

Comparative study of dexmedetomidine versus midazolam infusion with local anesthesia for middle ear surgeries

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Abstract: *Background:* Middle ear surgeries can be performed under local anesthesia, which is well tolerated when used with sedation. *Objective:* compare the effect of dexmedetomidine versus midazolam as a sedative in middle ear surgeries done under local anesthesia. *Methods:* 60 adult patients undergoing middle ear surgeries were randomly allocated into two groups, Group D (n=30) received inj Dexmedetomidine loading dose of 1 mcg/kg over 10 minutes followed by maintenance of 0.2 mcg/kg/hr. Group M received inj. midazolam loading dose of 0.03mg/kg over 10 minutes followed by maintenance of 0.02 mg/kg/hr. Parameters recorded were sedation, patient's & surgeon's satisfaction, pain, side effects. *Results:* Demographic data were comparable in both the groups. Mean RSS was 2.27 ± 0.45 in group M and 2.90 ± 0.31 in group D ($P < 0.001$), significant. Mean VAS for pain was 2.24 ± 0.9 and 1.36 ± 0.6 in group M and group D respectively ($P = 0.001$), significant. Patient's and surgeon's satisfaction were significant in group D, ($P \leq 0.001$) compared to group M. Side effects were minimal and treated effectively ($P = 0.212$), statistically not-significant. *Conclusion:* Dexmedetomidine compared to midazolam found to be better drug with respect to sedation, analgesia, patient's and surgeon's satisfaction for middle ear surgeries done under local anesthesia.

Keywords: Dexmedetomidine, Midazolam, Middle ear surgeries.

Introduction

Middle ear surgeries (MES) like myringoplasty, tympanoplasty, mastoidectomy, stapedotomy etc., are performed under either local or general anesthesia [1]. Many advantages have been reported with the local anesthetic techniques, such as it helps in early recovery, early ambulation, less postoperative pain, economical and most important is the ability to test hearing of the patient during surgery [2]. However, local anesthesia alone is known to cause anxiety, dizziness, claustrophobia and discomfort due to manipulation of instruments [2-3]. To overcome these problems intravenous (IV) sedation can be combined with local anesthesia.

Various drugs have been used for sedation like midazolam, propofol, ketamine, dexmedetomidine and opioids [4]. But each drug has its own advantages and disadvantages. Dexmedetomidine is a highly selective alpha-2 adrenoceptor agonist

acts as both sedative and analgesic [5]. It has sympatholytic effect and hence maintains hemodynamic stability, by attenuating sympathetic activity, it inhibits norepinephrine release and provides modest reduction in arterial blood pressure and heart rate [6-7]. These effects could be advantageous in surgeries in which near bloodless field are required to facilitate surgical view and dissection [8]. Midazolam, a short acting benzodiazepine, causing anxiolysis, sedation and anterograde amnesia but has relatively longer half-life of 3-4 hours compared to dexmedetomidine which is 2 hours [9]. A few clinical trials involved in comparison between dexmedetomidine and midazolam sedation for middle ear surgery [9]. Thus this randomized double blind clinical study undertaken to compare effects of dexmedetomidine with that of midazolam in terms of sedation, pain relief, surgeon and patient satisfaction and adverse effects.

Material and Methods

This prospective randomized comparative study was conducted in 60 patients in tertiary care teaching hospital after obtaining the approval of the institutional ethics committee and written informed consent from the patients for participation in the study. Patients aged between 18 and 60 years of either gender belonging to ASA physical status 1 and 2 scheduled for MES were enrolled in the study. Patients allergic to local anesthetics, midazolam and dexmedetomidine, patients on pain perception modifying drugs, with impaired mental status, alcohol or drug abuse were excluded from the study.

All the patients underwent thorough pre-anesthetic evaluation including detailed history, examination and necessary investigations. All patients were kept nil per oral for 8 hrs. Tab. alprazolam 0.5mg, oral was given the night before surgery. Patients were shifted to the operating room, 18G IV cannula secured and IV fluids infusion ringer's lactate started at 5 ml/kg/hr. Standard monitors including pulse oximeter, noninvasive blood pressure (NIBP), 3 lead ECG were connected and baseline readings noted. All patients received inj. glycopyrrolate 0.2 mg IV and started on oxygen 2 l/min via nasal prongs.

Patients were randomly divided using a computer generated random number table into two groups, Group D received an inj. dexmedetomidine loading dose of 1 mcg/kg over 10 minutes followed by maintenance dose of 0.2 mcg/kg/hr. Group M received inj. midazolam loading dose of 0.03mg/kg over 10 minutes followed by maintenance dose of 0.02mg/kg/hr. The drugs were diluted with 0.9% saline. The infusion of the drug prepared for sedation started (syringe pump – AKAS). Randomization was done by computer generated randomized number table. Random number was enclosed in a sealed opaque envelope and opened by one of the investigators to know the study drug/combination, who administers the infusion. Observer anaesthesiologists was blinded to the test drug/combination.

Intraoperative sedation was assessed using the Ramsay sedation score [10] (RSS) by auditory stimulus and analgesia level was recorded using the 10-point Visual Analogue Scale (VAS) by

asking patient (0-3 mild pain, 4-7 moderate pain, 8-10 severe intolerable pain). After achieving RSS 3, a standardized technique of local block, using 15 ml of local anesthesia was infiltrated at posterior auricular area to block greater auricular nerve and lesser occipital nerve, between tragus and helix to block sensory branch of vagus nerve and anterior to tragus blocking auriculotemporal nerve using 2% lignocaine with 1 in 200000 dilution of adrenaline by the surgeon, after confirming successful blockade the procedure started.

Intraoperatively sedation score recorded at 5 mins. interval for the first 15 mins. and then every 15 mins. till the end of surgery. Vital parameters like blood pressure, pulse rate, SpO₂ and respiratory rate were recorded at these intervals. If sedation score found <2 or patient complains pain anytime during the surgery, a rescue sedoanalgesics dose of inj. fentanyl 0.5µg/kg is given and frequency of rescue sedoanalgesics dose recorded. If more than 2 rescue doses requirement arises then that patient was excluded from the study.

When the surgeon starts closing the skin, infusion of sedatives stopped. After the procedure, patient was shifted and monitored for 2 hours in the recovery room. Vitals recorded every 15 mins. inj. paracetamol one-gram IV. given when VAS>3 (analgesic dose) and time noted. Surgeons were asked to grade the surgical conditions as well as satisfaction with sedation technique on 7- point Likert rating scale (1- extremely dissatisfied, 2- dissatisfied, 3- somewhat dissatisfied, 4- undecided, 5- somewhat satisfied, 5- satisfied, 6- extremely satisfied). Patients were asked to rate their satisfaction using the same 7-point Likert rating scale and intraoperative pain scores using pain score (VAS), after 2 hours of post surgery. Side effects like nausea, vomiting any other were recorded and treated accordingly.

Sample size was calculated based on a previous study conducted by Tubachi R et al, [9] in which it was observed that, the intraoperative clinical data for time (mins) to achieve RSS 3 was 14.52 ± 1.418 in dexmedetomidine group vs. 3.44 ± 0.82 in

midazolam group. In the present study considering mean difference of 1 and power of 90%, alpha error of 5% minimum sample size was estimated to be 29 in each group. Considering dropout rates, 30 patients will be enrolled in each group (Total= 60).

Statistical analysis: Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven`s test for homogeneity of variance has been performed to assess the homogeneity of variance. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher Exact test used when cell samples are very small. P value of less than 0.05 was considered significant. The Statistical software namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

Results

Demographic profiles were comparable between both the group (Table 1).

Parameter	Group D	Group M	P value
Age in Years	37.1±9.74	37.90±10.52	0.761*
Sex (Male-Female)	14 : 16	16:14	0.606*
Weight in kgs	61.2	61.1	0.972*
ASA Grade(1/2)	19/11	18/12	0.791*
*P value observed > 0.05 are found to be statistically not significant			

The mean sedation score achieved was RSS 2.9±0.3 in group D and 2.3±0.4 in group M showing significant difference between the two groups (P<0.001). Group D patients experienced less pain, VAS score 1.3±0.3 compared to group M whose VAS score was 2.0±0 , which showed significance (P<0.001). Both patient`s and surgeon`s satisfaction was better in group D compared to group M (P=0.001). In Group D, 5 patients had side effects like bradycardia among

them 3 patients required treatment with inj. Atropine 0.6 mg IV and 2 patients had hypotension which was treated with IV- fluid bolus. 2 patients in group M experienced nausea in the postoperative period and were successfully treated with inj. ondansetron 0.1 mg/kg i.v. The side effects were statistically insignificant (P value 0.212) (Table 2).

Parameter	Group D	Group M	P value
Sedation score(RSS)	2.9±0.3	2.3±0.4	<0.001
Pain Score (VAS)	1.3±0.3	2.0±0	<0.001
Patient`s satisfaction score	6.2±0.4	5.6±0.7	0.001
Surgeon`s satisfactions score	6.1±0.4	5.4±0.7	0.001
Side effects (yes/no)	5/25	2/28	0.212*
* P value observed >0.05 are found to be statistically not significant			

Discussion

Middle ear surgeries pose various challenges for patients, surgeons and anesthesiologists. General anesthesia can be preference to surgeon and patient but it has its own associated potential complications such as sore throat, cough, emergence delirium etc [11]. Local anesthesia techniques provide early recovery, post-operative analgesia, reduced bleeding, cost effective, reduced hospital stay and ability to test the hearing of the patient intraoperatively [3].

Due to sympathetic stimulation and movements of an anxious patients results in disturbance in the fine microscopic nature of the surgery that may even lead to graft failure. Hence to avoid all these complications sedatives can be administered as a supplements to local anesthesia. Also good patients selection preoperative counseling and use of appropriate sedation are important factors for successful surgery under local anesthesia [12-14]. Ideal drug used for sedation should have a rapid onset of action, minimal excitation effects, minimal

cardiorespiratory depression, produce anxiolysis, amnesia and rapid recovery after discontinuation of it [15].

In our study we compared the effectiveness of dexmedetomidine and midazolam as sedatives for middle ear surgeries using Ramsay sedation score. The mean RSS was 2.27 ± 0.45 in the group M and 2.90 ± 0.31 in group D. P value was <0.001 , significant. Sedation was better and hence the movement of the patient was limited in dexmedetomidine group compared with midazolam. Sharma S et al., [16] comparing combination of propofol with nalbuphine, fentanyl and dexmedetomidine in middle ear surgery, group receiving Dexmedetomidine showed mean RSS 3.9 ± 0.80 , significant compared to propofol group.

Nallam SR et al., [17] comparing nalbuphine/dexmedetomidine versus nalbuphine/ propofol for middle ear surgeries showed mean RSS in dexmedetomidine group was 4.24 ± 1.54 and in propofol group was 2.58 ± 0.95 . These results were comparable with our study but Thota RS et al., [1] comparing dexmedetomidine versus combination of midazolam-fentanyl for tympanoplasty surgery showed both the drugs were comparable in terms of sedation as none of the patients required additional sedation. Vyas DA et al [18] comparing dexmedetomidine versus midazolam sedation, showed though better sedation with dexmedetomidine but was statistically comparable in midazolam and dexmedetomidine groups, probably due to higher loading dose of midazolam used that is, 0.05 mg/kg compared to our study.

We found patient's and surgeon's satisfaction was better in group D compared to group M. Dexmedetomidine as a sedative and analgesic reduces pain and anxiety in patients, provide a comfortable condition to undergo surgery resulting in better patient's satisfaction. The results were consistent with the other studies like Vyas DA et al. [18], Parikh DA et al. [19], which showed higher satisfaction with dexmedetomidine. We assessed pain using VAS. The mean VAS for pain was 2.24 ± 0.9 and 1.36 ± 0.6 in group M and group D respectively, found significant. Dexmedetomidine, activating presynaptic α_2 adrenoceptor inhibits the release of norepinephrine, terminating the propagation of

pain signals and postsynaptic activation decreases sympathetic activity as it had both sedative as well as analgesic property, pain was better tolerated by Group D, 80% of patients in group M required rescue sedoanalgesia doses compared to 36.7% of patients in group D, but not more than 2 doses.

Tubachi R et al., [9] comparing efficacy and safety of dexmedetomidine in comparison to midazolam there was a statistically significant difference in VAS scores over time among both groups, with dexmedetomidine group showing lower VAS scores of pain ($p < 0.0001$). Gandhi M et al. [20], compared nalbuphine and dexmedetomidine versus nalbuphine and propofol for tympanoplasty surgeries showed mean VAS in dexmedetomidine group was 1.60 ± 0.670 and propofol group was 2.70 ± 0.691 , p value <0.001 . The requirement of midazolam as rescue sedative was higher in propofol group. The results of these studies were concurrence with our study.

In the present study, 2 patients in group M had experienced nausea in the postoperative period and were successfully treated with inj. ondansetron 0.1 mg/kg IV . The reduced incidence of postoperative nausea and vomiting in our study than that reported in literature could be due to antiemetic properties exhibited by dexmedetomidine. 3 patients in group D had bradycardia which was treated by inj. atropine 0.6 mg IV and improved the heart rate.

Also 2 Patients in group D had hypotension and were treated with fluids bolus. An increase in vagal activity may be involved in the hemodynamic effects of dexmedetomidine. These side effects were comparable between both the groups ($p=0.212$) and were statistically non-significant. Tubachi R et al. [9], did not show any serious side effects. Gandhi M et al. [20], showed dexmedetomidine group were treated with inj. atropine 0.6 mg IV . Hypotension did not require any intervention. The results were comparable with our study. Limitations of the study is that, further studies with large sample sizes are warranted to validate these findings.

Conclusion

Dexmedetomidine is superior to midazolam in providing better sedation, analgesia, comfortable to patients and surgeons, hence dexmedetomidine can be used as an effective sedative when middle

ear surgeries are done under local anaesthesia. However, appropriate patient selection, adequate preparation and careful monitoring are mandatory.

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