

**Original article****A COMPARATIVE OBSERVATIONAL STUDY BETWEEN DEXMEDETOMIDINE V/S COMBINATION OF MIDAZOLAM-FENTANYL FOR TYMPANOPLASTY SURGERY UNDER MONITORED ANESTHESIA CARE**

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**Abstract:**

**AIMS AND OBJECTIVES:** Comparison of efficacy of dexmedetomidine v/s combination of midazolam-fentanyl during monitored anaesthesia care in tympanoplasty with special emphasis on the sedative properties and the effectiveness of sedation, the number of doses of rescue analgesics given and the haemodynamic parameters measured. **MATERIALS AND METHOD:** 60 patients aged between 15-60 years undergoing tympanoplasty under local anaesthesia were divided into Group A patients received intravenous dexmedetomidine in the dose of 1µg/kg over 10 minutes and group B patients received combination of intravenous midazolam 0.02mg/kg and 1µg/kg fentanyl over 10 minutes. Sedation was titrated to Ramsay sedation score (RSS) of three. Vital parameters, intra operative pain intensity by visual analogue scale (VAS) >3, rescue analgesic given if required in the form of fentanyl 1µg/kg was recorded. **RESULTS:** The mean sedation score in group A is 3.18 ± 0.19 and in group B is 3.03 ± 0.21 (p>0.05). Intra operative heart rate and mean arterial pressure in group A were lower than the base line values and the corresponding values in group B (p<0.05). Group A patients have less requirement of rescue analgesic as compared to the midazolam-fentanyl group (40%). **CONCLUSION:** Dexmedetomidine and combination of Midazolam fentanyl were comparable in the effectiveness of sedation. The lesser requirement of rescue analgesics and decrease in MAP facilitating improved surgical field makes Dexmedetomidine a better choice due to sedative effect and control over hemodynamics in ENT surgical procedures.

**Keywords:** Dexmedetomidine, fentanyl, tympanoplasty, monitored anaesthesia care.

**INTRODUCTION:**

Monitored anaesthesia care involves administering a combination of drugs for hypnotic, analgesic, anxiolytic and amnestic effect. Monitored anaesthesia care provides less physiological disturbance and allow more rapid recovery than general anaesthesia. It involves administration of local anaesthesia in combination with I.V. sedatives, anxiolytic and analgesic drugs. Tympanoplasty is an ENT surgical procedure which involves reconstruction of perforated tympanic membrane with or without ossiculoplasty. Patients may feel discomfort due to pain, noisy suction, manipulation of instruments and head and neck position. Advantages of monitored anaesthesia care (MAC) are less bleeding, cost effectiveness, postoperative analgesia, faster mobilization of the patient and the ability to test hearing intra operatively.

Commonly used medications for MAC are benzodiazepines, opioids and propofol. Midazolam with its quick onset, but a relatively long half-life causes good sedation in combination with opioids like fentanyl.

Dexmedetomidine is a selective  $\alpha_2$  receptor agonist with properties of analgesia, sympatholysis and titrating sedation without major respiratory depression. It reduces opioid requirements and stress response to surgery ensuring a stable hemodynamic state. Dexmedetomidine is increasingly being used as a sedative for MAC for various surgical procedures.

This study compares dexmedetomidine with a combination of midazolam-fentanyl in patients undergoing tympanoplasty under local anesthesia (LA) with primary end point being the patient satisfaction score with stable hemodynamics. The need of intra operative rescue analgesics to maintain a cooperative state of the patient was the secondary end point.

#### **MATERIAL AND METHODS:**

This comparative observational study was undertaken after Institutional Review Board approval. The present study was conducted on sixty patients of American Society of Anaesthesiologist grade I and II between 15 – 60 years of either sex scheduled for tympanoplasty. All the patients were examined a day before surgery. They were counseled with regards to sedation, local anesthesia as well as the operative procedure. Data was then collected of these patients for the study.

All sixty patients were divided into two groups with thirty patients in each group. Group A had patients who had received intravenous dexmedetomidine in the dose of  $1\mu\text{g}/\text{kg}$  over 10 minutes and group B had patients who had received combination of intravenous midazolam  $0.02\text{mg}/\text{kg}$  and  $1\mu\text{g}/\text{kg}$  fentanyl over 10 minutes. During this period the patients were assessed every two minutes using Ramsay sedation score (RSS (1 = agitated, restless; 2 = cooperative, tranquil; 3 = responds to verbal command while sleeping; 4 = brisk response to gabelar tap or loud voice while sleeping; 5 = sluggish response to gabelar tap or loud voice; 6 = no response to gabelar tap or loud voice). The target end point was a patient having RSS = 3.

Children, mentally unstable patients, uncooperative patients, patients requesting general anesthesia, patients with known sensitivity to local anesthetic drug Lignocaine, allergy to study drugs, pregnant and lactating females were excluded from the study.

On arrival to the operation theatre, baseline vital parameters of the patient were recorded using ECG monitor, pulse oximetry and blood pressure monitoring. An intravenous cannula was inserted and i.v. fluid started. All the patients received injection Glycopyrrolate  $0.2\text{mg}$  intravenously as a premedication.

Adverse events like tachy/bradycardia, hyper/ hypotension (deviation of HR, MAP >20% of baseline), bradypnea (RR < 90%), nausea, vomiting, dry mouth or any other event during or within two hours after the procedure were noted. Bradycardia was treated with intravenous Atropine sulphate  $0.01\text{mg}/\text{kg}$  and hypotension with fluid resuscitation. De-saturation was treated by administration of O<sub>2</sub> by mask up to 6 liters/min.

After the completion of surgery patients were shifted to the Post Anaesthesia Care Unit and were monitored for hemodynamic parameters, degree of analgesia and adverse events if any for 2 h. RSS was assessed immediately on arrival in the Post Anaesthesia Care Unit and every 30 min thereafter till transfer to surgical ward. Requirement of postoperative analgesia was noted. The first rescue dose of analgesic was given at VAS >3 and was documented. Surgeons were asked to grade the surgical conditions as well as their satisfaction with sedation technique on numerical rating scale (NRS) with zero being least satisfied and 10 being most satisfied. Patients were asked to

grade their overall satisfaction with the procedure on a similar numerical scale (NRS 0-10) on postoperative Day one in the surgical ward.

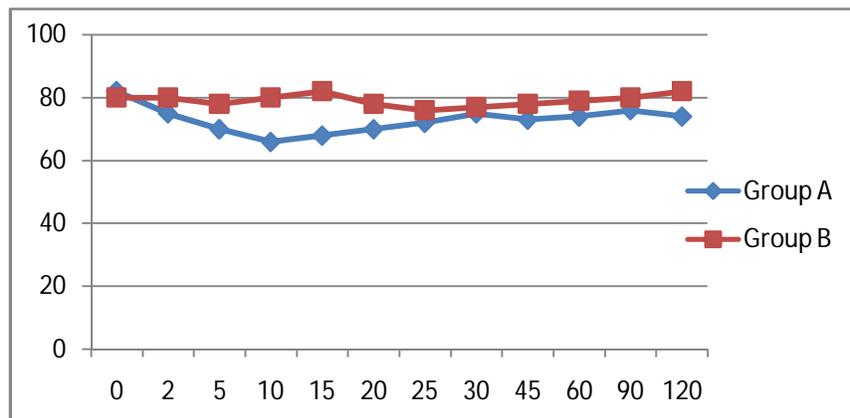
The primary end point of our study was the patient satisfaction score using NRS from 0 to 10. Efficacy of the sedation technique was defined as the ability to complete the surgery without any rescue sedatives and analgesics. Safety of the technique was determined based on the frequency of analgesia/sedation-related intra or postoperative adverse events.

**ANALYSIS:**

The patient’s characteristics and surgical data was compiled and statistically analyzed using SPSS software. Continuous variables were presented as mean+/-SD. Categorical variables were expressed as frequencies. Analysis of variance (ANOVA) test was used for comparison of continuous variables among the groups. All tests were considered significant if P<0.05.

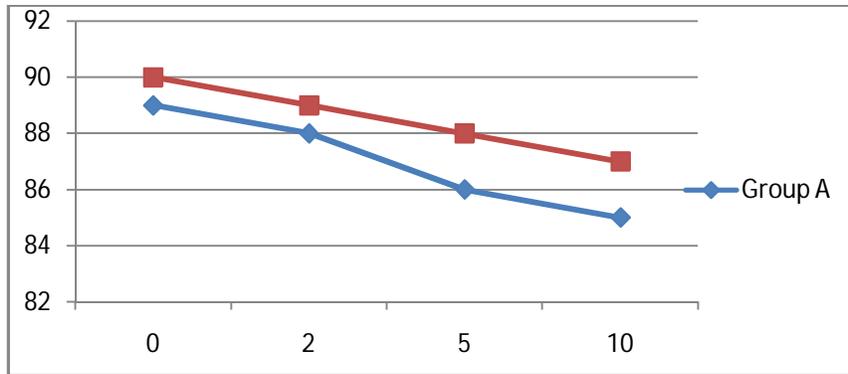
**RESULTS:**

Patient Characteristics	Group A (n=30)	Group B (n=30)
Age(year)	37 +/-17	38+/-12
Weight (kg)	55+/-4	58+/-7
Sex Male (n)	18	17
Female (n)	12	13



**Figure 1 Comparison of intraoperative heart rates**

Dexmedetomidine group shows more fall in pulse rate and systolic BP and diastolic BP than Fentanyl and midazolam combination at 30 sec, 60 sec, 90sec, 2min, 3min, 5min which is **statistically significant** at 95% confidence limit(p<0.05).



**Figure 2 Comparison of intra operative mean arterial blood pressure values**

Comparison of MAP at similar time intervals showed no significant difference between the two groups up to the 30<sup>th</sup> min after loading of the drug, subsequent to which Group A had a lower MAP till the end of surgery ( $P < 0.05$ ).

Group	Pre-op vitals			intra op vitals				Post op vitals	
	Pulse	Mean arterial pressure	Spo2					pulse	Mean arterial pressure
Group A	84.86+/-5	92.2+/-8	99+/-1	75+/-5	88+/-6	98.5+/-0.5	80+/-7	90+/-8	98+/-1
Group B	85+/-4	91+/-8	98+/-2	68+/-5	78+/-6	97+/-3	75+/-5	86+/-8	98+/-1

**Sedation Graph:**

Score	Group A	Group B
0	0	0
1	2	0
2	20	12
3	8	18

**RESULTS:**

Dexmedetomidine group shows more fall in pulse rate and systolic BP and diastolic BP than Fentanyl and midazolam combination at 30 sec, 60 sec, 90sec, 2min, 3min, 5min which is **statistically significant** at 95% confidence limit( $p < 0.05$ ).

There is no statistical difference found at 0sec.

Dexmedetomidine group shows longer sedation time than Fentanyl and midazolam combination at 30 sec, 60 sec, 90sec, 2min, 3min, 5min but it is **statistically NOT significant** at 95% confidence limit( $p > 0.05$ ).

There is no difference found in SpO<sub>2</sub> value between two groups.

Both the groups had patients of either gender and there was no statistical difference found as the P value was  $> 0.05$  (non-significant).

Inter-group comparison of MAP at similar time intervals showed no significant difference between the two groups up to the 30<sup>th</sup> min after loading of the drug, subsequent to which Group A had a lower MAP till the end of surgery ( $P < 0.05$ ).

## **DISCUSSION:**

Dexmedetomidine can be safely and effectively used for procedural sedation and surgeries done under MAC. Its use in other ENT surgeries like functional endoscopic sinus surgery (FESS), septoplasty, and thyroplasty under Monitored Anaesthesia Care has also been documented. Middle-ear surgeries pose a different set of challenges for the patient, surgeons and anesthesiologists. Sympathetic stimulation and movements of an anxious patient cause increased bleeding and disturb the fine microscopic nature of the surgery which may even lead to graft failure. The advantages of local anesthesia include testing hearing intra operatively, immediately detecting complications and a truncated postsurgical emergence. Good patient selection, preoperative counseling and use of appropriate sedation are important factors for success of this surgery under local anaesthesia.

The lower HR and MAP in Group A in comparison to the midazolam-fentanyl group could be explained by the markedly decreased sympathetic activity. Also, intra operatively Group B had more number of patients who complained of pain which was initially treated with infiltration of lignocaine 2% with adrenaline (when VAS  $< 4$ ). Our findings are similar to other studies where lower HR and MAP were observed in the dexmedetomidine group. These results suggest that dexmedetomidine has clinical advantage over midazolam in providing a better operative field for microscopic surgery. Our study demonstrated significantly higher patient and surgeon satisfaction scores with dexmedetomidine suggesting a difference in the quality of sedation of both the drugs.

Both the groups had significant reduction in MAP from their respective baseline values, however on analyzing the magnitude of decrease, patients in Group A had a greater fall (10-15%) in comparison to Group B (5-10%) over a period of time.

One patient in Group A developed hypotension and bradycardia after completing the loading of the drug which was successfully treated with intravenous atropine 0.6 mg and intravenous ephedrine 6mg. No patient in either group had any episode of hypertension. Respiratory rate and SpO<sub>2</sub> were comparable and within normal limits in both the groups ( $P > 0.05$ ). There was no episode of de-saturation in either group.

The lower HR and MAP in these patients could have probably resulted in a better surgical field thus attributing to better surgeon satisfaction. Moreover, surgeons are satisfied if there is no patient movement during surgery. Lesser number of patients (11.1%) receiving dexmedetomidine demanded rescue analgesics as compared to the midazolam-fentanyl group (40%).

#### **CONCLUSION:**

Based on RSS, surgeon and patient satisfaction scores; Dexmedetomidine and Midazolam-Fentanyl provided adequate analgesia and sedation in adult patients undergoing middle ear surgery under local anesthesia. Dexmedetomidine is a better alternative sedative than combination of Midazolam-Fentanyl in tympanoplasty as it provides calm sedated patients, stable hemodynamic effect and less bleeding so bloodless surgical field.

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