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Original Research Article

Comparative Assessment of Dexmedetomidine-Fentanyl and Dexmedetomidine-Pentazocine for Monitored Anesthesia Care during Tympanoplasty Surgery: A Randomized Clinical Study

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Conflict of interest: Nil

Abstract

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

Methods: A prospective, randomized controlled study was undertaken in Department of Anesthesiology for the period of two years. This study was approved by institutional research and ethical committee. Informed consent was taken from the participants before the procedure. The patients were randomly assigned into two groups, DF and DP with 50 participants in each groups.

Results: The demographic data in terms of age and sex were compared in both groups and not significant statistically. Changes in Haemodynamic parameters (Diastolic Blood Pressure, Systolic Blood Pressure, Heart Rate, Respiratory Rate, and SPO_2) were recorded and compared between both groups. The Haemodynamic parameters are highly significant statistically. Haemodynamic parameters of group DF were stable than group DP. Intra-operative mean Ramsay Sedation Score (RSS) in group DF was 2.7138±0.4723 while group DP was 2.348±0.5232. Group DP required more sedation than DF and was highly significant statistically. 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. The more satisfactory results were noted on Dex-Fentanyl than Pentazocine.

Conclusion: We concluded that, Dexmedetomidine-Fentanyl is a better combination than the Dexmedetomidine-Pentazocine for Monitored anesthesia care in Tympanoplasty surgery.

Keywords: Tympanoplasty, Dexmedetomidine, Pentazocine, Monitored Anaesthesia Care.

Introduction

Tympanoplasty involves reconstruction of perforated tympanic membrane with or without ossiculoplasty. [1] It is usually done under local anesthesia with sedation under monitored anesthesia care (MAC) or general anesthesia. [2-4] Patients may feel discomfort due to pain, noise due to suction, manipulation of instruments and head-neck position. [5] Commonly used medications for MAC are benzodiazepines, opioids and propofol. [6] Midazolam with its quick onset, but a relatively long half-life can cause prolonged sedation after repeated administration. [7] Combining midazolam with opioids increases the risk for hypoxemia and apnea. [8,9] The addition of propofol may cause cardio-respiratory depression. [9] Oversedation leading to respiratory depression has been reported to cause patient injuries during MAC. [10]

Dexmedetomidine is a selective α-2 adrenoreceptor agonist, 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. [11] Fentanyl is a derivative of phenylpiperidine and it is a synthetic opioid agonist with a high affinity for μ receptors. Fentanyl is used as an analgesic and when used for MAC in combination with another sedative agent, it causes dose dependent respiratory depression. [12] Pentazocine is the first synthetic agonist-antagonist which was used as an analgesic. It has weak μ antagonist and higher agonistic actions. [13] 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. [14]

Tympanoplasty, also called eardrum repair, refers to surgery performed to reconstruct a perforated tympanic membrane (eardrum) or the small bones of the middle ear (ossiculoplasty). Tympanoplasty

is usually performed under local anaesthesia with sedation under monitored anaesthesia care or rarely under general anaesthesia. Various drugs and drug combinations are used for this purpose: Benzodiazepines, Opioids, Propofol and recently alpha-2 agonist Dexmedetomidine.

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 Department of Anesthesiology ,SKMCH, Muzaffarpur, Bihar, India for the period of two years. Informed consent was taken from the participants before the procedure.

Selection of Participants

The patients were randomly assigned into two groups, DF and DP with 50 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, atrioventricular 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). [15]

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), SpO2, 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). [16] 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 [17]

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

Table 1: Demographic Profile of the Participants

Parameters	Dex-Fentanyl	Dex-Pentacozine	P-Value
Age in Years	34.06±9.5020	32.68±8.9112	0.0782
Sex			
Male/Female	42/8	40/10	0.2448

The demographic data in terms of age and sex were compared in both groups and not significant statistically.

Table 2: Haemodynamic Parameter of both groups

	Dex-Fentanyl (Mean ± SD)	Dex-Pentacozine (Mean ± SD)	P-Value
DBP	78.314±3.320	76.454±2.812	0.0002
SBP	114.616±4.745	110.232±4.016	<0.0001
MAP	87.963±2.971	86.042±3.216	0.0012
RR	14.542±0.884	12.918±0.9130	<0.0001
SPO_2	0.980±0.0120	0.946±0.0300	0.0034
HR	83.14±3.748	82.58±3.976	0.0234

Changes in Haemodynamic parameters (Diastolic Blood Pressure, Systolic Blood Pressure, Heart Rate, Respiratory Rate, and SPO_2) were recorded and compared between both groups. The Haemodynamic parameters are highly significant statistically. Haemodynamic parameters of group DF were stable than group DP.

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	2.7138±0.4723	2.348±0.5232	0.0024
VAS (Intra Operatively)	2.316±0.8440	2.26±0.5248	0.4226
VAS (Post Operatively)	0.5941±0.2346	2.18±1.120	0.0032

Intra-operative mean Ramsay Sedation Score (RSS) in group DF was 2.7138±0.4723 while group DP was 2.348±0.5232. Group DP required more sedation than DF and was highly significant statistically.

Table 4: Rescue Sedatives and Analgesic

No. of Doses	No. of Participants		P- Value
	Dex-Fentanyl	Dex-Pentacozine	
0	3	3	0.4604
1	36	10	
2	11	25	
3	0	12	
Mean ± SD	6±8.32	6.24±4.46	

In group D-P, patients required more rescue dose of analgesic (Pentazocine) than group D-F.

Table 5: Likert Score of Both groups

Likert Score	Dex-Fentanyl	Dex-Pentacozine
1	0	0
2	0	0
3	0	2 (4%)
4	0	6 (12%)
5	15 (30%)	13 (26%)
6	12 (24%)	9 (18%)
7	23 (46%)	20 (40%)

The more satisfactory results were noted on Dex-Fentanyl than Pentazocine.

Discussion

Middle ear surgeries are significantly challenging for the surgeons, patients and Anesthesiologists. [18] Tympanoplasty procedure involves the reconstruction of perforated tympanic membrane with or without ossiculoplasty. [19] 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, earache, claustrophobia, dizziness. [20] 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. [21] In MAC, various sedative drugs are used like opioids, benzodiazepines and α-2 agonist. [22] Middle‑ear

surgeries pose a different set of challenges for the patient, surgeons and anesthesiologists. Sympathetic stimulation and movements of an anxious patient cause increased bleeding and disturb the fine microscopic nature of the surgery which may even lead to graft failure. The advantages of local anesthesia include testing hearing intraoperatively, immediately detecting complications and a truncated postsurgical emergence. Good patient selection, preoperative counseling and use of appropriate sedation are important factors for success of this surgery under local anesthesia. [2,5]

The demographic data in terms of age and sex were compared in both groups and not significant statistically. Changes in Haemodynamic parameters (Diastolic Blood Pressure, Systolic Blood Pressure, Heart Rate, Respiratory Rate, and SPO_2) were recorded and compared between both groups. The Haemodynamic parameters are highly significant statistically. Haemodynamic parameters of group DF were stable than group DP. Intra-operative mean Ramsay Sedation Score (RSS) in group DF was 2.7138±0.4723 while group DP was 2.348±0.5232. Azatshatru et al., 2020 observed Dexmedetomidine was better than a combination of Midazolam-Fentanyl for Tympanoplasty surgery. [23] 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. [24]

Group DP required more sedation than DF and was highly significant statistically. 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. The more satisfactory results were noted on Dex-Fentanyl than Pentazocine. Alhashemi JA et al., 2006 [25] 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. Analgesic property of α2 agonists like dexmedetomidine with its opiate‐sparing properties has been documented [26] and has been reported in studies conducted in general anesthesia with dexmedetomidine. [27]

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 concluded that, Dexmedetomidine-Fentanyl is a better combination than the Dexmedetomidine-Pentazocine for Monitored anesthesia care in Tympanoplasty surgery.

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