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# COMPARATIVE STUDY OF INTRAVENOUS DEXMEDETOMIDINE VS INTRAVENOUS MIDAZOLAM FOR SEDATION DURING TYMPANOPLASTY

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**ABSTRACT** **Background:** Tympanoplasty, a surgical procedure is performed under local anaesthesia. Various medications have been used for achieving adequate sedation during this procedure. Aim : The aim of present study was to compare i.v. dexmedetomidine with iv midazolam for sedation during tympanoplasty. **Materials And Methods:** This prospective, randomized control study was conducted by acquiring institutional ethics committee approval. Duration of study was 6 months. 100 patients were randomly selected for tympanoplasty who were divided in 2 categories- a) Group I: 50 Patients undergoing tympanoplasty under i.v. dexmedetomidine and b) Group II: 50 patients administered i.v. Midazolam before performing tympanoplasty. Inclusion criteria were- 1) subjects of either genders, 2) patients who satisfied ASA I or II criteria and 3) age between 18-60 years while the exclusion criteria were- 1) hypersensitivity reaction to lignocaine, 2) any drug allergies, 3) pregnant and/or lactating females, 4) patients on any analgesic medication and 5) patients with drug history of opioids or any other sedative medication use one week before scheduled surgery. Statistical analysis: Data analysis was done by SPSS Version 20.0 statistical software. Non-Normal dataanalysis was done by Mann Whitney 'U' test whereas Categorical data was tested by 'Chi-square' test. *P* value <0.05 was set as significant. **Results:** 1 patient in group I while 5 patients in group II were administered rescue analgesia. On analyzing patient satisfaction in both the study groups, median value of 8 (group I) while median score of 9 (group II) was observed using Ramsay sedation score with no ststistical difference (P=0.06). Comparison of surgeon's satisfaction scores gave median values of 7 and 8 (in group I and II, respectively) with no statistically significant difference (P=0.06). Mean ± S.D. duration (in minutes) required to achieve rescue analgesia post-surgery were 161.87 ± 98.12 minutes in Group I and 154.02 ± 101.2 minutes in Group II, respectively with no statistical significance (P=0.06). **Conclusion:** Present study found no statistical difference in i.v. dexmedetomidine when compared with i.v. midazolam.

**KEYWORDS :** Dexmedetomidine, midazolam, sedation, efficacy, tympanoplasty

## INTRODUCTION

Tympanoplasty is a surgical procedure involving the reconstruction of perforated tympanic membranes with or without performing ossiculoplasty. [1] Although, this surgical procedure is also used for managing middle ear cleft-associated pathologies, for example chronic infection or cholesteatoma and sometimes, any problem associated with ossicles. Tympanoplasty is generally performed under local anesthesia along with sedation under monitoring or under general anesthesia. [2,3] Patients might report with complaints like- pain, noise produced during suctioning, head and neck positioning during the procedure. [4]

Common medications that are used for monitoring during anesthetic care include- propofol, benzodiazepines and opioids. [5]

Midazolam, a imidazobenzodiazepine has rapid onset with relatively longer half-life which can result in prolongation of sedation following administration repeatedly. [6] Combination of midazolam with opioid analgesics causes an increase in risk of developing hypoxemia and/or apnea. [7] Adding propofol might result in cardio-respiratory depression during anesthetic care. [8]

It has typical properties of a benzodiazepine like- anticonvulsant, hypnotic, sedative, amnestic and anxiolytic. However, use of Midazolam has been associated with side effects such as- restlessness, amnesia paradoxical reactions, cognitive impairment and respiratory depression. [9,10] It induces sedation by activation of GABA receptors found in pontine locus ceruleus, an important part of sympathetic nervous system within forebrain.

Hence, newer drugs for example, α2-agonist agents are now used as alternative agents for intravenous sedation. Dexmedetomidine, a selective α2-receptor agonist exhibits properties such as- analgesia and sympatholysis with no respiratory depression. [9,10,11] Dexmedetomidine administration cause reduction in requirements of opioid drugs and responsiveness to stress caused by surgery thereby maintaining stable hemodynamics. [12,13] Dexmedetomidine, recently has been increasingly administered as sedative agent for Monitored anesthetic care following different surgeries due to its ability to maintain hemodynamic stability. [14,15,16,17]

There are various advantages of administering local anesthesia along with intra-venous sedative agents. These include- less amount of bleeding, low cost, better post-operative analgesia, fast patient mobilization and ability for testing one's hearing intra-operatively. [18] 'Monitored anaesthesia care' incorporates local anaesthetic along with intravenous sedative agents, anxiolytics and/or analgesics surgeries of ear, nasal passages and throat. [19]

Hence, this study was planned with an aim for comparing i.v. dexmedetomidine with iv midazolam for sedation during tympanoplasty.

## MATERIALS AND METHODS:

Study design and setting: This was a prospective, randomized controlled, double-blinded study conducted in Department of Anesthesiology at Dr Kiran C Patel Medical College , Bharuch. This study was undertaken following approval from institutional ethics committee. The duration taken for conducting this study was six months. Patient consent was taken after explaining the purpose of the study.

### Study Participants And Sampling:

Total 100 patients who were indicated for undergoing tympanoplasty under local anesthesia were randomly selected. Patients were then equally divided into two groups- a) Group I: 50 Patients who had to undergo tympanoplasty under intravenous dexmedetomidine and b) Group II: Patients (n.50) who were administered intravenous Midazolam before performing tympanoplasty.

### Sample Size Calculation:

Sample size was calculated was based upon population standardized deviation= 1.1 with 80% power and 5% α error. A sample of 47 subjects per group was obtained which was rounded off to 50.

Inclusion criteria: These were as follows- a) both genders, b) patients satisfying the American Society of Anesthesiologists (ASA) Grade I or II and c) age ranged between 18 to 60 years,

Exclusion criteria: These were- a) Patients who had known hypersensitivity to lignocaine, b) Patients who were allergic to drugs used in the study, c) pregnant and/or lactating females, d) patients who were prescribed with any analgesic drug and e) those patients who gave a drug history of opioid or any other sedative medication use one week before scheduled surgery.

Pre-operative procedure: Selected patients received medical examination one day prior to surgery. Counselling sessions related to Sedation procedure, local anesthesia and surgical procedure was done. Visual analogue scale (VAS) scoring system was explained to the

patient. Score '0' indicated- no pain whereas score '10' indicated maximum level of pain.

Observed data was noted by single blinded investigator. Study drugs preparation was done by an anesthesiologist who was not involved in the study.

Two syringes (50 ml) which were labeled as- a) 'loading' and b) 'maintenance' were provided for each of the patient. Group I patients received dexmedetomidine (1mcg/ kg) while Group II received midazolam ( 0.06 mg/ kg) each diluted to 30 ml normal saline.

Operative procedure: On arrival in operation theatre, patient's heart rate, respiratory rate, arterial blood pressure, level of oxygen saturation, and ECG were monitored. Intra-venous line was secured using a 20G cannula and Ringer's lactate solution at 2 ml/ kg. Oxygen administration was done via nasal cannula at a rate of 2 L/ min. In either of the study groups, no premedication with sedative agent was done.

Group I was given intravenous dexmedetomidine (1mcg /kg) for 10 minutes which was followed by continuous 0.2 mcg /kg/h infusion. The patients were then assessed at regular 2 minutes intervals by Ramsay sedation score where, score 1- agitated and restless; score 2 - co-operative and tranquil; score 3- patient responded to verbal commands when asleep; score 4- quick responsiveness to gabellar tapping or any loud sound when sleeping; score 5- slow response to gabellar tapping or loud command and score 6- no response to gabellar tap or loud voice.

Target end-point was patient with Ramsay Sedation Score - 3. If target end-point was achieved before the completion of loading infusion, further infusion was stopped. Maintenance dose infusion in both study groups was started immediately after stopping loading infusions. Intra-operative intensity of pain was assessed using the VAS score system.

Adverse reactions within two hours of surgery such as- like bradycardia, hypotension or hypertension, bradypnea, SpO2 level < 90%), dry mouth nausea or vomiting were then noted.

Post-surgery, patients were then monitored closely for hemodynamic parameters, analgesia degree and adverse reactions, for duration of 2 hours.

Ramsay Sedation Score was analyzed immediately after arrival in PACU at 30 minute interval until they were transferred to ward. For post-operative analgesia, first rescue analgesic dose was administered at Visual Analogue Scale >3.

Surgeons graded surgical as well as the sedation techniques used on a numerical rating scale ranging from zero (least satisfaction) to 10 (most satisfaction). Similar, patients graded their satisfaction over a similar numerical scale (NRS 0-10) postoperatively.

Primary outcome of present study was patients' satisfaction scoring system by means of Ramsay Sedation score and Efficacy of sedation technique was defined as 'surgeon's ability in completing a surgery with no rescue sedative agents and/or analgesics. Safety margin of technique was ascertained depending upon "frequency of analgesia or sedation-associated intra- or post-operative adverse reactions.

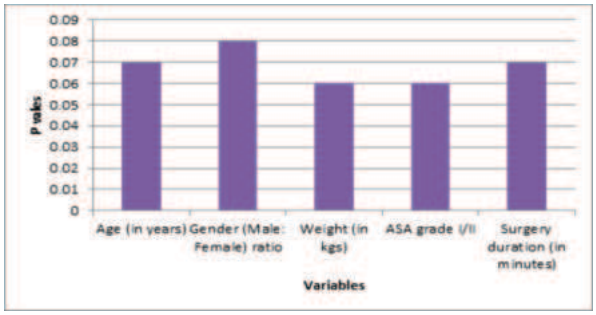
**Statistical Analysis:**
Analysis of collected data was performed by using SPSS Version 20.0 statistical software. Data pertaining to hemodynamics and respiratory system were analyzed by unpaired '*t*' test for inter-group while paired '*t*-test' was employed for intra-group comparisons. Non-Normal data was evaluated by Mann Whitney 'U' test while Categorical data was analyzed by 'Chi-square' statistical test. *P* value <0.05 was set as statistically significant.

## RESULTS AND OBSERVATIONS

Patient demographic data: On analyzing the mean ± S.D. age scores (in years), Group I patients were found to have 31.9 ± 1.59 while Group II patients had 30.18 ± 0.67 years with no statistically significant difference P=0.07). Gender distribution showed male-female ratio of 24:26 in Group I and 27:23 in Group II, respectively with no statistical significance (P=0.08). Mean ± S.D. weight (in kgs) was found to be 49.12 ± 1.12 and 56.21 ± 0.19 in Groups I and II, respectively. This was found to have no statistical significance (P=0.06). On comparing ASA I or II grades, 43 patients were in ASA I while 07 patients were of ASA II type, however, no statistically significant difference (P=0.06) was found. On comparing the mean ± S.D. duration of surgery in minutes, Group I patients underwent surgery for 80.21 ± 0.98 minutes while Group II subjects had undergone surgical procedure for 81.78 ± 0.94 minutes. On statistical analysis no significant difference in mean duration of surgery was fond between both the study groups (P=0.07). (table and graph 1)

**Table 1: Table Showing Patient Data**

| Study variables | Group I (mean ± S.D.) (i.v. dexmedetomidine) | Group II ((mean ± S.D.) (Midazolam) | P values |
|---|---|---|---|
| Age (in years) | 31.9 ± 1.59 | 30.18 ± 0.67 | 0.07 |
| Gender (Male: Female) ratio | 24:26 | 27:23 | 0.08 |
| Weight (in kgs) | 49.12 ± 1.12 | 56.21 ± 0.19 | 0.06 |
| ASA grade I/II | 43/07 | 42/08 | 0.06 |
| Surgery duration (in minutes) | 80.21 ± 0.98 | 81.78 ± 0.94 | 0.07 |

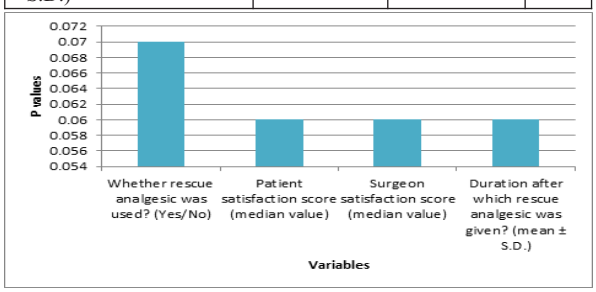



**Graph 1:** Graph showing P values obtained after evaluating Patient characteristics

On comparing the efficacy of i.v. Dexmedetomidine and i.v. Midazolam by analyzing rescue analgesic use and the duration following surgery after which rescue analgesia was used, only one patient in group I and five patients in group II were required to be administered rescue analgesia. On analyzing patient satisfaction in both the study groups, median value of 8 (group I) while median score of 9 (group II) was observed using Ramsay sedation score with no ststistical difference (P=0.06). On the other hand, on comparing surgeon's satisfaction scores, median values of 7 and 8 (in group I and II, respectively) with no statistically significant difference (P=0.06) was obtained. Mean ± S.D. duration (in minutes) required to achieve rescue analgesia post-surgery were 161.87 ± 98.12 minutes in Group I and 154.02 ± 101.2 minutes in Group II, respectively which was found to have no statistical significance (P=0.06) (table and graph 2).

**Table 2: Table Showing Rescue Analgesic Use And Time Duration For Administration In Study Groups**

| | Group I | Group II | P values |
|---|---|---|---|
| Whether rescue analgesic was used? (Yes/No) | 01/49 | 05/45 | 0.07 |
| Patient satisfaction score (median value) | 8 (6.5 to 9.5) | 9 (8.5 to 9.5) | 0.06 |
| Surgeon satisfaction score (median value) | 7 (5.5 to 8.5) | 8 (7.5 to 8.5) | 0.06 |
| Duration after which rescue analgesic was given? (mean ± S.D.) | 161.87 ± 98.12 | 154.02 ± 101.2 | 0.06 |




**Graph 2:** Graph depicting p values comparing different parameters in

studied groups

## DISCUSSION

Surgeries of middle-ear are challenging for patients, surgeons as well as anesthesiologists. Sympathetic nerve stimulation coupled with bodily movements by patient can result in an increase in bleeding which can result in fine microscopic surgeries leading towards failure of graft. Advantages of using local anesthetic agent include intra-operative hearing test and immediate detection of complications. Proper Selection of patient, pre-surgical counseling and appropriateness of sedative used and sedation technique constitute important factors underlying success of surgeries performed. [22,23]

Present prospective, cross-sectional study compared efficacy of intravenous Dexmedetomidine and Midazolam in patients who underwent tympanoplasty. No statistically significant differences in efficacy of both the sedative agents were observed when mean duration of time elapsed at which rescue analgesia was administered, number of patients who required the same, patients' and surgeons' satisfaction were compared. Our study findings are in contrst with that of Vyas et al (2013) who reported better satisfaction score in patients who were administered i.v. Dexmedetomidine than in patients who were give i.v. Midazolam before ndergoing tympanoplasty. [24] Similarly, Parikh et al in their study demonstrated that in patients who were on Dexmedetomidine sedation had used significant less amount of rescue drug, Tramadol when compared with patients who were given Midazolam. [25]

Although Dexmedetomidine when used as an adjunct with general anaesthesia in patients of tympanoplasty has been fond to reduce bleeding thus, providing a relatively bloodless field for surgery. [25]

Tubachi R et al (2020) compared the efficacy as well as safety margin of dexmedetomidine in comparison with midazolam. They reported a statistically significant difference ($p<0.0001$) in Visual Analogue Scale scores with the patients who were administered dexmedetomidine were found to be lower. [26]

Hence, in most studied that are reported Dexmedetomidine in comparison with midazolam has been observed as a better pharmacological agent in terms of sedative properties, quality of analgesia, both patient and surgeon satisfaction in operative procedures of middle ear. [27]

## CONCLUSION

Tympanoplasty is a surgical procedure that is performed under local anaesthesia. This study has compared the efficacy of Dexmedetomidine with Midazolam by evaluating the patient and surgeon satisfaction scoring, usage and duration of rescue analgesia, hemodynamics and other clinical parameters. However, present study found no difference in efficacy of either drug which is contrast with previously published reports. This can be attributed to the lower sample size studied. Hence, a large sample population need to be evaluated to test the drugs.

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