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Dexmedetomidine versus midazolam and fentanyl for monitored anaesthesia care in tympanoplasty under local anesthesia: Ramsay sedation score

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Abstract
The most common discomforts that were faced by the patients of SMES under local anesthesia were noise during surgery and anxiety, followed by dizziness, backache, claustrophobia and ear ache. To reduce these discomforts, careful patient selection, adequate preparation for anesthesia, and appropriate sedation are necessary. All patients were randomly divided into two groups. Two 50-ml syringes, labelled as loading and maintenance were given for each patient. Group D patients had dexmedetomidine 1 µg/kg and Group MF had midazolam 0.05 mg/kg plus fentanyl 1.5 µg/kg in their respective loading syringes diluted up to 30 ml of normal saline. Group D 1µg/ml of dexmedetomidine and Group MF had normal saline in their respective maintenance syringes. Rescue infiltration was required in 8 patients in group D and 20 patients in group MF. Rescue sedation, infiltration & analgesia, were statistically significant between group D and group MF.

Keywords: Dexmedetomidine, midazolam, RAMSAY sedation score

Introduction
Simple Middle Ear Surgeries (SMESs) can be performed under either local or general anesthesia. Many advantages has been reported with the local anesthetic techniques, as early recovery, cost effective, less post-operative pain and of great importance the surgeon ability to test hearing while during surgery. Despite these advantages, most of SMES are still done under general anesthesia due to special concerns; some are related to patient's anxiety which is augmented in some by their hearing loss, limiting their ability to cooperate. Other concerns are related to surgeon comfort with the hypotensive general anesthetic techniques, and the fear of sudden patient movement during operation [1, 2].

The most common discomforts that were faced by the patients of SMES under local anesthesia were noise during surgery and anxiety, followed by dizziness, backache, claustrophobia and ear ache. To reduce these discomforts, careful patient selection, adequate preparation for anesthesia, and appropriate sedation are necessary. Local anesthesia with sedation is a well-established approach used for tympanoplasty [3].

A monitored anesthesia care (MAC) is a planned procedure during which the patient undergoes local anesthesia together with sedation and analgesia.

For conscious sedation during a MAC there are 3 fundamental elements and purposes: a safe sedation, the control of the patient anxiety and the pain control. The patients undergoing conscious sedation are able to answer to verbal orders appropriately and to protect airways. Last but not the least, another purpose of any MAC is to get the patient appropriately satisfied, allowing him to get his discharge as faster as possible [4].

An ideal sedative agent should be consistently effective in having rapid onset, easy titration, high clearance, and minimal side-effects; particularly a lack of cardiovascular and respiratory depression. Due to lack of an ideal agent, sedation techniques for MAC often utilizes a combination of agents to provide analgesia, amnesia, and hypnosis with complete and rapid recovery that suits a particular operative procedure with minimum side effects like postoperative nausea and vomiting (PONV), prolonged sedation, and cardiorespiratory depression. Variety of drugs are being used for Monitored Anesthesia Care (MAC) *viz*., benzodiazepines, opioids and propofol have been used for hypnosis, sedation and analgesia in the middle ear surgery in order to enhance the patient and surgical comfort; however, none has been completely complication free.

Among various complications reported are over-sedation, respiratory depression, disorientation and hampered patient's cooperation during surgery [5].

Dexmedetomidine is a highly selective alpha-2 adreno-receptor agonist that produces anxiolysis, amnesia, sedation, potentiation of opioid analgesia, and sympatholysis. It is currently approved by the U.S. Food and drug Administration for the sedation of adults in the intensive care setting for upto 24 hours during mechanical ventilation. Given its sedative and anxiolytic properties and limited adverse effect profile, it has been used in several other scenarios [6].

Methodology

Patient refusal to local anaesthesia, impaired mental status, known allergy to local anaesthetics or any of the study drugs, coagulation disorders, history of cardiac arrhythmias, sleep apnoea, patient's on treatment with alpha and beta blockers as antihypertensive agent, chronic use of analgesics, sedatives, alcohol or drug abuse were excluded from the study. Patients were also excluded if it's a re-surgery, and if the expected surgery time was more than 2 hr. Patients who developed intraoperative severe pain and required general anaesthesia were excluded from the study.

Randomization was done by computer generated random number and sealed envelope. To eliminate the bias, anesthesiologist conducting the case, the patients and the anesthesiologist in the post anesthesia care unit (PACU) were all blinded to group assignment. The anesthesiologist who prepared the drugs did not participate in patient management or data collection. Data was recorded by a blinded observer.

All patients were randomly divided into two groups. Two 50-ml syringes, labelled as loading and maintenance were given for each patient. Group D patients had dexmedetomidine 1 µg/kg and Group MF had midazolam 0.05 mg/kg plus fentanyl 1.5 µg/kg in their respective loading syringes diluted up to 30 ml of normal saline. Group D 1µg/ml of dexmedetomidine and Group MF had normal saline in their respective maintenance syringes.

All patients were thoroughly assessed a day before surgery and screened for any associated medical illness like hypertension, diabetes, asthma, ischemic heart disease, cerebrovascular disease, COPD, epilepsy, liver and renal disorder, major disease in past, any eventful previous anaesthesia exposure or post-operative anaesthetic complications, drug allergy, family history etc. Routine investigations like haemoglobin, blood sugar, Serum creatinine estimation, blood urea, Chest X-ray and ECG were carried out and documented. Patients were assessed for vitals like temperature, pulse rate (PR), blood pressure and respiratory rate and SpO_2. Systemic examination was also assessed. Airway assessment was done by Malampatti grading.

All patients were informed with regard to sedation, local anaesthesia as well as operative procedure and written consent was obtained. The visual analogue scale (VAS) (0-10, where 0 indicated no pain while 10 corresponded to maximum pain), were explained to the patient during the preoperative visit.

Visual Analogue Scale is a simple tool which measures the subjective pain of the patient at a given time.

The patients were randomly and equally divided into two groups of 25 each.

Group D: Loading dose given with dexmedetomidine 1 µg/kg in 30 ml NS over 10 min followed by infusion with dexmedetomidine at a rate of 0.2 µg/kg/hr using an infusion pump.

Group MF: Loading dose given with midazolam 0.05 mg /kg plus fentanyl 1.5 µg/kg in 30 ml NS over 10 min followed by infusion with NS at a rate of 0.2ml/kg/hr using an infusion pump.

Results

Table 1: Intra operative Ramsay sedation score

Time(min)	Group-D	Group-MF	T value	P value
Pre induction	2.04 ± 0	2 ± 0	1	0.32
0	2.04 ± 0	2 ± 0	1	0.32
5	2.04 ± 0	2 ± 0	1	0.32
10	2.96 ± 0.19	2.92 ± 0.27	0.58	0.56
20	2.96 ± 0.19	3 ± 0	-1	0.32
30	3 ± 0	2.92 ± 0.27	1.44	0.16
40	2.96 ± 0.19	2.88 ± 0.32	1.03	0.3
50	2.92 ± 0.27	2.72 ± 0.44	1.86	0.06
60	3 ± 0	2.96 ± 0.19	1	0.32
70	3 ± 0	2.96 ± 0.19	1	0.32
80	3 ± 0	2.95 ± 0.20	1	0.32
90	3 ± 0	2.94 ± 0.22	1	0.33
100	3 ± 0.28	2.49 ± 0.26	-0.11	0.9
110	3 ± 0	2.22 ± 0.31	1	0.34
120	3 ± 0	3 ± 0	0	-

(Statistical analysis done with students t test. $p<0.05$* significant and $p<0.001$** highly significant)

Table 2: Post operative Ramsay sedation score

Time(min)	Group-D	Group-MF	T value	P value
0	2.04 ± 0.19	2.16 ±0.36	-1.41	0.16
30	2 ± 0	1.96 ±0.19	1	0.32
60	2 ±0	2 ±0	-	-
90	2 ±0	2 ±0	-	-
120	2 ±0	2 ±0	-	-

(Statistical analysis done with students t test. $p<0.05$* significant and $p<0.001$** highly significant)

Table 3: Patients requiring rescue sedation, infiltration & analgesia

	Group D (n=25)	Group MF (n=25)	P value
Rescue midazolam	2	14	0.001**
Rescue la infiltration	8	20	0.001**
Rescue fentanyl	2	14	0.001**

Data expressed as number (proportion)

Rescue infiltration was required in 8 patients in group D and 20 patients in group MF. Rescue sedation, infiltration & analgesia, were statistically significant between group D and group MF.

Discussion

Gul Caner *et al.* [7] in his study found that patients mean score &distress for pain (0.94), anxiety (1.11), noise during surgery (0.96), irritability (1.19) and preoperative sedation and local anaesthesia allows the patient to undergo a comfortable procedure.

Yung MW[8] reported that although the intense sensation of noise and anxiety were the most common discomforts.

In order to reduce the anxiety, discomfort due to noise & neck posture intra-operatively, sedation of adequate level

would benefit the patient and increase the success rate of local anaesthesia.

We assessed the depth of sedation by using Ramsey sedation score. The target sedation score was RSS =3 (responds to verbal command while sleeping). Sedation was stopped if patient developed bradypnea (RR< 8) & desaturation (SpO_2<90%).

In our study, all patients in group D attained an RSS= 3 at the end of loading dose but in group MF 2 patients required a rescue sedation dose after completion of loading dose at 10th min to attain RSS=3.

On the contrary, Parikh D A *et al.* [19], found that none of the patients in both the groups required rescue sedation after completion of loading dose, instead two patients each in both the groups required stopping the loading dose infusion at 8th minute as RSS= 3.

In present study majority of patients required rescue sedation dose between 40th and 70th min in both the groups. Only 2 patients in group D and 14 patients in group MF required rescue sedation. Two patients in group D required single rescue dose while in group MF 9/14 patients required single rescue dose, 3/14 patients required 2 rescue sedation doses and 2/14 patients required 3 rescue sedation dose.

Immediately on arrival to recovery room, 1 patient in dexmedetomidine & 4 patients in group MF were having an RSS=3 rest had an RSS=2, this probably depended on the time of last rescue sedative & analgesic dose.

Parikh D A *et al.* [9], in their study found that one patient in Group D required rescue sedation with midazolam when RSS <3 in contrast to four (8.8%) patients in Group MF, though the difference was not significant (P = 0.17).

Padmaja A *et al.* [10] in their study found that sedation score in dexmedetomidine group (Mean = 3.18 ± 0.19) compared to midazolam group (Mean = 3.03 ± 0.21) (*P*>0.05) was statistically not significant.

Dexmedetomidine is a centrally acting α2 receptor agonist that can be titrated to the desired level of sedation without significant respiratory depression. Because of its analgesic properties, "cooperative sedation," and lack of respiratory depression, dexmedetomidine is increasingly being used as a sedative for MAC.

Conclusion

In our study, all patients in group D attained an RSS= 3 at the end of loading dose but in group MF 2 patients required a rescue sedation dose after completion of loading dose at 10th min to attain RSS=3. Majority of patients required rescue sedation dose between 40th and 70th min in both the groups. Rescue sedation dose was required in only (2/25) patients in group D & (14/25) patients in group MF. Two patients in group D required single sedation rescue dose while nine patients in group MF required single rescue sedation dose, 3 patients required two rescue sedation doses & 2 patients required three rescue sedation dose.

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