ in the dexmedetomidine group compared with propofol, suggesting better respiratory stability with dexmedetomidine in their study population [20]. These differences may be attributed to variations in drug dosing regimens, adjunct opioid use, and differences in procedural stimulation. It is also well established that sedative doses of propofol have minimal effects on tidal volume and minute ventilation, with negligible changes in end-tidal CO₂ and arterial blood gases [26].

In the postoperative period, both groups showed similar recovery profiles, with no significant difference in time to achieve an Aldrete score of 10. However, dexmedetomidine demonstrated better analgesic efficacy as reflected by lower VAS scores, although this was not clinically significant as pain scores remained below 4 in both groups. The analgesic-sparing effect of dexmedetomidine is well documented, likely due to its action on α_2 -adrenergic receptors [27]. Its relatively longer half-life also contributes to sustained postoperative analgesia [28]. This results in continued postoperative analgesic benefit without delaying

recovery or discharge. Similar findings of improved analgesia with comparable recovery times have also been reported by Arain and Ebert. [13]

Another important finding of our study was that surgeon satisfaction with the level of sedation was comparable between the dexmedetomidine and propofol groups, indicating that both agents provided equally acceptable operative conditions. In the dexmedetomidine group, sedation was associated with stable patient cooperation and a still surgical field, which is essential for the delicate nature of tympanoplasty.

Overall, monitored sedation for tympanoplasty under local anesthesia remains a challenging aspect for anesthesiologists. While benzodiazepines may cause respiratory depression and confusion, particularly in elderly patients [29], and opioids are associated with an increased risk of respiratory depression and apnea leading to oxygen desaturation [23], propofol continues to be widely used due to its favorable recovery profile and relatively stable cardiorespiratory effects [13].

This study compared dexmedetomidine, a highly selective α_2 -adrenergic agonist, with propofol for sedation in patients undergoing tympanoplasty under local anesthesia. We found that dexmedetomidine provided sedation equivalent to propofol in terms of hemodynamic stability, respiratory safety, PACU discharge time, and surgeon satisfaction. In addition, it offered better analgesic properties and comparable patient satisfaction.

In conclusion, dexmedetomidine appears to be a valuable alternative sedative agent and useful adjuvant for monitored anesthesia care in tympanoplasty, providing effective sedation with good safety and analgesic benefits.

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