Section: Anaesthesia

Original Research Article

A CLINICAL COMPARATIVE ASSESSMENT OF DEXMEDETOMIDINE-FENTANYL AND DEXMEDETOMIDINE-PENTAZOCINE FOR MONITORED ANESTHESIA CARE DURING TYMPANOPLASTY SURGERY

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ABSTRACT

Background: The aim of the present study was tocompare Dexmedetomidine Pentazocine and Dexmedetomidine-Fentanyl in terms of VAS, RSSand Haemodynamic parametersduring Tympanoplasty Surgery. **Materials and Methods:** A prospective, randomized controlled study was undertaken 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 70 participants in each group. **Result:** The demographic data, including age and gender, were compared in both groups and found to be statistically insignificant. Changes in hemodynamic parameters (diastolic and systolic blood pressure, heart rate, respiratory rate, and SPO2) were measured and compared between the two groups. The hemodynamic parameters have a high level of statistical significance. The hemodynamic values in group DF were more stable than in group DP. The intra-operative mean Ramsay Sedation Score (RSS) in group DF was 2.7134±0.4424, whereas in group DP it was 2.342±0.5216. Group DP required greater sedation than DF, and the difference was statistically significant. Patients in group D-P required a higher rescue analgesic dosage (Pentazocine) than in group D-F. Dex-Fentanyl had better outcomes than Pentazocine. **Conclusion:** Dexmedetomidine-Fentanyl is a superior combination for Tympanoplasty operations performed under monitored anesthesia. It enhances both intraoperative and postoperative analgesia.

INTRODUCTION

Middle ear procedures provide major challenges for surgeons, patients, and anesthesiologists.[1] Tympanoplasty is the reconstruction of a perforated tympanic membrane, with or without ossiculoplasty.[2] It is often performed under local anesthetic with sedation during monitored anesthesia care (MAC) or general anesthesia.[3-5] Patients may experience discomfort as a result of pain, noise from suction, instrument manipulation, and head-neck positioning.[6] The major benefits of doing surgery with local anesthetic under MAC are reduced operational discomfort, faster recovery, lower cost, and the opportunity to test hearing during surgery.[7] Furthermore, hearing improvement may be measured in patients following stapedectomy procedures on the table. Many MES are still performed under general anesthesia because to patient anxiety, concern of unexpected patient movement at a critical surgical phase, and the benefits of hypotensive general anesthetic procedures. The most common patient pain under local anesthetic is anxiety produced by loudness during surgery, which can be exacerbated if a burr is used to drill the bone, as well as dizziness and discomfort from head and neck placement during surgery.[1,3]

MAC uses sedative medications such as opioids, benzodiazepines, and α-2 agonists. Dexmedetomidine is a centrally acting α-2 adrenoceptor agonist.[8] It is increasingly employed as a sedative in monitored anesthetic care (MAC) because of its analgesic properties, "cooperative sedation," and absence of respiratory depression.[9,10] It is known to drastically minimize opioid needs during and after surgery. Its sympatholytic activity reduces the anxiety-induced stress response to surgery (tachycardia and hypertension) while preserving hemodynamic stability.[11] Although safe, bradycardia and hypotension are the most predictable and common adverse effects, which help

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to reduce bleeding during surgery and offer a blood-free operative field, which is critical for microsurgical techniques.

Fentanyl, derived from phenylpiperidine, is a synthetic opioid agonist with a high affinity for μ receptors. Fentanyl is pain analgesic, and when used for MAC in conjunction with another sedative, it induces dose-dependent respiratory depression.[12] Pentazocine was the first synthetic agonist-antagonist used as an analgesic. It exhibits modest μ antagonist and strong agonistic properties.[13] However, a large dosage of Pentazocine may produce elevated blood pressure during surgery owing to sympathetic activation. Vomiting happens less often; additional adverse effects include sweating and light-headedness. The study's goal was to evaluate VAS, RSS, and hemodynamic parameters between Dexmedetomidine Pentazocine and Dexmedetomidine-Fentanyl.

MATERIALS AND METHODS

A prospective, randomized controlled study was undertaken 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 70 participants in each group.

Cardiovascular dysfunction, allergies to drugs or other treatments, a history of long-term sedative or opioid use, morbid obesity, severe liver illness, atrioventricular block, and pregnancy were among the exclusion criteria for patients.

Methodology

A day prior to surgery, each patient underwent a complete examination and investigation in accordance with hospital policy. Written agreement was obtained from each participant, and all patients received counseling regarding local anesthetic, sedation, and the surgical procedure. Prior to surgery, patients were told to fast for eight hours. During the pre-operative appointment, the patients were given an explanation of the VAS (Visual Analogue Scale), which is a scale from 0 to 10, with 0 denoting no discomfort and 10 denoting the highest level of agony.[14]

Interventions

The study was recorded by the blind observer, while the anesthesiologist was blind to the patient's group assignment. Intravenous access was initiated as soon as the patient entered the operating room. The following baseline measurements were made and recorded: heart rate (HR), respiratory rate (RR), diastolic blood pressure (DBP), systolic blood pressure (SBP), and ECG. 4L/min of oxygen were given to each patient. There was no premedication or usage of sedatives.

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).[15] 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-pointLikert 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.

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	35.05±8.4010	33.57±7.8122	0.0782
Sex			

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Male/Female	60/10	58/12	0.2336

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	79.316±3.317	77.464±2.822	0.0001
SBP	112.614±4.743	111.222±4.012	<0.0001
MAP	88.953±2.951	85.045±3.218	0.0012
RR	13.540±0.880	12.910±0.9115	<0.0001
SPO2	0.984±0.0126	0.948±0.0300	0.0044
HR	84.16±3.749	83.59±3.961	0.0356

Changes in Haemodynamic parameters (Diastolic Blood Pressure, Systolic Blood Pressure, Heart Rate, Respiratory Rate, and SPO2) were recorded and compared between both groups. The Haemodynamicparameters 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-FentanylMean ± SD	Dex-PentacozineMean ±SD	P-Value
RSS	2.7134±0.4424	2.342±0.5216	0.0048
VAS(IntraOperatively)	2.316±0.8440	2.26±0.5248	0.006
VAS(PostOperatively)	0.5941±0.2346	2.18±1.120	0.0022

Intra-operative mean Ramsay Sedation Score (RSS) in group DF was 2.7134±0.4424 while group DP was 2.342±0.5216. 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	9	7	0.4204
1	40	15	
2	21	30	
3	0	18	
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	4
4	0	10
5	35	17
6	15	12
7	20	27

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

DISCUSSION

Tympanoplasty, commonly known as eardrum repair, is the term for surgery used to replace the small middle ear bones (ossiculoplasty) or a perforated tympanic membrane (eardrum). Tympanoplasty is often done under sedation and local anesthesia with close monitoring, while it is sometimes occasionally done under general anesthesia. Various medications and pharmacological combinations are utilized for this purpose: Benzodiazepines, Opioids, Propofol and recently alpha-2 agonist Dexmedetomidine.

When age and sex demographic data were examined between the two groups, the results were statistically insignificant. Changes in the two groups' heart rates, respiratory rates, diastolic and systolic blood pressures, SPO2, and heart rates were noted and compared. From a statistical perspective, the hemodynamic parameters are quite significant. Group DF's hemodynamic parameters were more stable than those of group DP. The mean Ramsay Sedation Score (RSS) throughout the operation was 2.7134±0.4424 for group DF and 2.342±0.5216 for group DP. Dexmedetomidine was found by Azatshatru et al., 2020 to be superior to a midazolam-fentanyl combination for tympanoplasty surgery.[16] In 2013, Parikh D et al. examined the hemodynamic parameters of both the Dexmedetomidine and the Midazolam-Fentanyl combination. They discovered that both groups performed similarly and had good results, meaning that no further sedation was needed during the Tympanoplasty procedure.[17]

In comparison to group DF, group DP required more sedation, and the statistical difference was

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substantial. Patients in group D-P needed a higher rescue dose of the analgesic pentazocine compared to group D-F, and Dex-Fentanyl produced more satisfying results than pentazocine. In a study published in 2006, Alhashemi JA et al. compared the effects of dexmedetomidine with pentazocine and promethazine. They found that dexmedetomidine outperformed the combination and that it also reduced intraoperative hemorrhage and hypotension.[18] The analgesic effect of α2 agonists, such as dexmedetomidine, has been demonstrated in trials including general anesthesia and its opiate-sparing characteristics.[19,20]

CONCLUSION

Dexmedetomidine intravenous infusion generally results in improved sedation, decreased VAS scores, and a decreased need for rescue analgesia. We came to the conclusion that for monitored anesthetic management during tympanoplasty surgery, dexmedetomidine-fentanyl is a superior combination than dexmedetomidine-pentazocine.

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