COMPARISON OF DEXMEDETOMIDINE AND FENTANYL-MIDAZOLAM FOR TYMPANOPLASTY UNDER MONITORED ANAESTHESIA CARE

ABSTRACT: - Tympanoplasty surgery can be done under local anaesthesia plus sedation. **Materials and Methods** 60 patients undergoing tympanoplasty under local anaesthesia randomly received either IV dexmedetomidine 1 mcg/ kg over 10 min followed by 0.3-0.5 mcg/ kg/hour infusion (Group D) or IV midazolam 0.015-0.03 mg/ kg plus IV fentanyl 2 mcg/ kg slowly (Group MF). Vital parameters, rescue analgesics fentanyl 20 mcg and midazolam 0.5 mg, patient and surgeon satisfaction scores were recorded **Results**: Patient and surgeon satisfaction score was better in Group Dexmedetomedine (Group D) than Group Midazolam-Fentanyl (Group MF). Intraoperative heart rate and mean arterial pressure in Group D were lower as compared to Group MF. Patients required more rescue fentanyl or midazolam doses in Group MF than Group D. A few patients in Group D and in Group MF complained of dry mouth. One patient in Group D had bradycardia with hypotension which was effectively treated. **Conclusion:** Dexmedetomidine is preferred for tympanoplasty. Haemodynamics need to be closely monitored.

Key words: Dexmedetomidine, sedation, midazolam-fentanyl sedation,

INTRODUCTION

Tympanoplasty is usually done under local anaesthesia with sedation under monitored anaesthesia care (MAC). Fentanyl-midazolam was used which requires rescue analgesic doses if patient feels pain or is uncooperative. If patient is not sleeping and continues to have pain, we need to administer general anaesthesia to patient. Dexmedetomidine, α2 receptor agonist has analgesic and conscious sedative effect without major respiratory depression and attenuates the stress response to surgery (tachycardia and hypertension) and is drug of choice. Midazolam with its quick onset, but a relatively long half-life can cause prolonged sedation after repeated administration.[1] Combining midazolam with opioids increases the risk for hypoxemia and apnoea[1,2] Over sedation leading to respiratory depression has been reported. Patients may feel discomfort due to pain, noise due to suction, manipulation of instruments and head-neck position.

Ramsay sedation scale Score

1 Anxious, agitated or restless

2 Cooperative, oriented and tranquil.

3 Asleep, responds to command

4 Asleep but has a brisk response to light glabellar tap or loud

auditory stimulus.

5 Asleep has a sluggish response to a light glabellar tap or loud

auditory stimulus.

6 Asleep without response

Visual Analogue Scale VAS (0–10cm)

0 No pain

2

4

6

8

10 Worst pain

MATERIALS AND METHODS

After obtaining approval from Institutional Ethical Committee,60 patients belonging to (ASA) I & II patients (18- 60 years) of both sexes, posted for Tympanoplasty under local anaesthesia and sedation, were divided into two groups. Those having cardiac disease lung disease, renal, hepatic, endocrine, metabolic and central nervous system disease, pregnant and lactating female, sensitivity to Lignocaine, α2 agonist or antagonist therapy were excluded from study. After checking the consent and NBM status patient was shifted to OT. I.V. line was secured. Inj. emset 4 mg and injection pantoprazole 40 mg was given. P, BP, ECG, SpO2 and ETCO2 was monitored. Oxygen was given via Hudson's mask/nasal cannula at 4-6 L/minutes. Group D: Dexmedetomidine group: received a loading dose of 1 mcg/kg (infused over 10 min) +at rate of @ 0.3- 0.5 mcg/kg/hour. Group fentanyl-midazolam: inj. fentanyl 2mcg/kg (and Inj. Midazolam0.015 - 0.03 mg/kg was given slowly titrated to response. Once patient achieves Ramsay sedation score (RSS)of 3, ENT surgeon administered LA using 2% Lignocaine with Adrenaline (1:2,00,000), (6-7 ml/Kg). Pain was recorded on 10 point (visual analogue scale) after surgery patients were shifted to the PACU and were monitored for hemodynamic parameters, degree of analgesia and adverse events, if any for 2 hours. Ramsay sedation score was assessed immediately on arrival in the PACU and every 30 min thereafter till transfer to surgical ward. Requirement of intraoperative and postoperative analgesia was noted. During surgery first rescue dose of analgesic fentanyl 10-20 mcg is given at VAS >4. Inj. midazolam 0.5 mg was given if patient is showing movement during infiltration till (RSS)of 3 is achieved. If target point of RSS of 3 is achieved before completing the loading infusion, then the infusion was stopped. If after completion of loading drug, RSS is less than 3, then bolus IV midazolam 0.5 was given and repeated if necessary till RSS was 3. Sedation level (RSS) was assessed every 10 min and. The number of rescue doses of drugs was recorded. Intraoperative pain intensity was evaluated using VAS. Inadequate analgesia was treated with filtration of 2% lignocaine with adrenaline (2-3 ml) at the surgical site. If the pain was still persistent and VAS >3, then rescue IV fentanyl in the dose of 10-20 mcg was given. If maximum doses of drugs are given and still patient is un-cooperative, alternative sedative or anaesthetic can be used. Maintenance infusions were discontinued 15 min before end of surgery. Heart rate (HR), mean arterial pressure (MAP), respiratory rate (RR), and peripheral oxygen saturation (SpO2) were recorded every 10 min till the end of surgery. Intraoperative bleeding was treated with additional rescue dose of drugs or antihypertensive can be administered. All adverse events like bradycardia (HR < 45beats/min)

atropine is given. Hypotension (MAP < 60 mmHg sustained for >10min) iv fluids or phenylephrine or ephedrine is given. For respiratory depression (respiratory rate< 10 bpm) oxygen to be provided. Watch for bradycardia, hypotension, respiratory depression nausea or vomiting.

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). Efficacy of the sedation technique was defined as the ability to complete the surgery without any rescue sedatives and analgesics.

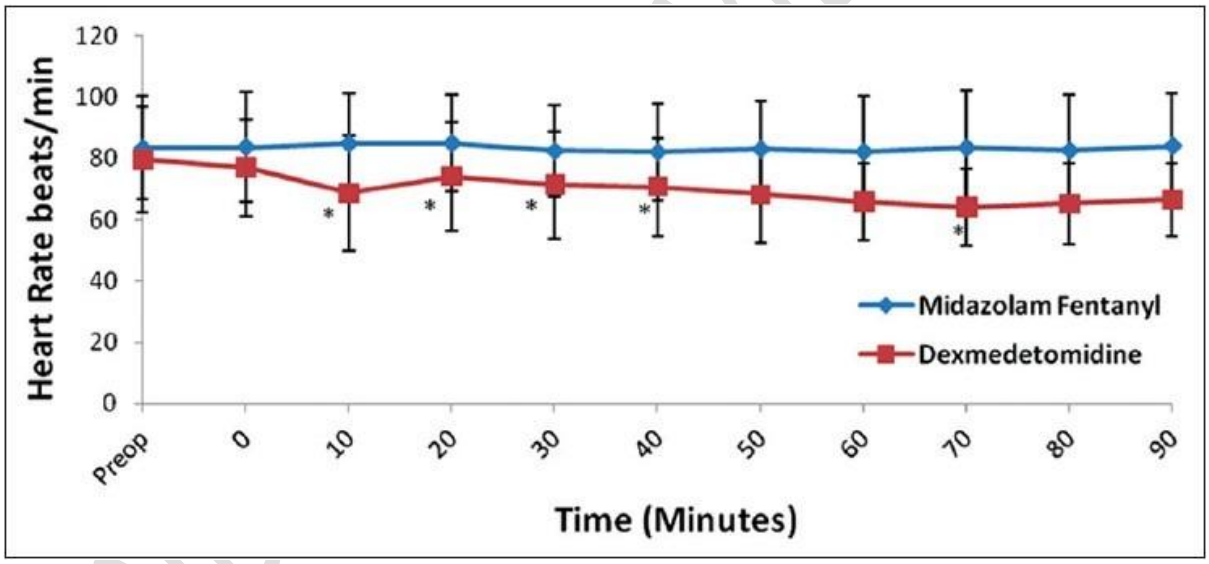
RESULTS

Statistical analysis revealed non-significant differences between the two study

groups as regards age, gender distribution, body weight and duration of surgery

There were no differences in baseline measurements of HR and MAP between the two groups, but Group D had significant fall in heart rate (15-20%) (P<0.001). In contrast, Group MF had no significant change(P<0.001). [Figure 1]. patients in Group D had a greater fall (10-15%) (P>0.05).in mean arterial pressure in comparison to Group MF (5-10%) (P<0.05).

Changes in heart rate between two groups



Changes in mean arterial pressure between two groups

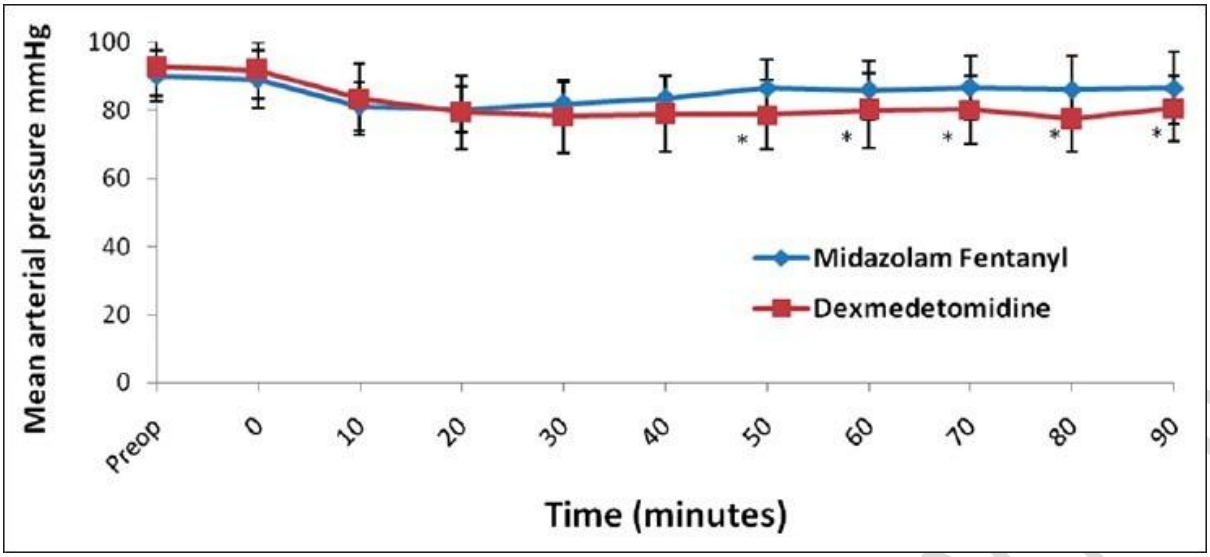


Table 2: Rescue sedatives and analgesics.

	Group D	Group MF	P vaiue
Rescue Midazolam Yes/No	yes	yes	
No. of top-ups 1/2/3	1/0/0	1/2/1	(P>0.05).
Rescue LA infiltration Yes/No	yes	yes	
No. of top-ups 1/2/3	5/3/0	8/2/0	(P<0.05).
Rescue fentanyl Yes/No	yes	yes	
No. of top-ups 1/2/3	3/0/0	8/2/1	(P<0.05).

in either group eight patient in Group D required rescue local anaesthetic infiltration in contrast to 10 in Group MF. In Group D 1 patient required rescue midazolam dose and 3 patients required rescue fentanyl dose. In Group MF, 8 patients requiring one dose, two patients requiring two doses and 1 patient required 3 doses of fentanyl and 1 ,2 and 1 patient required 1 dose, 2 doses and 1 dose of midazolam respectively.

Table 2 Patient satisfaction and Surgeon satisfaction score

Study variables	Dexmedetomidine	fentanyl-midazolam	P vaiue
Patients' satisfaction score	9	8	(P<0.05).
Surgeon's satisfaction score	9	8	(P<0.05).

Immediately upon arrival into the recovery room, all the patients were able to obey commands. At the end of 30 min patients in both the groups had reached RSS of 2. Time until need for postoperative analgesic was comparable in both the groups. [Table 3]. Average patients'

satisfaction with sedation and analgesia was higher in Group D than Group MF [Table 3]. Similarly, surgeons' satisfaction with patients' sedation and surgical conditions was higher in Group D than in Group MF. Requirement for rescue analgesia was also less in group D than group FP However, no major adverse events were observed in this study and no patients had to be converted to an alternative sedative or anaesthetic therapy in either of the group

Table 3 Measured particular time until need for postoperative analgesics

Study variables	Dexmedetomidine	fentanyl-midazolam
Time to first rescue analgesic	160	145

Table 4 Adverse reactions

Study variables	Dexmedetomidine	fentanyl-midazolam
Nausea & Vomiting	0	1
Dry mouth	5	0
Tachycardia	0	1
Bradycardia	2	0
Hypotension	2	0

Two patients in Group D developed hypotension and bradycardia after completing the loading infusion which was successfully treated with intravenous atropine 0.6 mg and intravenous ephedrine 6 mg. There was no episode of desaturation. In postoperative period one patient in Group MF had nausea and vomiting which was symptomatically treated. One patient in MF group had tachycardia.

DISCUSSION Dexmedetomidine can be safely and effectively used for

procedural sedation and surgeries done under MA

No significant differences were noted between the two study groups related to age, gender distribution, body weight and duration of surgery.

In view of its short distribution half-life of 5 minutes dexmedetomidine necessitates that it be given as a maintenance infusion. We selected a maintenance dose of 0.3-0.5 mcg/ kg/hour, because the surgery was essentially done under local anaesthesia. Increasing the infusion rate of dexmedetomidine to maintain desired levels of sedation would also confer additional analgesia and probably reduce the number of rescue doses of drugs. Eren et al.[3]has used inj midazolam 0.06 mg/ kg with 1mcg/kg fentanyl. We have used IV midazolam 0.015-0.03 mg/ kg plus IV fentanyl 2 mcg/ kg initially and 0.5 mg midazolam and 20 mcg fentanyl as rescue doses.

There were no differences in baseline measurements of HR and MAP between the two groups, but Group D had significant fall in heart rate (15-20%). In contrast, Group MF had no significant change in heart rate [Figure 1]. patients in Group D had a greater fall (10-15%) in mean arterial pressure in comparison to Group MF (5-10%)

Our study demonstrated significantly higher patient and surgeon satisfaction scores with dexmedetomidine suggesting a difference in the quality of sedation of both the drugs.[4] Group D showed higher patient and surgeons satisfaction scores with dexmedetomidine Lesser number of patients receiving dexmedetomidine demanded rescue analgesics as compared to the midazolam-fentanyl group. Similar finding shave been reported by K. Karaaslan et al.[5]

A rescue dose of fentanyl 10-20 mcg if pain score >4 or inj. midazolam 0.5 mg was given if showing movement during infiltration till Ramsay sedation score (RSS)of 3 is achieved. All adverse events like bradycardia (HR < 45beats/min) atropine 0.01mg /kg is given in incremental doses. Hypotension (MAP < 50 mmHg sustained for >10min) is treated with iv fluids or phenylephrine or ephedrine 5 mg. Oxygen is given to prevent oxygen desaturation.

Durmus et al.[6] have evaluated this property of dexmedetomidine for providing controlled hypotension in general anaesthesia for tympanoplasty cases and concluded that it is a useful adjuvant to decrease bleeding when a bloodless surgical field is required

In the present study, in addition to comparable respiratory rates there was no evidence of bradypnea in either of the groups. Dexmedetomidine is unique in that it does not cause respiratory depression because its effects are not mediated by the Ỳ aminobutyric system.[7] These findings are similar to other studies.[8,9] However, Alhashemi et al.[4] in their comparative study of dexmedetomidine with midazolam for cataract had observed a higher ventilatory frequency in patients receiving midazolam. They attributed the increased respiratory rate to midazolam causing decreased tidal volume and an increase in the respiratory rate as a compensation to maintain minute ventilation.

Our findings are similar to other studies where lower HR and MAP were observed in the dexmedetomidine group.[6,7,8,9]These results suggest that dexmedetomidine has clinical advantage. Requirement of postoperative analgesia was noted. The first rescue dose of analgesic was given at VAS > 3 and was documented.

CONCLUSION

Dexmedetomidine is an excellent choice in Tympanoplasty under sedation with MAC in compared to fentanyl midazolam combination for better operative condition, patients' and surgeons' satisfaction.

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