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A STUDY OF DEXMEDETOMIDINE VERSUS FENTANYL FOR MONITORED ANAESTHESIA CARE DURING TYMPANOPLASTY IN ADULTs

Anaesthesiology

Dr Deepshikha Tripathi Professor, Department Of Anaesthesiology, B J Medical college, Ahmedabad-380016.

Dr Raag Patel Resident Department of Anesthesiology, B J Medical college, Ahmedabad-380016.

Dr Kinnari Kelaiya* Resident Department of Anesthesiology, B J Medical college, Ahmedabad-380016. *Corresponding Author

ABSTRACT

Introduction: Tympanoplasty is a commonly done ENT procedure which involves reconstruction of perforated tympanic membrane with or without ossiculoplasty.[1] It can be done both under local anaesthesia (LA) and general anaesthesia. [2-4] Sedation is usually required along with the local anaesthesia for the comfort of the patient and the surgeon during tympanoplasty under local anaesthesia. **Methods:** This is a prospective, randomized, single blind, clinical study. The study involves 100 patients with Age 18-40years, of either gender, ASA physical status I and II, Elective Tympanoplasty under local anaesthesia. All the patients were randomly allocated by computer generated random number sequence in one of the two groups, Group D: Patient was received a loading dose of 1 µg/kg of Dexmedetomidine dissolved in 100 ml of normal saline to be infused over 10 min followed by an infusion of 0.4µg/kg/hr through infusion pump. Group F: Patient was received a loading dose of 1 µg/kg of fentanyl followed by infusion of 0.4 µg/kg/hr through infusion pump. During surgery Non-verbal pain score was evaluated as behavioral dimensions (facial expressions, activity and guarding) and physiological dimensions (HR, blood pressure and respiratory rate) and were graded in severity. Sedation score also evaluated according to RAMSAY SEDATION SCORE. **Results:** In physiological dimension; In group D, there is statistically significant decrease noted in heart rate and blood pressure from baseline immediately after the bolus which continued till the completion of the procedure (p value <0.05). In group F, there is decrease in heart rate and blood pressure from baseline after bolus dose but is not significant statistically (p value>0.05). In sedation score; As compared to group F, there was statistically significant higher sedation score in group D, after bolus dose and remained so throughout the study. Inspite of higher sedation score in group D, no patient developed respiratory depression which shows safety of dexmedetomidine. **Conclusion:** Patients of dexmedetomidine group had better patient and surgeon satisfaction scores as compared to fentanyl group and less number of patients required rescue analgesic for patient posted for tympanoplasty.

KEYWORDS

Dexmedetomidine; Fentanyl; Tympanoplasty; Non-verbal pain score; Ramsay sedation score

INTRODUCTION

Tympanoplasty is a commonly done ENT procedure which involves reconstruction of perforated tympanic membrane with or without ossiculoplasty.**[1]** It can be done both under local anaesthesia (LA) and general anaesthesia. **[2-4].** However, local anaesthesia alone is associated with anxiety, dizziness, claustrophobia under the surgical drapes and patients may feel discomfort due to pain, noisy suction, manipulation of instruments and lateral head and neck position. **[5-6]** According to the American Society of Anesthesiologist (ASA), monitored anaesthesia care (MAC) is a planned procedure during which the patient undergoes local anaesthesia together with conscious sedation and analgesia.**[7]**

Commonly used drugs for MAC are propofol, benzodiazepines, and opioids.**[8]** Propofol and benzodiazepines are good sedatives but lack analgesia which reduces their efficacy to be used as ideal agents during MAC in procedures under local anaesthesia. Thus, the present study is planned to evaluate the efficacy and safety of dexmedetomidine during MAC in tympanoplasty under LA and its clinical comparison with fentanyl.

Fentanyl is a potent, synthetic opioid analgesic with a rapid onset and short duration of action, a strong agonist at the µ-opioid receptors which combines the features of sedation and analgesia and is one of the most commonly used agents for MAC for various surgeries done under local anaesthesia but has an inherent tendency of causing respiratory depression.

Dexmedetomidine has properties of analgesia, sympatholysis and titrating sedation without major respiratory depression. It reduces opioid requirements and stress response to surgery ensuring a stable hemodynamic state. Thus, the present study is planned to evaluate the efficacy and safety of dexmedetomidine during MAC in tympanoplasty under LA and its clinical comparison with fentanyl.

MATERIAL AND METHODS

This prospective, randomized controlled, double-blind study was undertaken After obtaining institutional ethical approval from Institutional ethical committee, B J Medical college and civil Hospital, Ahmedabad, eighty patients of either sex, having American Society of Anesthesiologists (ASA) Grade I/II, aged between 18 and 60 years, undergoing tympanoplasty surgery under local anaesthesia were included and written informed consent was obtained from all the participants. Patients with refusing consent, anticipated difficult airway, BMI >25, Alcohol or drug addiction, Neuropsychiatric disease, History of drug allergy including allergy to local anesthetics, Patient taking sedatives, analgesics or any other agent having a cardiac, respiratory and gastrointestinal effects, Antenatal and lactating females were excluded from the study. Patients on pain perception modifying drugs and those with history of use of any opioid or sedative medications in the week prior to surgery were also excluded. All the patients were examined a day before surgery and were thoroughly investigated according to the institute protocol. The patients were randomly divided into two equal groups, Group D (dexmedetomidine) and Group F (fentanyl) on basis of a computer-generated randomization scheme. One of our team members was prepare and start the infusion. The investigator assessing the effect of drug infusion was not aware of the content of the solution.

All patients had undergone routine pre-anesthetic evaluation the day before surgery, written informed consent was taken and were kept nil per oral for a minimum duration of eight hours before surgery. On arrival of the patient in the operating room, a20-gauge intravenous cannula was inserted and an infusion of DNS (dextrose normal saline) was started @ 2 ml/kg. The baseline haemodynamic and vital parameters were recorded including heart rate (HR), non-invasive blood pressure (NIBP), electrocardiogram (ECG) and arterial oxygen saturation (SpO2). After that, the patients were premedicated with glycopyrrolate 4µg/kg given intravenously. Oxygen was supplemented via oxygen mask @ 4 liters/min. Group D- Patient was received a loading dose of 1 µg/kg of Dexmedetomidine dissolved in 100 ml of normal saline to be infused over 10 min followed by an infusion of 0.4 µg/kg/hr through infusion pump. Group F- Patient was received a loading dose of 1 µg/kg of fentanyl followed by infusion of 0.4 µg/kg/hr through infusion pump. As per assigned group, sedative drug infusion was started. After achieving a Ramsay sedation score **[9]** of 3, patient was shifted to the operation theatre. After local area preparation, operative field was infiltrated with lignocaine 2 % 15 ml mixed with 5µg/ml (75 µg) of adrenaline. {Ramsay sedation score (RSS) [10](1 = agitated, restless; 2 = cooperative, tranquil; 3 = responds

to verbal command while sleeping; 4 = brisk response to glabellar tap or loud voice while sleeping; 5 = sluggish response to glabellar tap or loud voice; 6 = no response to glabellar tap or loud voice)}. During the procedure, study drug infusion rate was adjusted to maintain a sedation score of 3 and normal cardiovascular and respiratory variables (HR>60 /min, MAP>60mmHg, RR >12 breaths /min, SpO2>94%). Intraoperative pain intensity was evaluated using VAS. Inadequate analgesia was treated with infiltration of 2% lignocaine with adrenaline (2-3 ml) at the surgical site and noted. If the pain was still persistent and VAS >3, then If the patient is not adequately sedated through drug titration and complaints of pain, 0.5 mg/kg ketamine was injected as rescue analgesic once.

The study drug was stopped at the end of the surgery and patients were shifted to **P**ost **A**naesthesia **C**are **U**nit (PACU). Patients was monitored in PACU at 10 min interval till Aldrete recovery score of 10 is achieved Adverse events like bradycardia (HR <45 bpm), hypotension (drop in systolic blood pressure >20% of baseline or MAP <60 mmHg), hypertension (an increase in systolic blood pressure or MAP >20% of baseline), bradypnea (RR <8 breaths/min), desaturation (SpO_2 < 90%), nausea, vomiting, dry mouth or any other event during or within two hours of the procedure were noted. Bradycardia was treated with intravenous atropine sulphate 0.01mg kg^{-1}, hypotension with fluid replacement and if needed, intravenous ephedrine hydrochloride 5 mg in incremental doses was administered. In case of bradypnea, patient was woken up and was asked to take deep breaths. Desaturation was treated by increasing O_2 flow up to 6 liters and if needed, using bag mask ventilation with 10 liters of oxygen. Both, the surgeons and patients were asked to rate their satisfaction using seven-point scale, the Likert scale13 [1- Extremely dissatisfied;2- Dissatisfied; 3- Dissatisfied somewhat; 4- Undecided; 5- Somewhat satisfied; 6- Satisfied; 7- Extremely satisfied].

Data And Statistical Analysis:-

The data obtained in the study for various parameters were presented in the tabulated and graphical form. Using statistical software (graph pad Instat3.0 software) mean and standard deviation was calculated for all the quantitative variables. Intra group comparison was made using the Repeated measures ANOVA and inter group comparison among the different groups were done using unpaired t - test. Inter group comparison of qualitative data were done by Chi square test. P value <0.05 was considered statistically significant. Mean age of the patients in the study was 31.16 ± 9.82, Gender wise distribution includes 54% (27) Males and 46% (23) Females, ASA 1 PS of 36% (18) and ASA 2 PS of 64% (32).

RESULT: -

100 patients were recruited. All of them underwent their planned surgical procedure and received their allocated study drug. No assigned patients dropped out of the study. The two groups were comparable with respect to demographic profile of the patients including mean age, mean weight, gender, ASA grade and mean duration of surgery, (P>0.05). (Table 1)

As compared to group F, there was statistically significant higher sedation score in group D, after bolus dose and remained so throughout the study. Inspite of higher sedation score in group D, no patient developed respiratory depression which shows safety of dexmedetomidine. The mean RSS was found to be higher in Group D than Group F i.e. The mean RSS was 02.70 ± 00.47 and 02.70 ± 00.57 in Group D and Group Irrespectively at the end of 20 min of loading infusion which was statistically significant, (P = 0.0073). (Table 2)

As compared to group F, there were statistically significant lower pain scores in group D, after bolus dose and remained so throughout the study. (Table 3)

Baseline heart rate is comparable in both the groups. Statistically significant reduction in heart rate is seen in group D as compared to group F after bolus dose and remained so throughout the procedure (p value <0.05). Four patients developed bradycardia in group D which responded to atropine. No patient developed bradycardia in group F. Baseline MAP is comparable in both the groups. Statistically significant reduction in MAP is seen in group D as compared to group F after bolus dose and remained so throughout the procedure (p value <0.05). Respiratory rate remained stable and comparable to baseline in the two groups throughout the study period. **(p>0.05)** SpO_2 remained stable and comparable to baseline in the two groups throughout the study period. (p>0.05)**.** (Table 4)

Four patients in group D developed bradycardia intraoperatively which responded to Inj atropine. No complications were noted in postoperative period. None of the patient in group F developed any intraoperative and postoperative complication. (Table 5).

Table 1: Demographic Profile Of Patients

Patient Characteristics	Group F (Mean± SD)	Group D (Mean± SD)	p-Value
Age (Years)	28±8.7	26±8.5	>0.05
Gender (M/F)	07/13	05/15	>0.05
Weight (Kg)	59.85±08.38	57.15±08.58	>0.05
ASA Physical Status (I/II)	11/09	10/10	>0.05
Duration of Surgery(min)	91.5±19.54	84±25	>0.05

Table 2 : Changes In Sedation Score

Time	Group F		Group D	
	Mean ± SD	Intragroup p Value	Mean ± SD	Intragroup p Value
Baseline	02.70±00.57		02.70±00.47	
After bolus dose	02.85±00.81	>0.05	03.20 ± 00.95	<0.001
5 Min	02.90±00.78	>0.05	03.25 ± 00.85	<0.001
10 Min	03.15± 00.87	<0.001	04.00 ± 01.00	<0.001
15 Min	03.15± 00.87	<0.001	04.00 ± 01.00	<0.001
20 Min	03.35 ± 00.81	<0.001	04.00 ± 01.00	<0.001
30 Min	03.05 ± 00.82	<0.001	04.00 ± 01.00	<0.001
40 Min	03.15 ± 00.87	<0.001	04.00 ± 01.00	<0.001
50 Min	03.00 ± 00.97	<0.001	04.00 ± 01.00	<0.001
60 Min	03.30± 00.73	<0.001	04.00 ± 01.00	<0.001

Table 3: Changes In Pain Score

Time	Group F		Group D	
	Mean ± SD	Intragroup p Value	Mean ± SD	Intragroup p Value
Baseline	00.80 ± 01.05		00.95 ± 01.23	
After bolus dose	01.40 ± 01.27	<0.001	01.20 ± 01.36	<0.001
5 Min	02.40 ± 00.99	<0.001	01.60 ± 00.75	<0.001
10 Min	02.75 ± 00.96	<0.001	01.55 ± 00.82	<0.001
15 Min	02.90 ± 00.91	<0.001	01.60 ± 00.82	<0.001
20 Min	03.15 ± 01.18	<0.001	01.85 ± 00.98	<0.001
30 Min	03.15 ± 01.08	<0.001	02.00 ± 00.79	<0.001
40 Min	03.15 ± 01.03	<0.001	01.95 ± 00.79	<0.001
50 Min	03.30 ± 01.17	<0.001	01.75 ± 00.78	<0.001
60 Min	03.25 ± 01.20	<0.001	01.95 ± 00.94	<0.001

Table 5: Complications

Complication	Group F		Group D	
	No. of patients	%	No. of patients	%
Bradycardia	0	0	4	10
Hypotension	0	0	0	0
Dry mouth	0	0	0	0
Respiratory Depression	0	0	0	0
Nausea/vomiting	0	0	0	0

DISCUSSION

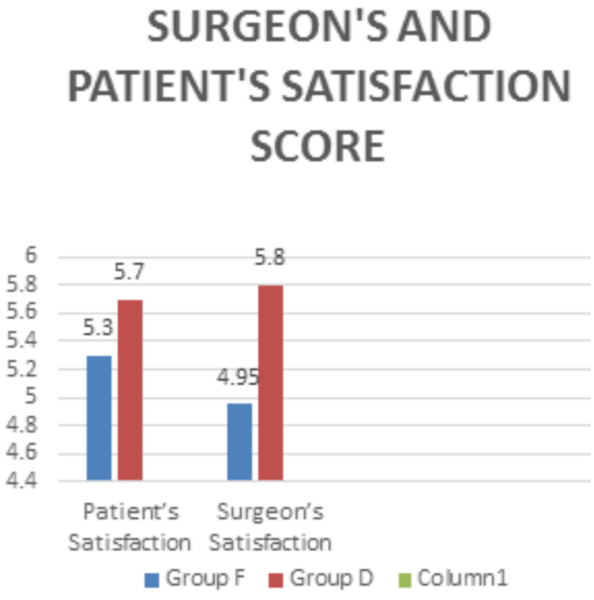
In our study, we compared two drugs dexmedetomidine and fentanyl given as a bolus followed by continuous infusion. In present study Ramsay sedation score was used to evaluate desirable sedation. This scale is widely used by several authors in studies on anaesthesiology and intensive care, has proven to be an established method in assessment of sedation quality. [11,12] In this study, dexmedetomidine achieved higher depth of sedation in short time and better pain scores as compared to fentanyl. Desirable sedation score was achieved more rapidly with dexmedetomidine (after bolus dose) than fentanyl (after 10 min of starting infusion.) Dexmedetomidine acts as an analgesic by modulating both the sensory-discriminative component of the pain and also the motivational-affective and cognitive component of pain.

The lower HR and MAP in Group D in comparison to the group F could be explained by the markedly decreased sympathetic activity. In the

present study, Respiratory rate and oxygen saturation remained stable and comparable in both groups. There was no evidence of bradypnea in either of the groups. Lesser number of patients (8%) receiving dexmedetomidine demanded rescue analgesics as compared to fentanyl group (16%). Limitation of the study could be that the effects of the drugs were seen only in ASA I/II patients. The effects of α agonists on the cardiovascular system may be beneficial in high-risk patients.[13]

Table 4: Changes In Heart Rate, Blood Pressure, Respiratory Rate And Oxygen Saturation

Time	HR			BP			SPO2			RR		
	Group F	Group D	Inter group p Value	Group F	Group D	Inter group p Value	Group F	Group D	Inter group p Value	Group F	Group D	Inter group p Value
Baseline	86.80 ± 08.28	86.30 ± 05.55	0.7519	85.75 ± 06.17	80.30 ± 04.71	>0.05	98.25 ± 00.85	99.00 ± 00.91	0.4512	13.00 ± 01.12	12.95 ± 01.14	0.17
After bolus dose	82.60 ± 07.31	74.65 ± 05.76	0.0213	87.55 ± 05.07	78.45 ± 06.63	0.0010	98.40 ± 00.88	98.70 ± 01.17	0.3463	12.25 ± 01.74	13.40 ± 00.99	0.81
5 Min	82.15 ± 06.53	71.95 ± 08.75	0.02	85.75 ± 06.18	75.85 ± 06.61	0.0023	98.20 ± 01.39	98.45 ± 01.27	0.3427	12.30 ± 01.75	13.35 ± 01.66	0.48
10 Min	81.30 ± 05.87	71.95 ± 07.50	0.0152	86.05 ± 05.69	74.60 ± 04.75	0.0025	97.80 ± 02.64	98.15 ± 01.59	0.8750	12.45 ± 01.35	12.70 ± 00.86	0.12
15 Min	81.95 ± 05.17	70.95 ± 06.84	0.0353	84.50 ± 04.62	76.00 ± 04.93	0.0093	98.35 ± 01.03	99.05 ± 00.82	0.8826	12.25 ± 01.74	13.45 ± 00.82	0.41
20 Min	81.45 ± 05.29	71.75 ± 05.73	0.029	84.75 ± 03.50	76.25 ± 05.19	0.0031	98.45 ± 00.82	98.60 ± 01.09	0.8446	11.80 ± 01.43	12.75 ± 00.91	0.30
30 Min	81.85 ± 05.03	70.85 ± 04.95	0.0231	84.15 ± 04.92	76.90 ± 05.65	0.0060	98.20 ± 01.05	98.50 ± 01.27	0.7309	12.15 ± 01.66	13.35 ± 01.56	0.41
40 Min	82.75 ± 06.67	69.90 ± 05.54	0.0054	83.55 ± 03.88	75.75 ± 05.03	0.0041	98.30 ± 00.92	98.20 ± 01.57	0.7830	12.55 ± 01.79	12.85 ± 00.87	0.57
50 Min	82.40 ± 05.15	71.75 ± 06.89	0.0058	84.05 ± 05.26	74.65 ± 05.06	0.0007	98.20 ± 01.10	98.80 ± 00.76	0.6600	12.25 ± 01.44	13.35 ± 01.03	0.19
60 Min	82.70 ± 04.72	70.00 ± 06.21	0.0003	83.00 ± 04.70	74.70 ± 04.10	0.0004	98.50 ± 01.19	99.00 ± 00.72	0.8184	12.55 ± 01.50	12.63 ± 00.83	0.51



CONCLUSION

Dexmedetomidine as sedative during tympanoplasty in the dose and regime used in present study provides significantly more favourable operating conditions, patients comfort and significantly decreased haemodynamic stress response in comparison to fentanyl used for the same purpose. We recommend routine use of dexmedetomidine 1 µg/kg bolus over 10 min followed by 0.7 µg/kg/hr. infusion in tympanoplasty. However, haemodynamic parameters need to be closely monitored.

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