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Original Research Paper

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

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ABSTRACT

Objective- To compare the sedation, analgesia, hemodynamics effects, surgeon satisfaction and quality of surgical field provided by dexmedetomidine with combination of midazolam and fentanyl.

Methods- 100 patients of ASA I or II posted for tympanoplasty were divided into two groups of 50 patients each. Group D received Dexmedetomidine 1 μg/kg intravenously over 10 minutes loading and 0.2 μg/kg/h intravenously maintenance dose. Group MF received intravenously 0.03 mg/kg midazolam plus 1 μg/kg fentanyl over 10 minutes loading dose and normal saline 0.2 ml/kg/h intravenously as maintenance. Heart rate (HR), Mean Arterial Pressure (MAP), Respiratory Rate (RR), level of Sedation and degree of Analgesia were assessed intraoperatively. Surgeon satisfaction with the operative field and quality of sedation was inquired post-operatively with assessment of Pulse Rate (PR), Mean Arterial Pressure (MAP), Respiratory Rate (RR), sedation and duration of analgesia.

Results- Dexmedetomidine showed statistically significant decrease in heart rate and mean arterial pressure, better sedation and analgesia intraoperatively needing lesser rescue doses for sedation and analgesia and better surgeon satisfaction and longer duration of analgesia postoperatively. The adverse effects were bradycardia and hypotension with dexmedetomidine and nausea with midazolam-fentanyl.

Conclusion- Dexmedetomidine is better than a combination of midazolam-fentanyl for sedation and analgesia for tympanoplasty surgery under monitored anaesthesia care which provides optimal hemodynamic profile, better sedation, analgesia, surgeon satisfaction and minimal adverse effects.

KEYWORDS : Tympanoplasty, Dexmedetomidine, Midazolam, Fentanyl, Monitored Anaesthesia Care(MAC), Sedation, Analgesia.

INTRODUCTION

Tympanoplasty implies reconstruction of perforated tympanic membrane with or without ossiculoplasty. Local anaesthesia with sedation under Monitored Anaesthesia Care (MAC) is a well-established approach used for tympanoplasty with advantages such as less bleeding and ability to test hearing intraoperatively. A variety of drugs have been used for hypnosis, sedation and analgesia such as benzodiazepines with opioids, in middle ear surgery as adjuncts to enhance the patient and surgical comfort. However, there is increased risk of hypoxemia, prolonged sedation and apnea. Dexmedetomidine is a selective alpha-2 agonist with properties of analgesia and sympatholysis without major respiratory depression and is being increasingly used for procedural sedation and surgeries done under MAC.

We compared dexmedetomidine and a combination of midazolam-fentanyl in terms of their hemodynamic effects, sedation quality, analgesia quality and duration and surgeon satisfaction with the quality of surgical field in 100 patients undergoing tympanoplasty under MAC.

MATERIALS AND METHODS

100 patients of ASA grade I or II aged 18 to 65 years, of either sex with no absolute contraindication to tympanoplasty under MAC were included in this prospective randomised study with a cross over design after Ethics Committee approval and obtaining informed consent. Patients were divided by computerised randomisation into 2 groups of 50 each.

Premedication with glycopyrrolate 0.2mg and ondansetron 4mg intravenously 30 minutes prior to surgery was administered. Two 50-ml syringes, labelled as loading and maintenance were assigned for each patient. Group D patients had dexmedetomidine 1 μg/kg and Group MF had midazolam 0.03 mg/kg plus fentanyl 1 μg/kg in their respective loading dose syringes diluted up to 30 ml of normal saline. Group D had 1 μg/ml of dexmedetomidine diluted till 50 ml with normal saline and Group MF had normal saline filled upto 50 ml in their maintenance syringes. Loading dose infusion was administered intravenously over 10 minutes in both groups, following which maintenance infusion was started with group D receiving of 0.2μg/kg/h dexmedetomidine intravenously and group MF receiving 50 mL 0.2 ml/kg/h normal saline intravenously. After aseptic painting and draping of the surgical field local anaesthesia was given with Inj. Lignocaine 2% with 1:200000 adrenaline 15 minutes after initiation of loading doses.

Heart rate (HR), Mean Arterial Pressure (MAP) and Respiratory Rate (RR) were recorded at baseline, then on completion of the loading dose at 10 minutes, at time of local anaesthetic infiltration at 15 minutes and then every 15 minutes till end of the surgery. Sedation and analgesia were assessed every 20 minutes till the end of the surgery and were titrated to RSS of 3 and VAS of 3 respectively. Midazolam 0.01 mg/kg and Fentanyl 1μg/kg intravenously were used as rescue sedation and rescue analgesia respectively in the event of inadequate effect with maximum of 4 doses of rescue drugs. If the desired level of sedation or analgesia was not obtained with clinically specified drug dose limit, another alternative anaesthesia technique was planned to be started and the study was to be discontinued. Any adverse effects were recorded. Any event of bradycardia (HR≤ 50 bpm) or Hypotension (MAP ≤ 65 mm Hg) was treated with 0.2 mg Glycopyrrolate and Mephenteramine 3 mg intravenously respectively.

Surgeon satisfaction with the operative field and quality of sedation was inquired and scoring was done against a nominal scale derived from Boezaart Scale[1], in the range of 1-10. Postoperative assessment of pulse rate, MAP, respiratory rate, duration of analgesia and Ramsay Sedation Score (RSS) was started in recovery room every 30 minutes for 2 hours. The surgeon was advised not to administer any analgesic agent post-operatively to the patient without consulting the investigator or until the patient demanded analgesia.

STATISTICAL ANALYSIS

The data was managed in Microsoft Excel spreadsheet. The data were expressed as mean ± SD or as median values. Nominal data were computed using 2 independent sample t-test and nonparametric Mann Whitney test. Ordinal data were computed using the Chi Square test and Fischers exact test.

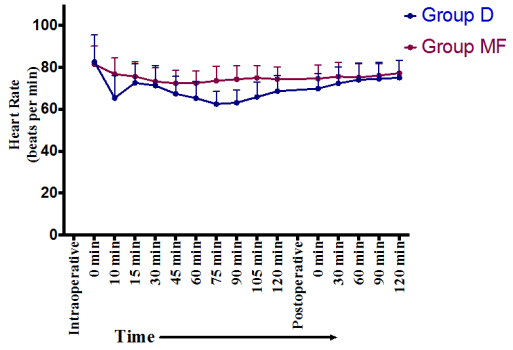
OBSERVATION AND RESULTS

The difference in mean pulse rates between Group D and Group MF intraoperatively at 10 minutes from administration of loading doses and from 45 minute onwards to the end of surgery and postoperatively till 60 minutes was significant. **(Table I) (Graph I)**

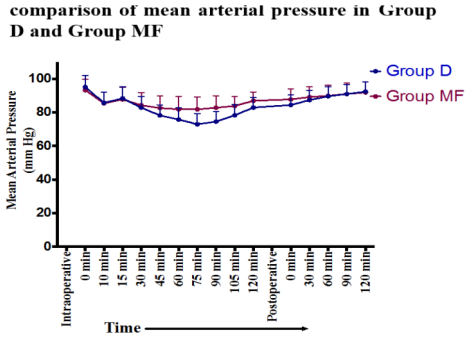
Table I. Comparison of heart rate (beats per minute) in Group D (Dexmedetomidine) and Group MF (Midazolam-Fentanyl)

Time	Group D (n=50)		Group MF (n=50)		p-value
	Mean	SD	Mean	SD	
Intraoperatively					
0 min	82.58	12.86	81.5	8.55	0.622
10 min	65.38	10.69	76.74	7.71	<0.001*
15 min	72.6	9.04	75.62	7.06	0.066
30 min	71.26	9.62	73.2	6.56	0.241
45 min	67.36	8.34	72.38	6.07	<0.001*
60 min	65.26	8.06	72.42	5.83	<0.001*
75 min	62.5	5.96	73.58	6.89	<0.001*
90 min	63.1	6.05	74.28	6.38	<0.001*
105 min	65.86	7.07	74.98	5.95	<0.001*
120 min	68.64	7.49	74.34	5.88	<0.001*
Postoperatively					
0 min	69.84	7.23	74.61	6.43	<0.001*
30 min	72.34	7.79	75.58	6.72	0.028*
60 min	74.06	7.97	75.18	6.51	0.444
90 min	74.49	7.91	76.06	5.61	0.258
120 min	75.06	8.17	77.26	5.9	0.126

***Significant; 2 independent sample t-test is applied**



Graph I. Graphical representation of comparison of mean heart rate in Group D and Group MF



Graph II. Graphical representation of comparison of mean arterial pressure in Group D and Group MF

The difference in mean arterial pressures between Group D and Group MF intraoperatively from 45 minute onwards to end of surgery and postoperatively till 30 minutes was significant (p<0.05) **(Table II) (Graph II).**

Table II. Comparison of mean arterial pressure (mm Hg) in Group D and Group MF

Time	Group D (n=50)		Group MF (n=50)		p-value
	Mean	SD	Mean	SD	
Intraoperatively					
0 min	95.16	6.77	93.24	6.44	0.149
10 min	85.76	6.24	85.4	6.84	0.784
15 min	88.36	6.91	87.78	7.21	0.682
30 min	82.8	6.68	84.24	7.49	0.313
45 min	78.24	6.24	82.6	7.29	0.002*
60 min	75.74	6.97	81.88	7.8	<0.001*
75 min	72.96	6.33	81.82	7.36	<0.001*
90 min	74.52	6.04	82.78	7.16	<0.001*
105 min	78.3	6.36	83.86	5.7	<0.001*
120 min	82.88	5.84	86.96	5.31	<0.001*
Postoperatively					
0 min	84.42	6.02	87.78	6.27	0.007*
30 min	87.34	5.76	89.14	6.07	0.132
60 min	89.58	5.71	89.9	6.28	0.79
90 min	90.94	5.74	90.98	6.63	0.974
120 min	92.38	5.75	91.9	6.25	0.69

***Significant; 2 independent sample t-test is applied**

The difference in median respiratory rates between Group D and Group MF intraoperatively from start to end of surgery and postoperatively till 120 minutes was significant (p<0.05)The difference in median Ramsay Sedation Scores (RSS) between Group D and Group MF intraoperatively at 20 minutes and from 60 minutes till 120 minutes was significant (p<0.05) **(Table III).** Significantly more number of patients in group MF (22%) required doses of rescue sedation intraoperatively as compared to those in group D (6%) [p value = 0.049]

Table III. Comparison of Ramsay Sedation Scores in Group D and Group MF

Ramsay Sedation Score (RSS)	Group D	Group MF	p value
	Median	Median	
Intraoperatively			
0 min	2	2	>0.999
20 min	3	3	0.014*
40 min	3	3	0.928
60 min	3	3	0.002*
80 min	3	3	<0.001*
100 min	3	3	<0.001*
120 min	3	3	0.505
Postoperatively			
0 min	3	3	>0.999
30 min	2	2	>0.999
60 min	2	2	>0.999
90 min	2	2	>0.999
120 min	2	2	>0.999

The difference in median VAS score between Group D and Group MF intraoperatively from 20 minutes to 80 minutes and from 100 minutes till 120 minutes was significant (p<0.05) **(Table IV).** In group D, rescue analgesia was required in 6 patients once and 4 patients twice in contrast to 10 patients requiring one and 9 requiring two and 3 requiring three doses of rescue analgesia in group MF, the difference being significant (p = 0.017). Thus, lesser number of patients (11.1%)

receiving dexmedetomidine demanded rescue analgesics as compared to the midazolam-fentanyl group (40%).

Table IV. Comparison of Visual Analog Scale (VAS) in Group D and Group MF

Visual Analog Scale (VAS)	Group D	Group MF	p value
	Median	Median	
Intraoperatively			
0 min	6	6	0.713
20 min	3	5	<0.001*
40 min	3	3	0.003*
60 min	3	3	<0.001*
80 min	3	3	<0.001*
100 min	3	3	0.536
120 min	3	4.5	<0.001*

Duration of postoperative analgesia was significantly more in Group D (86.62±9.48 minutes) as compared to Group MF patients (65.38±11.20 minutes) [p<0.001].

In Group D, 2 patients developed hypotension and bradycardia was observed in 3 patients as compared to none in group MF. Nausea was complained by 4 patients in group MF.

Mean surgeon satisfaction score on a scale of 1 to 10 was 7.70±1.27 in group D and 6.68±1.15 in group MF which was significantly more in group D (p<0.05).

DISCUSSION

Tympanoplasty involves tympanic membrane grafting to eradicate disease in the middle ear and re-construct the hearing mechanism. It can be done under general or local anaesthesia. The attending anaesthesiologist faces several challenges such as bloodless field, head positioning, effect of nitrous oxide on middle ear, and facial nerve monitoring intraoperatively and smooth and calm recovery, prevention of postoperative nausea and vomiting and adequate analgesia postoperatively[2]. Local anaesthesia alone has been associated with anxiety, dizziness, claustrophobia, noise of suction manipulation and earache which can be alleviated with adequate sedation[3]. Local anaesthesia with sedation has advantages such as less bleeding, early recovery, inexpensive, postoperative analgesia and ability to test hearing intraoperatively over general anaesthesia, and that the anaesthetist's capacity is released for other purposes. However, over-sedation, disorientation and confusion, particularly in elderly and increased risk of respiratory depression necessitates vigilant monitoring of sedation in MAC. Benzodiazepines, opioids, propofol and alpha-2 agonists have been commonly used for tympanoplasty under MAC[4,5].

In our study, mean heart rate was decreased in both the groups, with maximum decrease of 20.17% with dexmedetomidine as compared to combination of midazolam-fentanyl (5.84%). Also mean MAP were decreased in both groups with maximum decrease of 23.53% with dexmedetomidine and 12.24% with midazolam-fentanyl at 75 minutes from start of loading dose. Thus, the decrease in heart rates and MAP was significantly more with dexmedetomidine. Parikh D et al[6] in their study demonstrated significant decrease in heart rate and MAP with dexmedetomidine than combination of midazolam-fentanyl which are in accordance with our study.

Sedation and analgesia was better in patients receiving dexmedetomidine who also needed significantly less rescue sedation and analgesia as compared to patients receiving midazolam-fentanyl. Upendranath I et al[7] in 2016 compared Dexmedetomidine with Fentanyl for sedation in tympanoplasty (ENT Surgeries) under MAC, found that Dexmedetomidine provided less discomfort, better sedation, and analgesia when compared with fentanyl under monitored anaesthesia care which was corroborated in our study. Parikh D et al[6] concluded that with close hemodynamic monitoring, dexmedetomidine was comparable to midazolam-fentanyl for sedation and analgesia in tympanoplasty with better surgeon and patient satisfaction, as was found in this study.

In our study, dexmedetomidine appears to provide better surgeon satisfaction and significantly longer duration of postoperative analgesia than midazolam/fentanyl as was evidenced in a study by Yu C et al[8] which compared dexmedetomidine/ fentanyl with midazolam/fentanyl combination for sedation and analgesia during office-based unilateral impacted tooth extraction.

In our study hypotension (4%) and bradycardia (6%) were observed with dexmedetomidine whereas nausea was the main side effect in the group receiving combination of midazolam and fentanyl. It has also been observed by Parikh D et al[6] that one patient in dexmedetomidine group developed hypotension and bradycardia and one patient receiving midazolam-fentanyl combination developed nausea and vomiting which is comparable to our study.

CONCLUSION

Dexmedetomidine was better than a combination of midazolam-fentanyl for sedation and analgesia for tympanoplasty surgery under monitored anaesthesia care with better quality of sedation and analgesia, an optimal hemodynamic profile, better surgeon satisfaction and quality of surgical field as well as minimal adverse effects.

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