Section: Anaesthesia

Original Research Article

COMPARISON OF DEXMEDETOMIDINE WITH FENTANYL FOR SEDATION IN TYMPANOPLASTY (ENT SURGERIES)

Madgula Shravan Kumar[1], Kiran Cheryala[2], Mohammad Heifzur Rahman[3]

[1]*Assistant professor, Department of Anaesthesia, Osmania Medical college, Telangana, India.*
[2]*Assistant professor, Department of Anaesthesia, GMC Sanga Reddy, Telangana, India.*
[3]*Associate professor, Department of Anaesthesia, GMC Yadagiri, Telangana, India.*

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Corresponding Author:
Dr. Mohammad Heifzur Rahman, Associate Professor, Department of Anaesthesia, GMC Yadagiri, Telangana, India.
Email: drmohammasheifzurrahman222@gmail.com

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ABSTRACT

Background: The aim is to evaluate the efficacy of dexmedetomidine and fentanyl as an appropriate sedative drug for Monitored Anaesthesia Care in Tympanoplasty (ENT surgeries).

Materials and Methods: A total of 60 patients between the age group of 18-60 years were included in the study. They were ASA I &II and scheduled for the elective Tympanoplasty surgery under Monitored anaesthesia care. Patients were randomized into 2 groups, as group F (Fentany group) received Inj.Fentanyl 1µ/kg bodyweight I.V and group D (Dexmedetomidine) received dexmedetomidine 1µ/kg body weight infusion over 10 mins. Patients fasted at least 8 hours before operation and did not receive any pre-operative sedative drug.

Results: Intra operatively & Post operatively SBP levels were relatively high in Dexmedetomidine group than fentanyl group and difference was statistically significant. DBP levels high at all times among dexmedetomidine group than fentanyl and diference was statistically significant and Post operatively there was statistically insignificant. MAP levels intra operatively higher at all times noted among dexmedetomidine group than the fantanyl Group and difference was statistically significant, Post operatively insignificant. Heart rate and SPO2 were Statistically insignificant intraoperatively and Post operatively. Pain and Discomfort scores are less at all times intraoperatively in dexmedetomidine group and there were statistically significant. Post operatively insignificant. sedation scores were less in dexmedetomine group at all till 45 mins s urgery and these were statistically significant than Fentanyl group. after 45 mins pain scores were similar and statistically insignificant.

Conclusion: The present study demonstrates that dexmedetomidine is a safe and effective alternative to fentanyl for sedation in patients undergoing tympanoplasty under monitored anesthesia care.

Keywords: Dexmedetomidine, Fentanyl, Tympanoplasty, Amaesthesia.

INTRODUCTION

Monitored anaesthesia care involves administering a combination of drugs for anxiolytic, hypnotic, amnestic and analgesic effect. Ideally it should result in less physiological disturbance and allow for more rapid recovery than general anaesthesia. It typically involves administration of local anaesthesia in combination with IV sedatives, anxiolytic and analgesic drugs which is a common practice during various ENT surgical procedures. Tympanoplasty in ENT surgical procedures involves reconstruction of perforated tympanic membrane with or without ossiculoplasty. It is usually done under local anaesthesia with sedation under monitored anaesthesia care (MAC) or general anaesthesia. Patients may feel discomfort due to pain, noisy suction, manipulation of instruments and head and neck position. There are many advantages of local anaesthesia supplemented with intravenous sedation, such as less bleeding, cost effectiveness, postoperative analgesia, faster mobilization of the

patient and the ability to test hearing intraoperatively. Several drugs such as propofol, benzodiazepines and opioids have been used for MAC either alone or in combination.

Dexmedetomidine is a highly selective α2 adrenoceptor agonist with eight times higher specificity for receptor compared to clonidine.[1] It provides excellent sedation and analgesia with minimal respiratory depression.[2] Dexmedetomidine can be safely and effectively used for procedural sedation and surgeries under MAC. Since the approval of Midazolam by FDA in 1985, practitioners of all medical disciplines embraced the versatility provided by midazolam though the risk of losing airway control, hypoxia and hypotention with higher doses of midazolam has also been recognized.[3,4] Midazolam is the most frequently used sedative and has been reported to be well tolerated when used in MAC.[5] Dexmedetomidine has the both sedative and analgesic properties and has been used as a single agent in many painful procedures. It also allows patients to respond to the verbal commands during sedation. It has been used in various clinical fields such as sedation in ICU, awake intubation, shockwave lithotripsy, endoscopic examination and as an adjuvant to anaesthetics.

Fentanyl is a potent, synthetic opioid analgesic with a rapid onset and short duration of action, a strong agonist at the μ-opioid receptors. The present study is undertaken for comparison of dexmedetomidine and Fentanyl in undergoing tympanoplasty surgery for assessing the haemodynamic control, pain, discomfort and sedation under Monitored Anaesthesia care (conscious sedation).

MATERIALS AND METHODS

After obtaining approval from the Hospital Ethics Committee, patients of either sex undergoing Tympanoplasty surgery under local anaesthesia were enrolled in this study to compare dexmedetomidine with Fentanyl at Govt ENT Hospital Hyderabad. Sixty (60) patients undergoing Tympanoplasty surgery. Thus the study contains 30 patients in Dexmedetomidine group- (Group D) and 30 patients in Fentanyl group (Group F).

Inclusion Criteria

Prospective randomized study of 60 patients who underwent Tympanoplasty surgery under local anaesthesia were included in the study.

Criteria includes:

Patients of either sex between ages 18-60 years, ASA Grade I or II: patients were awake, alert and oriented and their medical condition was stable enough to allow them to understand and use verbal numeric rating pain scale (VNRPS)

Exclusion Criteria

Patients belonging to ASA class lll or IV, co-morbidities, presence of coagulopathies, Hypersensitivity to any of the drugs used and Pregnant and Lactating women

Preoperative assessment:

A pre-anesthetic checkup was done for all patients which included a detailed history, general physical and systemic examination. Basic investigations including a baseline ECG, HIV, HBsAG were done. Patients were kept nil per oral overnight. They were counseled with regards to sedation, local anesthesia as well as the operative procedure. The visual analogue scale (VAS) (0-10, where 0 indicated no pain,while 10 corresponded to maximum pain), was explained to the patient during the preoperative visit and taken consent from the enrolled patients for this study.

The patients were randomly divided into two equal groups, Group D (dexmedetomidine) and Group F (fentanyl l).

In the operating room, following monitors were used- Pulse oximetry probe, B.P cuff for non invasive blood pressure monitoring, 5 lead ECG

On arrival in the operation theatre, after confirming adequate starvation, patient‟s heart rate, Non invasive blood pressure, oxygen saturation, respiratory rate and ECG were monitor. Intravenous access was secured with 18G cannula and Ringer‟s lactate solution at 2 ml kg-1 was started. Oxygen was administered with Hudson‟s mask at 2 L min-1. No sedative premedication was used.

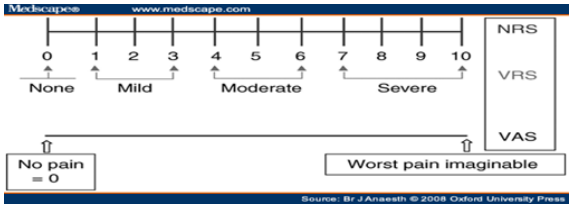
All patients were premedicated with Glycopyrolate 0.04mg/Kg, Ondansetron 0.8mg/kg Group D (n = 30) Dexmedetomidine 1 μg/kg over 10 min I.V infusion was given Group F (n = 30) Fentanyl 1 μg/kg I.V given.

During this period the patients were assessed by: Scores for Pain, Discomfort, Sedation, Heart rate, S ystolic Blood Pressure (SBP), Diastolic Blood pressure (DBP), Mean arterial Blood Pressure (MAP), and Peripheral oxygen saturation were recorded preoperatively (baseline), intraoperatively (at 5,10,15,20,30 & 45 min), until the completion of surgery & Post Operative monitoring at 30 mins interval for next 2hrs.

Pain was measured by a verbal numeric rating pain scale (VNRPS) from 0 to 10 (0:No pain, 10: The worst pain imaginable)

Visual Analogue Scale

0-No Pain 1,2,3- Mild pain 4,5,6- Moderate pain 7,8,9,10- Worst ever felt pain.



Discomfort was assessed using an 11-point verbal numeric rating discomfort scale (VNRDS) from 0 to 10 (0:None, 10: Extream discomfort);

Sedation was measured by Ramsay Sedation Score

1. Patient anxious and agitated or restless
2. Patient co-operative, oriented, and tranquil

3. Patient responds to verbal commands while sleeping
4. Patient exhibits brisk response to light glabellar tap or loud voice while sleeping
5. Patient exhibits a sluggish response to light glabellar tap or loud voice
6. Patient exhibits no response

After administering the drugs and when RSS of 3 was achieved, the ENT surgeon administered LA using 2% lignocaine with adrenaline (6-7 ml) (1:2,00,000) in the postauricular area to block greater auricular and lesser occipital nerves in the incisura terminalis to block auriculotemporal nerve and the four quadrants of the external auditory canal. Surgery was commenced after co nfirmi ng adequate a nalgesia. Intraoperatively heart rate (HR), Non invasive blood pressures, SPO2, pain, 32

discomfort and sedation were recoreded e very 5 mins inte rvals in intraoperatively and every 30 mins interval post operatively for next 2hrs. Respiration events were defined as oxygen saturation by pulsoxymetry (spo2)<92%. A decrease in spo2 to <92% for >30sec was treated sequentially with verbal stimulation, Guedel airway and bag & mask assisted ventilation.

Cardiovascular events were defined as a single episode variation in heart rate (HR) and Systolic blood pressure (SBP) by >20% from patient baseline. Persistent (two reading 3 min apart) or recurrent SBP<90mmHg, was treated with boluses of IV Ephedrine 6mg repeated and/ or persistent(>30s) or recurrent HR <50 bpm was treated with IV atropine 0.6mg and repeated as necessary.

The Surgical procedure lasted for 45 minutes in almost all the patients, After the completion of surgery patients were shifted to the PACU and were monitored for hemodynamic parameters, degree of analgesia and adverse events, at 30 mins interval for next 2hrs post operatively. RSS was assessed immediately on arrival in the PACU and every 30 min thereafter till transfer to surgical ward. Requirement of postoperative analgesia was noted.

Statistical Analysis:

The data thus collected was entered into an Excel sheet. It was further subjected to statistical analysis in MS Excel and SPSS v.16. Data was expressed in frequencies and percentages when qualitative and in Mean ± SD when quantitative. Chi square test and Fisher‟s exact tests were applied for qualitative data. Unpaired Student T test was used for comparing the trends for all parameters in the two groups. A P value of <0.05 was considered significant.

RESULTS

Both the groups were similar in the age, gender, weight distribution in Fentanyl group and Dexmedetomidine group was not statistically significant, thus making the groups comparable to each other.

Table 1: Age distribution of the sample.

Age group (years)	Fentanyl Group (N=30)	Dexmed Group (N=30)
<20	6 (20%)	6 (20%)
21-30	12 (40%)	12 (40%)
31-40	9 (30%)	9 (30%)
41-50	2 (6.67%)	2 (6.67%)
51-60	1(3.33%)	1(3.33%)
Total	30 (100%)	30 (100%)
Mean age	29.50 years	30.33 years
StDev	9.37 years.	9.44 years
Chi sq = 0; Df = 4; p=1.000 t = 0.3418; p= 0.734		
Gender		
Males	17 (56.67%)	19 (63.33%)
Females	13 (43.33%)	11 (36.67%)
Chi sq = 0.278; Df = 1; p=0.598		
Weight in kgs		
41 – 50	12(40%)	5 (16.67%)
51 – 60	14 (46.67%)	21(70%)
61 – 70	4 (13.33%)	4 (13.33%)
Total	30 (100%)	30 (100%)
Mean weight	53.50	54.80
SD	6.43	4.86
Chi sq = 4.282; Df = 2; p=0.118 t = 0.8833; p= 0.190		

Table 2: Baseline vitals of the groups.

Variable	Fentanyl group		Dexmed group		T test statistic	P value
	Mean	SD	Mean	SD.		
Age (yrs)	29.50	9.37	30.33	9.44	0.342	0.734
Weight (kgs)	53.5	6.43	54.8	4.8.	0.883	0.190
Pulse rate (bp m)	77.23	9.15	79.60	6.82	1.535	0.130
SBP (mm Hg)	120.57	6.76	122.10	11.02	1.139	0.259
DBP (mm Hg)	78.63	5.07	77.50	8.91	1.105	0.274
MAP (mm Hg)	95.76	5.16	92.00	9.09.	2.270	0.027*
SpO2	98.93	1.23	100.00	0.00	4.94	0.000*

Pain score	1.47	0.51	1.50	0.51.	0.848	0.400
D isco mfor t score	1.47	0.51	1.50	0.51	0.848	0.400
Sedation score	2.00.	0.00	2.00	0.00 .	NA	NA

The baseline characteristics preoperatively were almost similar in both the groups, with whatever differences observed were statistically insignificant, except for Mean arterial pressures and SPO2 levels.

Table 3: Intra and post op SBP trend over time

Time (min)	Fentanyl group		Dexmed group		T test statistic	P value
	Mean	SD	Mean	SD.		
Intra op SBP						
5 min	84.13	2.57	85.53	2.81	2.311	0.024*
10 min	84.27	.2.61	84.27	2.45	0.679	0.500
15 min	83.87	1.96	84.27	2.1.	1.221	0.227
20 min	84.87	2.33	83.80	1.69.	2.327	0.023*
30 min	83.60	1.69	83.80	1.52	1.012	0.316
45 min	84.13	2.22	84.00	2.17.	0.835	0.407
Post op SBP						
60 min	83.93	2.07	83.13	1.55	2.025	0.048*
90 min	83.93	2.07	83.13	1.55	2.025	0.048*
120 min	83.80	2.64	84.33	1.67	1.367	0.177
180 min	84.13	2.62	84.07	1.44	0.758	0.452

The SBP levels over time intra-operatively did not vary much in the fentanyl group and however around 84 mm Hg mark. The variations were relatively higher in dexmed group, with significant difference observed at 5 min and 20 min when compared to fentanyl group.
The SBP levels were observed to be lower at 60 & 90 minutes among dexmed group than fentanyl group and this difference was statistically significant.

Table 4: Intra and post op DBP trend over time

Time (min)	Fentanyl group		Dexmed group		Ttest statistic	P value
	Mean	SD	Mean	SD.		
Intra op DBP						
5 min	53.73	2.45	55.60	2.70	3.054	0.003*
10 min	54.60	.1.50	55.60	2.06	2.437	0.018*
15 min	55.13	.2.15	54.93	1.95	0.936	0.353
20 min	54.33	.1.75	55.53	1.9.	2.778	0.007*
30 min	55.53	2.08	56.20	2.31	1.567	0.122
45 min	55.13	2.15	55.80	1.99.	1.630	.0.109
post op DBP						
60 min	54.80	2.01	55.00	1.95	.0.945	0.348
90 min	54.80	2.01	55.00	1.95	0.945	0.348
120 min	54.20	1.99 .	54.87	2.81	1.471	0.14
180 min	53.87	2.46	54.53	2.16	1.517	0.13

The DBP levels were observed to be higher at all times noted among dexmed group than fentanyl group except at 15 min. The differences were statistically significant at 5 min, 10 min and 20 min. There is no statistically significant between two groups ($p>0.05$) when post OP DBP compared.
The MAP levels were observed to be higher at all times noted among dexmed group than fentanyl group except at 15 min. The differences were statistically significant at 5 min and 10 min. There is no statistically significant between two groups($p>0.05$) when post op MAP trends compared.

Table 5: Pulse rate trend in the groups

Time (min)	Fentanyl group		Dexmedgroup		T test statistic	P value
	Mean	SD	Mean	SD		
Baseline	77.23	9.15	79.60	6.82	1.535	0.130
5 min	63.87	2.98	62.73	2.88	1.848	0.070
10 min	64.63	3.83	62.43	3.10	2.713	0.009*
15 min	62.83	3.20	62.40	2.99	1.057	0.295
20 min	63.00	4.14	62.60	2.74	0.982	0.330
30 min	61.93	2.83	62.90	2.94	1.673	0.100
45 min	62.93	3.07	62.00	2.65	1.640	0.106
60 min	63.80 .	3.12	62.80	2.78	1.683	0.098
90 min	63.80	3.12	62.80	2.78	1.683	0.098
120 min	62.47	2.66	62.70	2.34	0.923	0.360
180 min	62.50	3.97	62.27	2.60	0.858	0.394

There is no statistically significant difference between the two groups ($p>0.05$), when Pulse rates are compared

Table 6: SpO2 trend in the groups

Time (min)	Fentanyl group		Dexmedgroup		T test statistic	P value
	Mean	SD	Mean	SD		
Baseline	98.93	1.23	100.00	0.00	4.94	0.000*
5 min	99.00	0.95	98.80	1.10	1.223	0.226
10 min	99.00	0.95	98.80	1.10	1.223	0.226
15 min	98.97	1.03	98.70	1.29	1.325	0.190
20 min	98.83	1.23	98.70	1.29	0.958	0.342
30 min	98.47	1.89	98.67	1.37	1.002	0.320
45 min	98.07	2.73	98.67	1.37	1.484	0.143
60 min	98.93	1.14	98.67	1.37	1.272	0.208
90 min	98.93	1.14	98.67	1.37	1.272	0.208
120 min	98.93	1.14	98.63	1.47	1.323	0.191
180 min	98.93	1.23	98.60	1.57	1.352	0.182

There is no statistically significant difference between the two groups (p>0.05), when SPO2 are compared

Table 7: Pain score trend in the groups

Time (min)	Fentanyl group		Dexmedgroup		T test statistic	P value
	Mean	SD	Mean	SD		
Baseline	1.47	0.51	1.50	0.51	0.848	0.400
5 min	4.77	0.73	3.97	0.81	4.234	0.000*
15 min	4.77	0.73	3.93	0.78	4.465	0.000*
30 min	4.50	0.51	3.83	0.70	4.427	0.000*
45 min	4.50	0.51	3.73	0.58	5.612	0.000*
60 min	3.33	0.48	2.43	0.50	7.265	0.000*
90 min	3.33	0.48	2.43	.0.50	7.265	0.000*
120 min	1.63	0.49	1.63	0.49	0.679	0.500
180 min	1.63	0.49.	1.63	0.49	0.679	0.500

At all points of time after admistration of fentanyl and dexmedetomidine, it was observed that the pain scores were less in dexmedetomidine group than fentanyl group and these were statistically significant (p= 0.00).

Table 8: Discomfort score trend in the group

Time (min)	Fentanyl group		Dexmed group		T test statistic	P value
	Mean	.SD	Mean	.SD		
Baseline	1.47	0.51	1.50	0.51	0.848	0.400
5 min	4.87	0.78	4.40	0.50	3.021	0.004*
15 min	4.87	0.78	4.40	0.50	3.021	0.004*
30 min	4.87	0.78	4.37	0.49	3.223	0.002*
45 min	4.83	0.79	4.40	0.50	2.800	0.007*
60 min	3.90	0.71	3.47	0.63	2.763	0.008*
90 min	3.90	0.71	3.43	0.57	3.054	0.003*
120 min	1.67	0.48	1.67	0.48	0.679	0.500
180 min	1.67	0.48	1.67	0.48	0.679	0.500

At all points of time after injection of fentanyl and dexmedetomidine, it was observed that the discomfort scores were less in dexmedetomidine group than fentanyl group and these were statistically significant (p<0.05).

Table 9: Sedation score trend in the groups

Time (min)	Fentanyl group		Dexmed group		T test statistic	P value
	Mean .	SD	Mean	SD .		
Baseline	2.00 .	0.00	2.00	0.00	NA	NA .
5 min	4.57	0.50	3.63	0.49	7.451	0.000*
15 min	4.57 .	0.50	3.63	0.49 .	7.451	0.000*
30 min	3.57	0.50	3.07	0.69	3.431	0.001*
45 min	3.57	0.50	3.07	0.69	3.431	0.001*
60 min	3.57	0.50	3.37	0.49	1.901	0.062
90 min	3.57	0.50	3.37	0.49	1.901	0.062
120 min	3.00	0.00	3.00	0.00	NA	NA
180 min	3.00	0.00	3.00	0.00	NA	NA

At all points of time after injection of fentanyl and dexmed till 45 minutes, it was observed that the sedation scores were less in dexmedetomidine group than fentanyl group and these were statistically significant(p<0.05).

Table 10: Cardiovascular events in the groups

Group	Cardiovascular events present	Cardiovascular events absent	Total
Dexamed	5 (16.67%)	25 (83.33%)	30
Fentanyl	2 (6.67%)	28 (93.33%)	30
Total	7 (11.67%)	53 (88.33%)	60

Chi square = 1.456; DF = 1; p= 0.228 = not significant

The cardiovascular events occurred in 16.67 % in dexmed group and in 6.67% of fentanyl group. But this was not statistically significant.

Table 11: Respiratory events in the groups

Group	Respiratory events present	Respiratory events absent	Total
Dexamed	1 (3.33%)	29 (96.67%)	30
Fentanyl	5 (16.67%)	25 (83.33%)	30
Total	6 (10%)	54 (90%)	60

Chi square = 2.963; DF = 1; p= 0.085 = not significant

The Respiratory events occurred in 16.67 % in fentanyl group and in 3.33% of dexmed group. But this was not statistically significant.

DISCUSSION

In all patients average duration of surgery was around 45 mins. Both groups of patients did not receive any analgesic during intraoperative and postoperative period as rescue analgesic for breakthrough pain. The differences in age, gender and average weight in two groups was also statistically insignificant. The difference in average preoperative vitals are statistically insignificant.

In the present study, we evaluated the effects of dexmedetomidine and fentanyl on intraoperative and postoperative systolic blood pressure (SBP) during tympanoplasty under monitored anesthesia care. Our findings revealed that SBP remained relatively stable in the fentanyl group, whereas the dexmedetomidine group demonstrated significantly greater fluctuations intraoperatively, particularly at 5 and 20 minutes, and a significantly lower SBP postoperatively at 60 and 90 minutes (P = 0.048).

These results are consistent with those reported by Gupta et al,[6] who found that dexmedetomidine was associated with significantly lower blood pressure and heart rate values compared to fentanyl during middle ear surgeries. The hemodynamic alterations observed with dexmedetomidine are attributed to its α2-adrenergic agonist action, which reduces sympathetic outflow and leads to vasodilation and bradycardia. This effect is beneficial for creating a controlled hypotensive environment, often desirable in ENT surgeries to improve the surgical field visibility by minimizing bleeding.

Similarly, Patel et al,[7] reported greater hemodynamic stability with fentanyl but noted better sedation quality and surgeon satisfaction with dexmedetomidine. While fentanyl offers strong analgesia and stable cardiovascular parameters, it carries a higher risk of respiratory depression, which is a concern in airway-compromised surgeries like tympanoplasty. In contrast, dexmedetomidine maintains adequate ventilation and allows arousable sedation, which is often preferred in awake or semi-awake procedures.

In our study, although dexmedetomidine caused significant reductions in SBP, no episodes of severe hypotension requiring intervention were noted. This suggests that while dexmedetomidine may induce measurable hemodynamic changes, these remain clinically manageable with proper monitoring. Notably, Bajwa et al,[8] also concluded that dexmedetomidine's hypotensive effects were beneficial without causing adverse outcomes, emphasizing its safety in ENT surgeries.

In addition to systolic blood pressure changes, our study also observed significant differences in diastolic blood pressure (DBP) between the two groups. Intraoperatively, the dexmedetomidine group exhibited higher DBP levels compared to the fentanyl group, and this difference was statistically significant ($P < 0.05$). Postoperatively, however, no statistically significant difference was noted between the two groups ($P > 0.05$). This finding partially contrasts with the hemodynamic profile typically associated with dexmedetomidine. Most studies, including Bajwa et al,[8] and Gupta et al,[6] report both systolic and diastolic blood pressure reductions during dexmedetomidine sedation due to central sympatholytic effects. However, transient increases in diastolic pressure can occur during the loading phase, due to peripheral vasoconstriction via stimulation of α2B receptors, before the central effects predominate. The higher intraoperative DBP in the dexmedetomidine group observed in our study may reflect this biphasic response, especially if the measurements coincided with or followed the loading dose phase. Additionally, variability in individual patient responses, dosing rates, and anesthetic technique could account for these differences. Patel et al,[7] also noted fluctuations in DBP during dexmedetomidine infusion but emphasized the overall cardiovascular stability and minimal need for pharmacologic intervention. The lack of significant difference in postoperative DBP aligns with prior studies, suggesting that once the acute pharmacodynamic effects wane, diastolic pressure returns to baseline, and the differences between groups diminish.

In our study, pulse rate was monitored at multiple time points intraoperatively and postoperatively. Although minor fluctuations were observed between the fentanyl group (mean baseline: 77.23 ± 9.15 bpm) and the dexmedetomidine group (mean baseline: 79.60 ± 6.82 bpm), the differences were not statistically significant throughout the perioperative period (P > 0.05). These findings are consistent with the results reported by Agarwal et al,[9] and Bajwa et al,[6] where dexmedetomidine was associated with a modest reduction in heart rate due to its central sympatholytic action, but without causing significant bradycardia in most patients. In our cohort, both drugs maintained heart rate within clinically acceptable ranges, and no episodes of symptomatic bradycardia or tachycardia were reported.

It is noteworthy that dexmedetomidine typically causes a dose-dependent decrease in heart rate, particularly after a bolus dose. However, the absence of statistical significance in our study could be attributed to Careful titration of the drug dose, Shorter procedural duration, Baseline hemodynamic stability of the patient population. On the other hand, fentanyl, being an opioid, may induce vagal stimulation or baroreflex modulation, leading to mild bradycardia, though less predictably than dexmedetomidine. The comparable heart rate profiles in both groups further support the hemodynamic safety of dexmedetomidine when used judiciously.

In the current study, cardiovascular events were noted in 16.67% of patients in the dexmedetomidine group compared to 6.67% in the fentanyl group. Although the incidence appeared higher with dexmedetomidine, the difference was not statistically significant (P = 0.228). These findings are consistent with previous studies by Agarwal et al,[9] and Bajwa et al,[8] who reported mild cardiovascular effects such as bradycardia and hypotension with dexmedetomidine, especially during the loading phase. However, with proper monitoring and dose adjustment, these events were mostly transient and manageable. In contrast, respiratory events were more frequently observed in the fentanyl group (16.67%) than in the dexmedetomidine group (3.33%), though this difference also did not reach statistical significance (P = 0.085). This aligns with established pharmacologic profiles: fentanyl, as a potent μ-opioid receptor agonist, can cause dose-dependent respiratory depression, particularly when combined with sedatives. Meanwhile, dexmedetomidine, known for its minimal impact on respiratory drive, has been widely supported in the literature (e.g., Gupta et al,)[6] as a safer alternative in procedures requiring spontaneous breathing and airway patency, such as tympanoplasty. Furthermore, the mean SpO_2 levels remained stable and comparable between both groups at all intraoperative and postoperative time points, with no statistically significant differences (P > 0.05). This further underscores the respiratory safety of both drugs when used appropriately, with dexmedetomidine offering a clear advantage in terms of minimizing adverse respiratory events without compromising oxygenation.

Pain perception, measured by the 10 cm Visual Analog Scale (VAS) at regular intervals up to 180 minutes postoperatively, revealed that patients in the dexmedetomidine group consistently reported lower pain scores compared to those in the fentanyl group. This difference was statistically significant at 5, 15, 30, 45, 60, and 90 minutes postoperatively (P = 0.00), whereas at other time points, the differences were not statistically significant (P > 0.05).This result aligns with findings from Bajwa et al,[8] and Gupta et al,[6] who demonstrated that dexmedetomidine, aside from its sedative and anxiolytic properties, also offers notable analgesic benefits by acting on spinal and supraspinal α2 receptors, thereby reducing pain perception and postoperative analgesic requirements. The extended period of statistically significant pain relief observed in our study, especially during the first 90 minutes, further supports the role of dexmedetomidine in enhancing postoperative comfort in ENT procedures such as tympanoplasty. In contrast, fentanyl, though a potent opioid analgesic, may provide shorter-acting pain relief due to its shorter half-life and rapid redistribution. Moreover, the development of acute tolerance and variability in individual opioid sensitivity may contribute to higher VAS scores in the fentanyl group during the early postoperative period. These findings highlight the dual advantage of dexmedetomidine in providing both adequate sedation and sustained analgesia, especially in the early recovery phase, thereby improving overall patient experience and reducing the need for rescue analgesics.

Discomfort levels, as assessed using the 10 cm Visual Numeric Rating Discomfort Scale (VNRDS) at regular intervals intraoperatively and postoperatively (up to 180 minutes), showed that the dexmedetomidine group consistently reported lower discomfort scores than the fentanyl group. The difference was statistically significant at 60 and 90 minutes (P < 0.05), indicating improved patient comfort with dexmedetomidine. These findings are in line with previous studies such as Tobias et al,[10] and Gupta et al,[6] which emphasize the anxiolytic and sedative properties of dexmedetomidine that contribute to enhanced patient comfort, especially in awake or semi-awake procedures like tympanoplasty. Dexmedetomidine's ability to produce a state of cooperative sedation—in which the patient is relaxed but easily arousable—may explain the consistently lower discomfort levels reported. In contrast, fentanyl, although effective as an analgesic, does not provide anxiolysis or muscle relaxation to the same extent, potentially contributing to higher discomfort scores, especially during the early recovery phase.

Sedation depth, assessed using the Ramsay Sedation Scale (RSS) at multiple time points intraoperatively and postoperatively, was consistently lower in the dexmedetomidine group than the fentanyl group. The difference was statistically significant at 5, 15, 30, and 45 minutes (P < 0.05), indicating that

dexmedetomidine provided more effective early sedation. This finding is supported by earlier studies such as those by Arain and Ebert,[11] and Tobias,[10] who reported that dexmedetomidine provides a state of conscious sedation with minimal respiratory compromise. The ability of dexmedetomidine to produce a calm yet arousable state makes it highly suitable for procedures like tympanoplasty, where patient cooperation and stable airway reflexes are essential. Although fentanyl contributed to adequate sedation, its profile is more analgesic-focused, and it may require adjunct sedatives to achieve similar sedation scores, potentially increasing the risk of respiratory depression.

A significant number of the patients from Dexmedetomidine group had fall in heart rate by >20% from base line than Fentanyl Group. Five patients in Dexmedetomidine had fall in bradycardia when compared to two patients in Fentanyl group (P=0.228). But not required to treat the bradycardia with I.V. Atropin, improved by verbal response with patient. This was not statistically significant. One patient in Dexmedetomidine group had fall in <90% SPO2 when compared to five patients in fentanyl group (P=0.085) and found statistically insignificant. The main findings of this study is that Dexmedetomidine reduces pain and discomfort better than Fentanyl and difference is statistically significant. 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 sedation provided with Dexmedetomidine is profound to Fentanyl. Even though cardiovascular events are high in dexmedetomidine group, they are statistically insignificant. Respiratory events are comparable in both groups. No groups showed serious adverse effects of the drugs, that required abandonment of the surgical procedure.

CONCLUSION

Dexmedetomidine provides less discofort, better sedation, analgesia when compared with fentanyl under monitored anaesthesia care(Conscious sedation). However the risk of adverse effects requires monitoring for ready intervention. It provides a unique type of sedation, “conscious sedation” in which patients appear to be sleepy but are easily arousable, cooperative and communicative when stimulated. It is sedative and analgesic agent, with opiod-sparing properties and minimal respiratory depression.

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