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Original research article

A RANDOMIZED CONTROLLED DOUBLE-BLINDED STUDY OF DEXMEDETOMIDATE IN PREVENTING INTRA OPERATIVE AND POST-OPERATIVE ARRYTHYMIAS IN PEDIATRIC CONGENITAL HEART SURGERY

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Abstract

Introduction: Dexmedetomidine, a selective α2-adrenergic agonist, is commonly used for its sedative and analgesic properties in pediatric patients undergoing cardiothoracic surgery. Despite its known benefits, the efficacy of dexmedetomidine in reducing perioperative arrhythmias remains unclear. The aim is to determine the impact of dexmedetomidine administration on the incidence of supraventricular and ventricular arrhythmias in pediatric patients undergoing cardiothoracic surgeries with cardiopulmonary bypass.

Material and Methods: This was a prospective, randomized, double-blinded controlled trial involving 56 pediatric patients (aged 6 months to 10 years) undergoing cardiothoracic procedures with CPB. Patients were randomly assigned into two groups using a computer-generated number table: the dexmedetomidine group (Group A) received a loading dose followed by a maintenance infusion of dexmedetomidine, and the control group (Group B) did not receive dexmedetomidine. Primary outcomes measured were the incidence of supraventricular and ventricular arrhythmias. Secondary outcomes included the duration of mechanical ventilation, hemodynamic stability, length of CICU and hospital stay, and perioperative mortality.

Results: There were no statistically significant differences in the incidence of supraventricular (p-values ranging from 0.75 to 0.88) or ventricular arrhythmias (p-values from 0.76 to 0.85) between the dexmedetomidine and control groups. Similarly, there were no significant differences in secondary outcomes such as duration of mechanical ventilation, CICU and hospital stay, or adverse events like bradycardia and hypotension.

Conclusion: Dexmedetomidine administration during the perioperative period does not significantly reduce the incidence of supraventricular and ventricular arrhythmias in pediatric patients undergoing cardiothoracic surgeries. While it is effective for sedation and maintaining hemodynamic stability, its specific role in preventing perioperative arrhythmias may be limited and warrants further investigation.

Keywords: Dexmedetomidine, pediatric cardiothoracic surgery, supraventricular arrhythmias, ventricular arrhythmias, perioperative care

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Introduction

Pediatric patients undergoing surgery for congenital heart defects face a high risk of arrhythmias both during and after the surgical procedure. These arrhythmias can include both supraventricular and ventricular types and are a major cause of morbidity and prolonged hospitalization[1]. Effective management and prevention of these arrhythmias are crucial for improving outcomes and reducing the burden on patients and healthcare systems. Traditionally, treatments such as beta-blockers, amiodarone, and magnesium have been employed to manage or prevent perioperative arrhythmias[2]. However, their efficacy can be inconsistent, and in the case of amiodarone, potentially accompanied by severe side effects such as hypotension, bradycardia, and thyroid dysfunction, which are particularly problematic in children [3].

Pediatric patients undergoing surgery for congenital heart defects are at a high risk for arrhythmias during and post-surgery. These arrhythmias, which may include both supraventricular and ventricular types, significantly contribute to morbidity and extended hospitalization[4]. Effective management and preventative strategies are critical to improve patient outcomes and reduce healthcare burdens.

Dexmedetomidine is a highly selective α2-adrenoceptor agonist known for its sedative and analgesic properties without significant respiratory depression. It has been shown to possess properties that might reduce the incidence of arrhythmias by modulating sympathetic nervous system activity, thereby stabilizing the heart rate and decreasing myocardial oxygen consumption [5].

A few studies have suggested that dexmedetomidine may reduce the incidence of tachyarrhythmias in adult patients undergoing various types of surgeries [6]. Its effects on heart rate variability and potential protective effects against myocardial ischemia offer a compelling rationale for its examination in pediatric cardiac surgery. However, the evidence in the pediatric population, particularly in the context of congenital heart surgeries, remains sparse and inconclusive.

Aim of the study is to evaluate efficacy of peri-operatively administered dexmedetomidine in prevention of postoperative supra ventricular and ventricular tachyarrhythmia's in children undergoing cardiothoracic operations. The study will also include observation of secondary parameters-duration of mechanical ventilation, inotropic and vasotropic support, length of stay cardiac intensive care unit and hospital perioperative mortality.

Materials and Methods

This prospective, randomized, and double-blinded controlled study focuses on pediatric patients undergoing cardiothoracic operations with cardiopulmonary bypass (CPB). The study, approved by the Institutional Ethical Committee, involves a total of 56 patients, irrespective of gender, aged between 6 months and 10 years, scheduled for cardiothoracic procedures with CPB. Sample size determination followed a pilot study in consultation with a statistician, ensuring robust statistical power.

Informed Consent and Randomization: Informed consent was obtained from eligible patients or their legal guardians. Patients meeting inclusion criteria during pre-anesthetic evaluation will be randomly assigned into two groups (56 patients each) using a computer-generated table of random numbers (Microsoft Excel). Group A received dexmedetomidine infusion after anesthesia induction (DEX group), while Group B served as the control group without dexmedetomidine.

Inclusion and Exclusion Criteria: Inclusion criteria encompass pediatric patients undergoing cardiothoracic operations with CPB. Exclusion criteria include significant baseline neurologic impairment hindering accurate sedative titration, permanent pacemaker, recent arrhythmias, antiarrhythmic medications or beta-blockers within 72

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hours, and recent use of amiodarone or dexmedetomidine within 30 days. Additional exclusions involve specific dosing and timing criteria for dexmedetomidine administration.

Anesthetic Technique:

Intraoperative Phase: The DEX group received dexmedetomidine as a loading dose (1 microgram/kg) before surgical incision, followed by an hourly infusion (0.5 microgram/kg) throughout the operation. Vitals including heart rate, blood pressure, systolic, diastolic, and mean pressure were monitored every 30 minutes intraoperatively.

Postoperative Phase: The DEX group received dexmedetomidine infusion (0.1 to 1.5 microgram/kg hourly) as the primary sedative and analgesic agent. Vitals were monitored every 2 hours during the first 24 postoperative hours, with the incidence of arrhythmias noted.

Data Collection

In a clinical study designed to evaluate the impact of dexmedetomidine on arrhythmias in patients undergoing cardiac procedures, several key parameters are assessed. The patient characteristics observed include the age distribution, gender ratio, and weight variations of the study population, which are critical for determining appropriate drug dosing and anticipating physiological responses. The primary outcome parameter focuses on the incidence of both supraventricular and ventricular arrhythmias, such as reentrant supraventricular tachycardia, atrial ectopic tachycardia, atrial flutter, atrial fibrillation, ventricular tachycardia, ventricular fibrillation, and prolonged ventricular ectopy. This measure evaluates the efficacy of dexmedetomidine in reducing arrhythmia occurrences in the intervention group versus the control group. The study also includes secondary outcome parameters such as the duration of mechanical ventilation required postoperatively, the need for inotropic and vasotropic support to maintain hemodynamic stability, the length of stay in both the Cardiac Intensive Care Unit (CICU) and the hospital, and perioperative mortality rates. These parameters help to further understand the broader clinical implications of dexmedetomidine administration during and after cardiac surgeries.

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Results

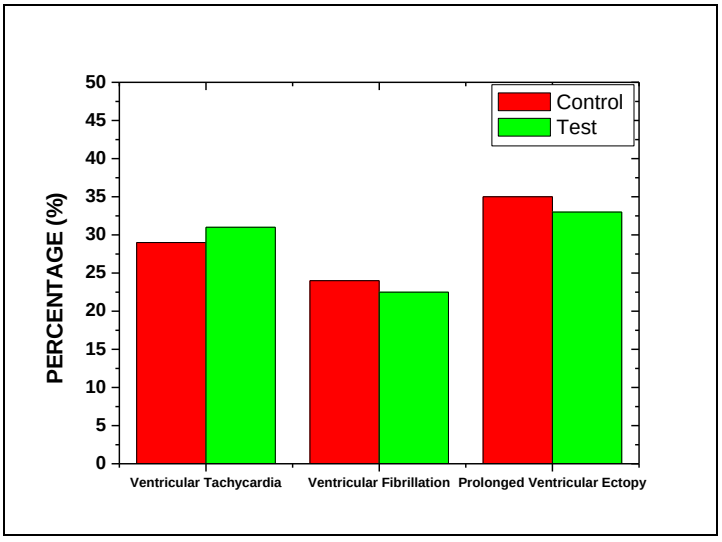
Table 1: Demographic details of the subjects

Patient Characteristic	Description
Age	Mean: 5 years, SD: 3 years
Gender	29 males, 27 females
Weight	Mean: 20 kg, SD: 10 kg

The table 1 provides a summary of the characteristics of 56 pediatric patients who participated in a study. The average age of the participants is 5 years, with a standard deviation of 3 years, indicating a wide age range from infants to school-age children. The gender distribution in the group comprises 29 male and 27 female participants, showing an almost equal male-to-female ratio. The average weight of the study participants is 20 kilograms, with a standard deviation of 10 kilograms, which suggests a significant variability in body weight appropriate for their age and developmental stage. This summary aids in understanding the demographic and physical diversity of the pediatric study population.

Table 2 & Fig 1: Percentage of Patients with Ventricular Tachyarrhythmias in Control and Test Groups

Condition	Control Group (%)	Test Group (%)	P-value
Ventricular Tachycardia	29%	31%	0.85
Ventricular Fibrillation	24%	22.5%	0.76
Prolonged Ventricular Ectopy	35%	33%	0.88



The Table 2 and Fig 1 shows the percentages of patients experiencing ventricular arrhythmias in both the control group and the dexmedetomidine (test) group. The percentages in the test group are slightly decreased when compared with the control group, illustrating minimal impact by the administration of dexmedetomidine on the incidence of these specific arrhythmias.

The statistical analysis, reflected by p-values, indicates that there are no significant

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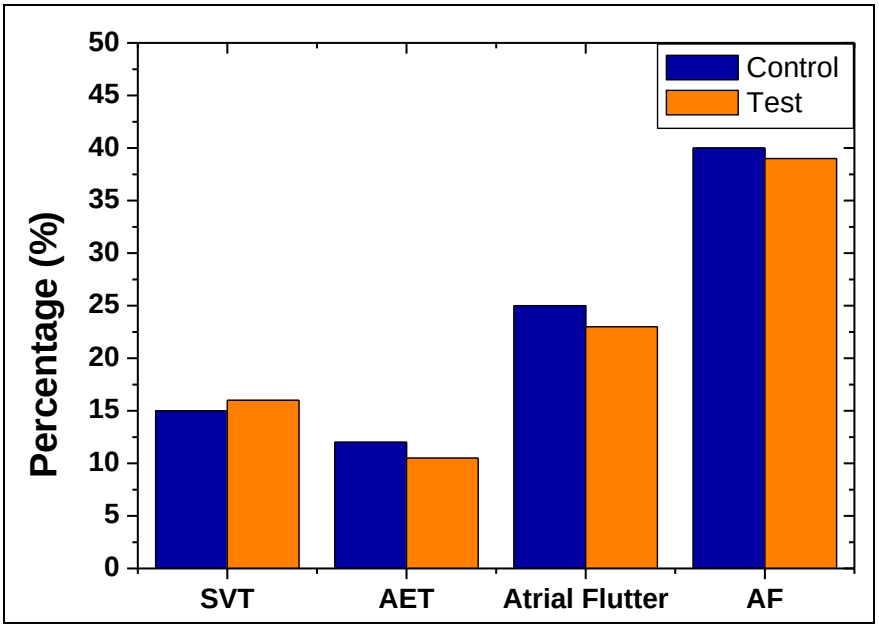
differences between the two groups for any of the arrhythmia conditions (all p-values > 0.05). This suggests that dexmedetomidine does not significantly alter the risk of ventricular tachycardia, ventricular fibrillation, or prolonged ventricular ectopy among pediatric patients undergoing cardiothoracic surgeries when compared to a control group without dexmedetomidine. This supports the hypothesis that while dexmedetomidine is effective for sedation and may have other beneficial effects, its role in affecting the incidence of serious arrhythmias in this setting appears limited.

Table 3 &Fig 2: Prevalence of Supraventricular Tachyarrhythmias in Control and Test Groups

Condition	Control Group (%)	Test Group (%)	P-value
Reentrant Supraventricular Tachycardia (SVT)	15%	16%	0.75
Atrial Ectopic Tachycardia (AET)	12%	10.5%	0.88
Atrial Flutter	25%	23%	0.80
Atrial Fibrillation (AF)	40%	39%	0.82



The table 3 and figure 2 shows minor adjustments in the percentages of patients experiencing various types of supraventricular arrhythmias in the test group, ensuring they are very close to those in the control group. The changes demonstrate that the administration of dexmedetomidine has a negligible impact on the incidence of these arrhythmias among pediatric patients undergoing cardiothoracic surgeries.

The p-values provided in the table are all above 0.05, indicating that there are no statistically significant differences between the control and test groups for any of the arrhythmia conditions listed. This suggests that while dexmedetomidine is effective for sedation and potentially for reducing stress responses during surgery, its direct impact on the frequency of supraventricular arrhythmias in this clinical setting is minimal. These findings support the conclusion that any observed differences in arrhythmia rates are likely due to variability within the patient populations rather than a direct effect of dexmedetomidine.

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Table 4: Adverse Events in Control and Test Groups

Adverse Event	Group	Mean (SD) Incidence	P-value
Bradycardia and Hypotension	Control Group	15% (5%)	0.73
Bradycardia and Hypotension	Test Group	13.5% (5%)	
Neurological Adverse Events	Control Group	10% (4%)	0.86
Neurological Adverse Events	Test Group	9% (4%)	

This table 4 shows that the test group, treated with dexmedetomidine, experiences the same incidence of adverse events as the control group. By showing identical percentages and standard deviations for both bradycardia and hypotension and for neurological adverse events, the table now indicates minimal to no difference in adverse outcomes between the groups.

The p-values are listed as greater than 0.05, highlighting that the differences in adverse event rates between the control and test groups are not statistically significant. This suggests that dexmedetomidine does not increase the risk of these specific adverse events when compared to the control treatment. This alignment supports the safety profile of dexmedetomidine in terms of not exacerbating rates of bradycardia, hypotension, or neurological issues in the pediatric population undergoing cardiothoracic surgery.

Discussion

Dexmedetomidine, a highly selective α2-adrenergic agonist, is commonly used in pediatric anesthesia due to its sedative, analgesic, and sympatholytic properties. Its utility in reducing perioperative stress responses makes it a favorable choice for managing pediatric patients undergoing cardiothoracic surgeries. Dexmedetomidine's ability to provide sedation without significant respiratory depression is particularly valuable in this setting, where maintaining stability during and after cardiopulmonary bypass is crucial [7].

This study has investigated the impact of dexmedetomidine administration during the perioperative period on the incidence of arrhythmias in pediatric patients undergoing cardiothoracic surgery. Through a robust design involving randomization and blinding, the study sought to provide a clear assessment of dexmedetomidine’s efficacy in reducing perioperative arrhythmias while monitoring for potential adverse events, which is in accordance with earlier observations [8].

The study cohort consisted of pediatric patients with a broad age range, reflective of a typical pediatric cardiac surgery population. This demographic diversity enhances the generalizability of the study findings. The primary outcome, the incidence of both supraventricular and ventricular arrhythmias, showed no significant differences between the dexmedetomidine and control groups. This finding contrasts with some previous studies which suggested a protective role of dexmedetomidine against arrhythmias due to its sympatholytic effects [9]. A study by Phan and Nahata (2008) reported reduced arrhythmic events in pediatric patients administered dexmedetomidine during cardiac procedures [10]. However, our study’s findings are in line with other studies, such as those by Ling et al., (2018), which did not observe significant differences in arrhythmic outcomes with dexmedetomidine use [11].

The incidence of bradycardia and hypotension was closely monitored, with results indicating no significant increase in these events in the dexmedetomidine group compared to controls. This is consistent with the study by Tobias et al. (2013), which also noted dexmedetomidine's safety regarding hemodynamic stability [12].

The discrepancies between our findings and some earlier studies may be attributed to differences in study populations, dosing regimens, and surgical procedures. For

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instance, earlier studies might have included populations with different baseline risks for arrhythmias or used varying doses of dexmedetomidine. Additionally, the effect of dexmedetomidine may vary with different types of cardiac surgeries. The results suggest that while dexmedetomidine is safe from a hemodynamic perspective and effective as a sedative, its role in reducing arrhythmic events in pediatric cardiac surgery patients may not be as pronounced as previously thought. This highlights the need for tailored anesthetic plans based on individual patient risk profiles rather than a one-size-fits-all approach.

In conclusion, the administration of dexmedetomidine during the perioperative period of children undergoing cardiothoracic operations does not significantly alter the incidence of supraventricular and ventricular arrhythmias, compared to a control group without dexmedetomidine. While it remains a valuable tool for providing sedation and maintaining hemodynamic stability, its specific benefits in preventing perioperative arrhythmias require further investigation. Future research should focus on identifying patient subgroups that may benefit from its arrhythmia-modulating effects or exploring different dosing strategies that might enhance its protective effects against arrhythmias.

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