

# A Comparative Evaluation of Dexmedetomidine and Midazolam in Monitored Anaesthesia Care for Tympanoplasty

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## Abstract

**Introduction:** Monitored Anaesthesia care (MAC) has been defined by the American Society of Anaesthesiologists as a diagnostic or therapeutic procedure done under local anaesthesia along with sedation and analgesia. Advantages of performing tympanoplasty under MAC with local anaesthesia are less bleeding, improved post-operative analgesia, early and smooth recovery and discharge from hospital with least expenditure. The biggest advantage is intra-operative communication and assessment of hearing in the patient.

**Aim:** The study was done to evaluate the efficacy of dexmedetomidine and midazolam for intra-operative sedation and analgesia in monitored anaesthesia care and to compare and assess any adverse effects in different groups of study.

**Methodology:** The study was conducted in the Department of Anaesthesiology, Gandhi Medical College and Hamidia Hospital, Bhopal on ASA Grade I and II patients scheduled for tympanoplasty. 90 patients of either sex of ASA Grade I and II, aged between 16 and 40 years were studied. All patients were premedicated with injection glycopyrolate 0.01mg/kg IV and Inj pentazocine 0.3 mg/kg over 1 min. Group A received Dexmedetomidine: Bolus dose 1mcg/kg IV followed by 0.4mcg/kg per hour, and Group B received Midazolam: Bolus dose of 0.04 mg given over 1 min. Oxygen supplementation through nasal catheter was given. Sedation was titrated to Ramsay Sedation score of  $\geq 3$ . Rescue sedation with Midazolam 0.01mg/kg was given if RSS was  $< 3$ . Surgery was allowed to commence when Visual Analogue Scale (VAS) was  $< 3$ . Sedation was assessed using Ramsay sedation Scale.

**Result and Conclusion:** Sedation with Dexmedetomidine was found to be better alternative to midazolam in monitored anaesthesia care performed in minor ENT surgical procedures. It provides a calm sedated patient. Also, fall in the HR and MAP was seen in more number of patients of Group A than in Group B. This caused decreased bleeding, thus providing bloodless surgical field comfortable for the surgeon.

**Keywords:** Dexmedetomidine; Midazolam; Monitored Anaesthesia Care; Tympanoplasty.

## Introduction

Monitored anaesthesia care includes sedation, anxiolysis and analgesia [1]. A number of diagnostic and therapeutic procedures are performed under MAC including Middle ear surgeries (MESS)

Advantages of performing tympanoplasty under MAC with local anaesthesia are less bleeding, improved post-operative analgesia, early and

smooth recovery and discharge from hospital with least expenditure [2]. The biggest advantage is intra-operative communication and assessment of hearing in the patient.

Commonly used medication for MAC are benzodiazepine opioids and propofol [3]. The aim of this study was to assess the efficacy of two different drugs viz Dexmedetomidine [4] and Midazolam for use in MAC with respect to sedation, haemodynamics, effect on respiration and need for

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rescue analgesia. Assessment of patient satisfaction and surgeon satisfaction were secondary aims. Analgesic property of  $\alpha_2$  agonists like dexmedetomidine with its opiate-sparing properties has been documented by studies carried by Smith H et al [5] and has also been reported in studies conducted in general anesthesia with dexmedetomidine by Keniya [6].

### Materials and Methods

A prospective comparative study was conducted in the Department of Anaesthesiology, Gandhi Medical College and Hamidia Hospital, Bhopal on ASA Grade I and II patients scheduled for tympanoplasty. After thorough physical examination and investigation, and informed written consent from patients, 90 patients of either sex of ASA Grade I and II, aged between 16 and 40 years were categorised randomly into 2 groups viz:

- I. *Group A*: Dexmedetomidine group: Bolus dose 1mcg/kg IV followed by 0.4mcg/kg per hour maintenance dose was used for MAC.
- II. *Group B*: Midazolam group: Bolus dose of 0.04 mg given over 1 min.

A fasting status of 6 hours was maintained. Monitoring of NIBP, ECG, SpO<sub>2</sub> and capnography were done. IV fluid was given through IV cannula. All patient were premedicated with injection glycopyrolate 0.01mg/kg IV and Inj pentazocine 0.3

mg/kg over 1 min. Group A received Dexmedetomidine: Bolus dose 1mcg/kg IV followed by 0.4mcg/kg per hour, and Group B received Midazolam: Bolus dose of 0.04 mg given over 1 min. Oxygen supplementation through nasal catheter was given. Sedation was titrated to Ramsay Sedation score of  $\geq 3$ . Rescue sedation with Midazolam 0.01mg/kg was given if RSS was  $< 3$ . After positioning, painting and draping, local anaesthetic infiltration was performed by the operating surgeon using 2% Lignocaine with adrenaline. Surgery was allowed to commence when Visual Analogue Scale (VAS) was  $< 3$ . Rescue analgesia was provided with IV infusion of Paracetamol 1g in case of intra-operative pain (VAS  $> 3$ ). Patients were kept in PACU for 3 hrs after the end of surgery. The intensity of post operative pain was recorded for all patients using VAS scale at 1, 1.5, and 2, 2.5 and 3 hrs. after surgery. Patients were also observed for adverse effects like hypotension, bradycardia, respiratory depression, nausea and vomiting. Sedation was assessed using Ramsay sedation Score [7].

### Result

*The patient characteristics were as shown in the table*

Table 1 shows that mean age in years of study participants in group A was 25.23 $\pm$  5.2 while that of group B was 26.5 $\pm$ 4.8 years. P value was calculated for gender which came out to be non significant.

**Table 1:**

Study variables		Dexmedetomidine (Group A) (n=45)	Midazolam (Group B) (n=45)	P value
	Mean age	25.23 $\pm$ 5.2	26.5 $\pm$ 4.8	
Gender	Male	15	11	>0.05
	Female	30	34	
BMI	Underweight	14	13	>0.05
	Normal	27	29	
	Preobese/ Obese	4	3	
Duration of surgery (min)		90	97	

**Table 2:**

Parameter	Number of Patients		P value
	Dexmedetomidine (Group A) (n=45)	Midazolam (Group B) (n=45)	
Fall in MAP	21	12	<0.05
Fall in HR	18	2	<0.05
Rescue Analgesia	2	7	<0.05

**Table 3:**

Parameter	Dexmedetomidine (Group A) (n=45)	Midazolam (Group B) (n=45)	P value
Ramsay Sedation Score	3.42 $\pm$ 0.27	3.03 $\pm$ 0.21	<0.05

Group A had a greater number of patients who had fall in MAP i.e 21 out of 45, than group B in which 12 out of 45 patients showed fall in MAP. Group A patients had significant reduction in MAP from the respective baseline values.

The mean sedation score in group A was  $3.42 \pm 0.27$  and that in group B was  $3.03 \pm 0.21$  p value observed was  $< 0.05$  hence it was significant.

## Discussion

Monitored anesthesia care (MAC) is useful for various clinical fields such as minimally invasive surgery, gastrointestinal endoscopy, and interventional or radiological procedures. It not only provides appropriate intra operative conditions but is also comfortable for the patients. Advantages of performing tympanoplasty under MAC with local anaesthesia are less bleeding, improved post-operative analgesia, early and smooth recovery and discharge from hospital with least expenditure. The biggest advantage is intra-operative communication and assessment of hearing in the patient.

Group A patients had significant reduction in MAP and HR from the respective baseline values. Also, more number of patients of Group A (18 out of 45) had fall in MAP than of group B (12 out of 45 patients). This lower HR and MAP in Group A in comparison to the midazolam-fentanyl group could be explained by the markedly decreased sympathetic activity as previously explained in the study carried by Kamibayashi et al [8].

Dexmedetomidine is a highly selective  $\alpha_2$ -adrenoceptor agonist with eight times higher specificity for the receptor compared to clonidine [9]. It provides excellent sedation and analgesia with minimal respiratory depression [10].

Dexmedetomidine can be safely and effectively used for procedural sedation and surgeries done under MAC.

Since the approval of Midazolam by FDA in 1985, practitioners of all medical disciplines embraced the versatility provided by Midazolam though the risk of losing airway control, hypoxia and hypotension with higher doses of Midazolam has also been recognized [11].

Midazolam is the most frequently used sedative and has been reported to be well tolerated when used in MAC [12]. Dexmedetomidine has both sedative and analgesic properties and has been used as a single agent in many painful procedures [13]. A loading dose of 1 mcg/kg of Dexmedetomidine

was used in our study. Since dexmedetomidine has a short distribution half life of 5 min., it is necessary that the loading dose is followed by a maintenance dose of 0.4 mcg/kg per hour.

A prospective randomized double-blind study which was conducted by Parikh DA et al comparing dexmedetomidine vs. combination of midazolam-fentanyl for tympanoplasty surgery under monitored anesthesia care also showed a similar results [14]. Another study conducted by Na HS, Song IA et al. showed Dexmedetomidine to be effective for monitored anesthesia care in outpatients undergoing cataract surgery [15].

Dexmedetomidine is unique in that it does not cause respiratory depression because its effects are not mediated by the  $\gamma$ -aminobutyric system [16]. However, Alhashemi et al. [17], had observed a higher ventilatory frequency in patients receiving midazolam in their comparative study of dexmedetomidine with midazolam for cataract surgery. Zeyneloglu et al [18] have reported better sedation scores with midazolam-fentanyl combination as compared to dexmedetomidine in extracorporeal shock wave lithotripsy (ESWL) when used alone.

## Conclusion

The fall in heart rate and mean arterial as well as sedation were more in the patients of Group A than that of the patients in Group B. This caused decreased bleeding in Group A patient, thus providing blood less surgical field comfortable for the surgeon.

Hence, our study concludes that in case of monitored anaesthesia care performed for minor ENT surgeries, dexmedetomidine appears to be a superior alternative to midazolam.

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