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Comparison of dexmedetomidine-fentanyl and dexmedetomidine-pentazocine for monitored anesthesia care during tympanoplasty surgery

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Abstract
Background: Several Middle Ear Surgeries have been done under Local or General Anesthesia and it has many advantages. However, there is inability of the patients to tolerate noise of suction, manipulation of instruments, positioning of head-neck, pain etc. Monitored Anesthesia care is a planned procedure for 10-30% of all surgeries. MAC typically involves administration of local anaesthesia in combination with IV sedatives, anxiolytic and/or analgesic drugs which is a common practice during Tympanoplasty.
Methodology: The present study was designed to compare α-2 agonist Dexmedetomidine with intravenous Pentazocine and Fentanyl. This study was approved by institutional ethical committee. 50 patients were registered in this study; patients were randomly allocated into 2 groups (group DF and group DP). Group DF and Group DP received IV Dexmedetomidine at a loading dose of 1mcg/kg over 10 minutes followed by continuous infusion 0.5 mcg/kg/hr till surgery was over. Degree of sedation and pain intensity was assessed by using Ramsay Sedation Score (RSS) and Visual analogue scale (VAS). Rescue doses of Fentanyl and Pentazocine were administered and noted. P-value was used for statistical analysis. **Results:** Higher repeated doses of Pentazocine were required for group DP patients (6.25±4.573) as compared to Group DF participants injected with Fentanyl (6±8.287). Surgeon satisfaction score was more satisfactory in Group DF (Fentanyl) than Group DP (Pentazocine). Post-operative Visual Analogue Score (VAS) was higher in group DP (2.18±1.1.8) than group DF (0.593±0.2392). No post-operative complications were seen in both groups.
Conclusion: We found that Dexmedetomidine-Fentanyl is a better combination in Tympanoplasty surgeries under monitored anesthesia care. It not only improves the intra-operative analgesia but also gives better post-operative analgesia.

Keywords: Tympanoplasty, dexmedetomidine, fentanyl, pentazocine, VAS, RSS, MAC

Introduction
Middle ear surgeries are significantly challenging for the surgeons, patients and Anesthesiologists [1]. Tympanoplasty procedure involves the reconstruction of perforated tympanic membrane with or without ossiculoplasty [2]. The procedure is usually done under local anesthesia under monitored anesthesia care (MAC). Tympanoplasty surgeries under local anesthesia have common problems of intolerance to noise during surgery, backache, anxiety, ear ache, claustrophobia, dizziness [3], The main advantages of doing surgery by Local anesthesia under MAC are less operative pain, early recovery, cost effective and ability to test hearing during surgery [4]. In MAC, various sedative drugs are used like opioids, benzodiazepines and α-2 agonist [5].
Dexmedetomidine is a selective α-2 adrenoreceptor agoinst, acts centrally with analgesic and sedative in the titrated dose without respiratory depression. Dexmedetomidine is widely used as a sedative for MAC for many surgical procedures [6]. Fentanyl is a derivative of phenylpiperidine and it is a synthetic opioid agonist with a high affinity for μ receptors. Fentanyl is used as a analgesic and when used for MAC in combination with another sedative agent, it causes dose dependent respiratory depression [7]. Pentazocine is the first synthetic agonist-antagonist which was used as an analgesic. It has weak μ antagonist and higher κ agonistic actions [8]. However, high dose of Pentazocine can cause high blood pressure during surgery due to sympathetic stimulation. Vomiting occurs less frequently; sweating and lightheadedness are the other side effects [9].

The purpose of the study was to compare Dexmedetomidine-Pentazocine and Dexmedetomidine-Fentanyl in terms of VAS, RSS and Haemodynamic parameters.

Materials and Methods

A prospective, randomized controlled study was undertaken in our tertiary care teaching hospital from December 2021 to July 2022. This study was approved by institutional research and ethical committee. Informed consent was taken from the participants before the procedure.

Institution ethical board number: KIMSDU/IEC/01/2021.

Selection of Participants

The patients were randomly assigned into two groups, DF and DP with 25 participants in each group. Patients were excluded if they had cardiovascular dysfunction, allergy to either drug or other medications, history of chronic use of sedatives or narcotics, morbid obesity, significant liver disease, atrioventicular block, pregnancy. All the patients were examined a day before surgery and investigated thoroughly according to the hospital protocol. All the patients were counseled with regards to local anesthesia, sedation and operative procedure and written consent was taken from all the participants. Patients were instructed to keep fasting for 8 hours pre-operatively. VAS (Visual analogue scale) was explained to the patients during the pre-operative visit (scale 0-10, where 0 represents no pain whereas 10 represent maximum pain) [10].

Interventions

The Anesthesiologist was blinded to the patient's group assignment and the study was recorded by the blind observer. After arrival of the patient at the operation theatre, intravenous access was started. Baseline parameters of Heart rate (HR), Systolic Blood Pressure (SBP), Diastolic blood pressure (DBP), SpO_2, Respiratory rate (RR), ECG were started and recorded. All the patients were administered oxygen (4L/min). No sedative or premedication was used. Group D-F patients were started with Dexmedetomidine infusion 1mcg/Kg over 10 minutes and IV bolus of Fentanyl 0.5 mcg/Kg. After 10 minutes Dexmedetomidine was injected 0.5mcg/kg/hr till the surgery was over. Repeated doses of Fentanyl (10 mcg) were given from bolus syringe if required.

Group D-P patients were started with Dexmedetomidine infusion 1mcg/kg over 10 minutes and Pentazocine 0.3mg/kg IV bolus. After 10 minutes Dexmedetomidine was injected 0.5 mcg/Kg/hr till the surgery was over. Repeated doses of Pentazocine (6mg) were given from bolus syringe if required. Intra-operatively Heart Rate, Blood pressure, Respiratory rate and SpO2 were recorded every 10 minutes during the loading infusion of the drug till the surgery was over and Ramsay sedition score (RSS) also assessed every 10 minutes. (1= agitated, restlessness, 2= cooperative, 3= responds to verbal commands 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 or glabellar tap or loud voice) [11]. During intra-operative procedure if RSS score was >3, maintenance infusion was discontinued. Pain intensity was evaluated every 10 minutes using Visual Analogue score, if VAS was >3, rescue analgesia was given (Fentanyl and Pentazocine). Total number of rescue analgesia doses were recorded.

After completion of surgery, patients were shifted to Post Anesthesia care Unit (PACU) and monitored for hemodynamic parameters. Post-operative pain was assessed again by using VAS. If VAS was > 3, then injection Diclofenac 1.5 mcg/kg analgesia was advised. Satisfaction with analgesia and sedation, comfort of patients was assessed by Anesthesiologist and Surgeons using 7 point Likert Scale (Verbal Rating Scale); acceptable satisfaction score being 4 and 5. Adverse events namely, bradycardia, hypotension, hypertension, desaturation, nausea, vomiting, dry mouth or any other symptoms developing post-operatively for 2 hours or during surgical procedure were noted and patients were treated accordingly.

Likert Scale [12]

1.	Extremely dissatisfied
2.	Dissatisfied
3.	Slightly dissatisfied
4.	Undecided
5.	Slightly satisfied
6.	Satisfied
7.	Extremely Satisfied

Statistical analysis

Data was expressed as Mean ± SD (Standard Deviation) and hemodynamic variables were analyzed by using P value. P Value less than 0.05 were considered statistically significant at 95% Class Interval.

Results

Number of Patient in each group was 25. The demographic data in terms of age and sex were compared in both groups and not significant statistically (Table 1).

Table 1: Demographic Profile of the Participants

Parameters	Dex-Fentanyl	Dex-Pentacozine	P-Value
Age in Years	35.08±9.5040	31.64±8.9110	0.0777
Sex			
Male/Female	20/5	18/7	0.2690

Changes in Haemodynamic parameters (Diastolic Blood Pressure, Systolic Blood Pressure, Heart Rate, Respiratory Rate, and SPO2) were recorded and compared between both groups. The Haemodynamic parameters are highly significant statistically (Table 2). Haemodynamic parameters of group DF were stable than group DP.

Table 2: Haemodynamic Parameter of both groups

	Dex-Fentanyl (Mean ± SD)	Dex-Pentacozine (Mean ± SD)	P-Value
DBP	76.313±3.318	74.453±2.815	0.0003
SBP	112.613±4.794	109.233±4.018	<0.0001
MAP	88.973±2.975	86.046±3.213	0.0015
RR	14.584±0.883	13.913±0.9126	<0.0001
SPO_2	0.983±0.0119	0.949±0.0300	0.0034
HR	82.12±3.744	81.53±3.979	0.0269

Intra-operative mean Ramsay Sedation Score (RSS) in group DF was 2.7133±0.4756 while group DP was 2.346±0.5261. Group DP required more sedation than DF and was highly significant statistically [Table 3].

Table 3: Mean Ramsay Sedation Score (RSS) and Visual Analogue Score in Both Groups

	Dex-Fentanyl Mean ± SD	Dex-Pentacozine Mean ± SD	P-Value
RSS	2.7133±0.4756	2.346±0.5261	0.0028
VAS (Intra Operatively)	2.313±0.8445	2.28±0.5252	0.4254 (Not significant)
VAS (Post Operatively)	0.5933±0.2392	2.18±1.118	0.0035

The VAS score was higher in group D-F with statistically insignificant difference from 10 minutes onwards throughout the entire duration of surgery. In group D-P, patients required more rescue dose of analgesic (Pentazocine) than group D-F (Table 4). Post-operatively, mean VAS was significantly less in group D-F than group D-P (Fig 5) and was statistically significant throughout the 60 minutes.

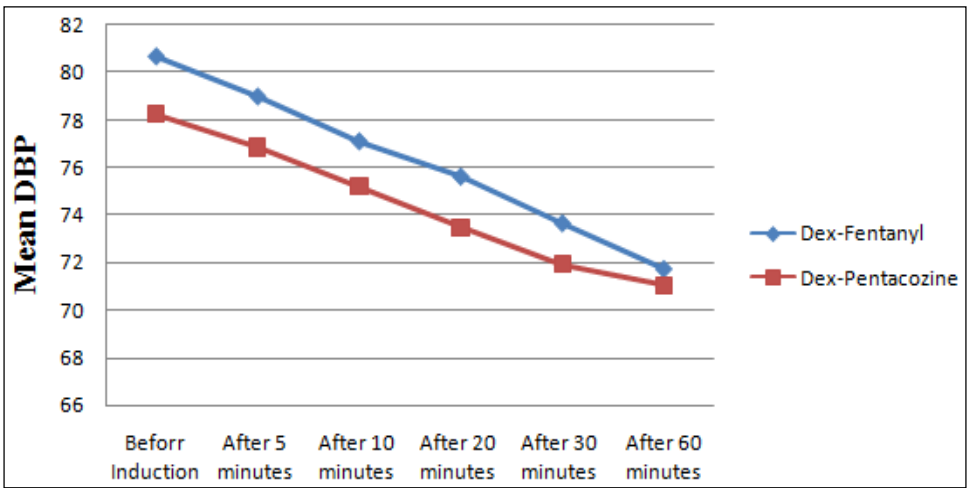

Fig 1: Mean Diastolic in Both Groups

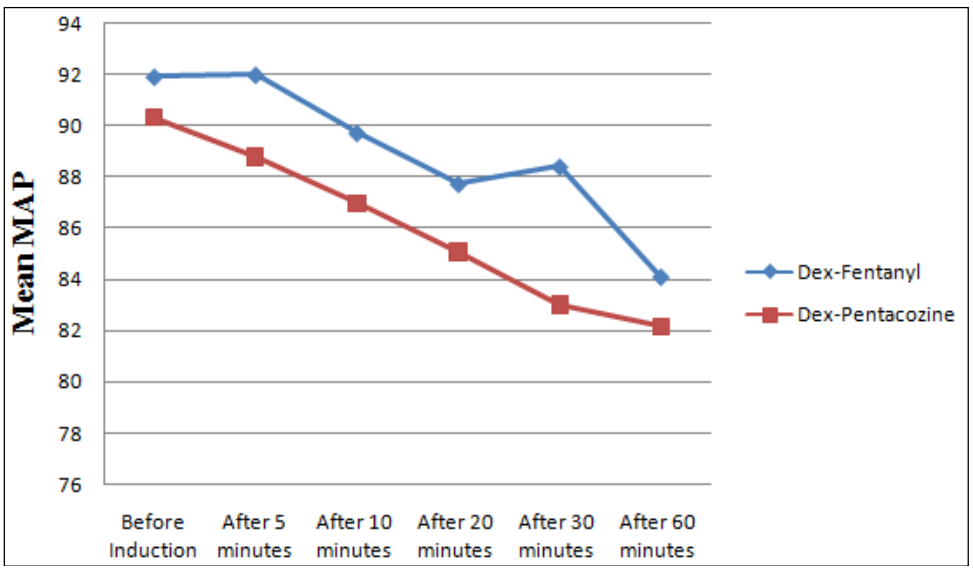

Fig 2: Mean Arterial Pressure in Both Groups

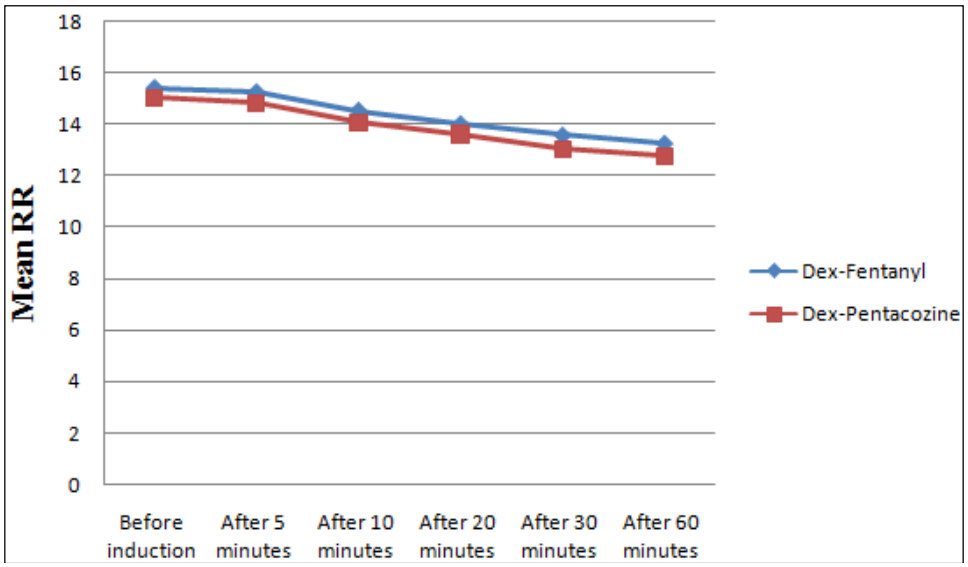

Fig 3: Mean Respiratory rate in Both Groups

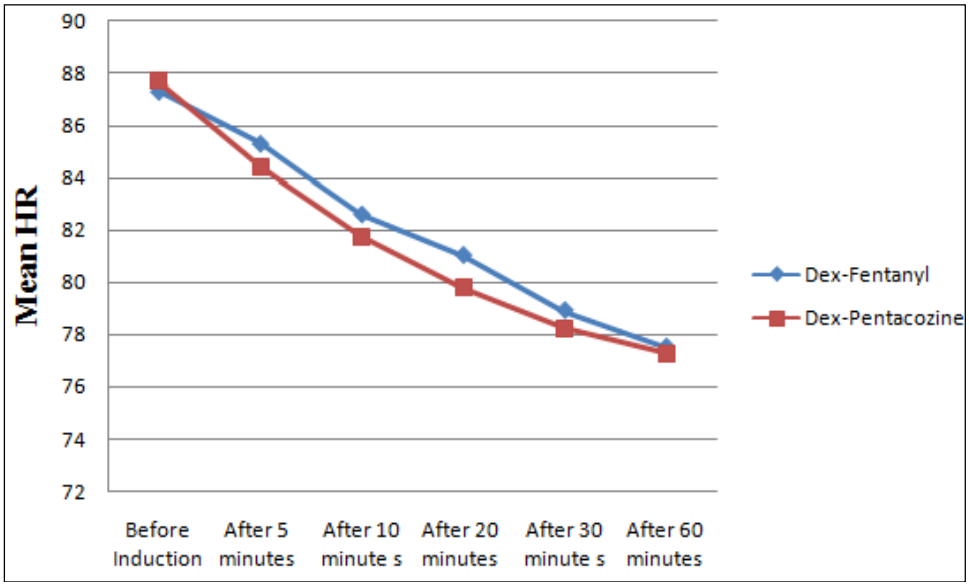

Fig 4: Mean Heart rate in Both Groups

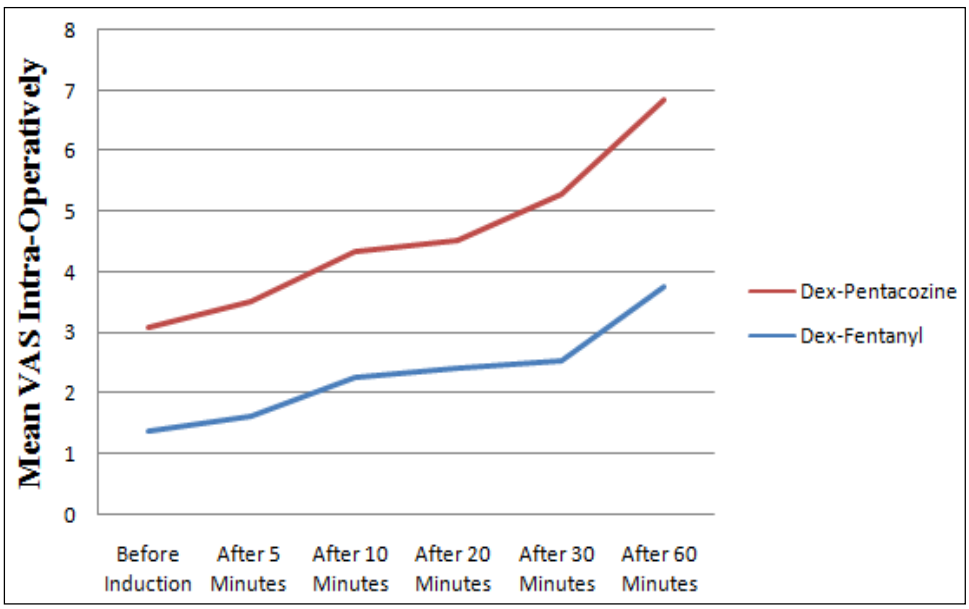

Fig 5: Visual Analogue Scale in two groups Intra-Operatively

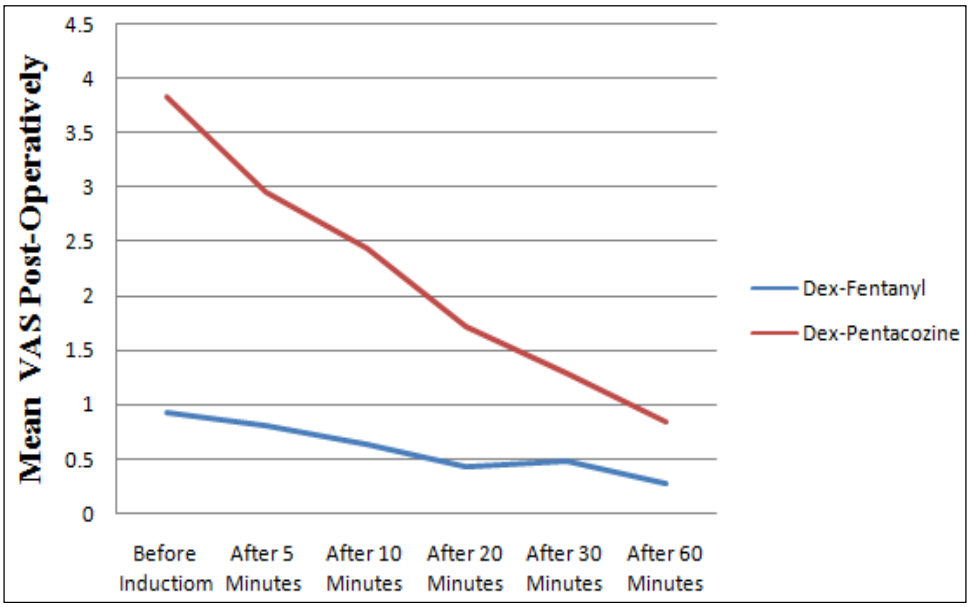

Fig 6: Visual Analogue Scale in Both groups Post-Operatively

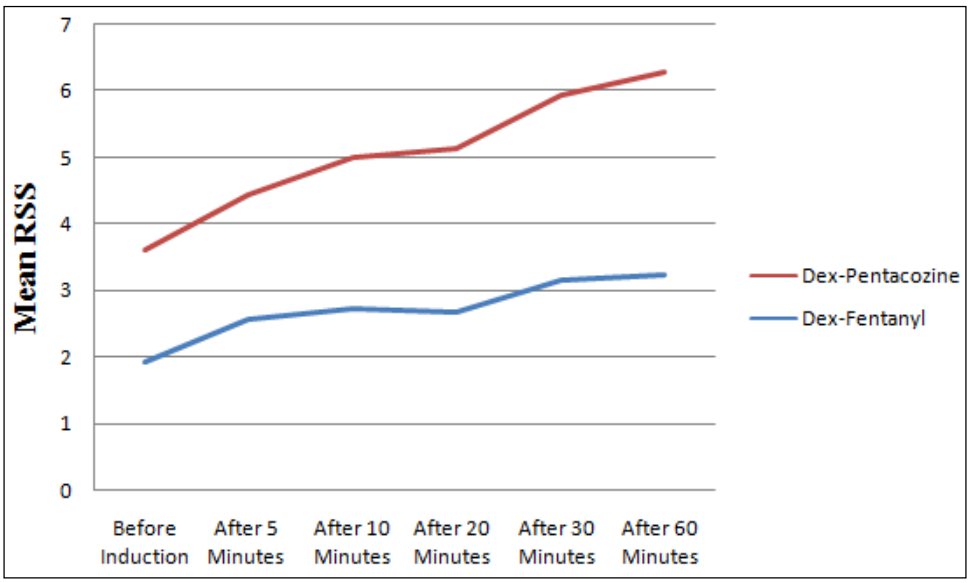

Fig 7: Ramsay Sedation Scale in Both Groups

Table 4: Rescue Sedatives and Analgesic

No. of Doses	No. of Participants		P- Value
	Dex-Fentanyl	Dex-Pentacozine	
0	1	1	0.4805
1	18	5	
2	5	12	
3	0	7	
Mean ± SD	6±8.287	6.25±4.573	

Surgeons were more satisfactory on Dex-Fentanyl than Pentazocine (Table 4) when compared to group D-F. There were a two incidence of Bradycardia and vomiting in group DP whereas no side effects were observed in group D-F.

Table 5: Likert Score of Both groups

Likert Score	Dex-Fentanyl	Dex-Pentacozine
1	0	0
2	0	0
3	0	1 (4%)
4	0	3(12%)
5	7 (28%)	6 (24%)
6	6 (24%)	5 (20%)
7	12 (48%)	10 (40%)

Discussion

They are several benefits of doing operations under local anesthesia with Monitored Anesthesia Care (MAC). Middle ear surgeries have difficult challenges for the Surgeons, Patients and Anesthesiologists [8]. During intra-operative Tympanoplasty surgeries, patients are restless, have pain, tachycardia, increased bleeding, sympathetic simulation etc. This leads to increased time of surgeries and graft rejection [14]. Hence, sedations are used during surgery with local anesthesia to reduce the above complications. In the present study, we compared Dexmedetomidine-Fentanyl and Dexmedetomidine-Pentazocine for MAC. We assessed the patients in terms of Patient satisfaction score, Surgeon satisfaction Score, analgesic, sedation and Hemodynamic parameters.

In the present study, we observed that intra-operative RSS was better in group D-F (Dexmedetomidine with Fentanyl) than group D-P (Dexmedetomidine with Pentazocine) and this was statistically significant [Table 3]. Azatshatru *et al*., 2020 observed Dexmedetomidine was better than a combination of Midazolam-Fentanyl for Tympanoplasty surgery [15]. Parikh D *et al*., 2013, observed hemodynamic parameters of Dexmedetomidine and combination of Midazolam-Fentanyl and found both groups to be comparable with satisfactory outcome without requiring any additional sedation during Tympanoplasty surgery [16].

In our study, we compared Dexmedetomidine-Fentanyl and Dexmedetomidine-Pentazocine. Dexmedetomidine alone gives better sedation and analgesia. However, we added Pentazocine and Fentanyl as a rescue dose after loading dose was completed if patients required any additional rescue dose. We observed that both groups had better hemodynamic effects but VAS pain score after surgery was better in D-F group than D-P. Minimum side effects were observed in group D-P (Vomiting, hypertension) than group D-F. In general, high dose of Pentazocine may cause high heart rate or High blood pressure, respiratory depression and drowsiness.

Solanki Uttama *et al*., 2018 [2], Arain SR *et al*., 2002 [17], Alhashemi JA *et al*., 2006 [18] studied Dexmedetomidine vs. Pentazocine-Promethazine and they observed Dexmedetomidine is better than the combination and also suggested that Dexmedetomidine helps in reducing the hypotension and gives less intra-operative bleeding. Devangi Parikh *et al*., [15] compared intravenous Dexmedetomidine with intravenous midazolam and fentanyl in 90 patients undergoing Tympanoplasty under local anesthesia and reported that Dexmedetomidine was comparable to Midazolam-Fentanyl for sedation and analgesia with good surgeon and patient satisfaction score.

Conclusion

In general, intravenous infusion of Dexmedetomidine causes better sedation, lower VAS scores and reduces the requirement of rescue analgesia. In present study, we compared Dexmedetomidine-Fentanyl and Dexmedetomidine-Pentazocine. We conclude that, Dexmedetomidine-Fentanyl is a better combination than the Dexmedetomidine-Pentazocine for Monitored anesthesia care in Tympanoplasty surgery.

Author Contribution: AAC and Dhul Conceived and designed the analysis; AAC Collected the data; AAC and AK Contributed data or analysis tools; AAC Performed the analysis; AAC, AK, Dhul, RAC Wrote the paper. All authors read and approved the final manuscript for publication.

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Conflict of Interest: Author declares that there is no conflict of interest.

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