Randomized controlled trial to evaluate the effect of prophylactic amiodarone versus dexmedetomidine on reducing the incidence of postoperative junctional ectopic tachycardia after pediatric open heart surgery

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ABSTRACT

Background : **Junctional ectopic tachycardia (JET) is the most common arrhythmia after pediatric open-heart surgeries (OHS), causing high morbidity and mortality. As diagnosis is often missed in patients with minimal hemodynamic instability, its incidence depends on active surveillance. A prospective randomized trial evaluated the efficacy and safety of prophylactic amiodarone and dexmedetomidine to prevent and control postoperative JET.**

Methods : **Consecutive patients aged under 12 years were randomized into amiodarone, dexmedetomidine (initiated during anesthetic induction) and control groups. Outcome measures included incidence of JET, inotropic score, ventilation, and intensive care unit (ICU) duration and hospital stay, as well as adverse drug effects.**

Results : **Two hundred and twenty-five consecutive patients with a median age of 9 months (range 2 days–144 months) and a median weight of 6.3 kg (range 1.8 kg–38 kg) were randomized with 70 patients each to amiodarone and dexmedetomidine groups, and the rest were controls. Ventricular septal defect and Fallot's tetralogy were the common defects. The overall incidence of JET was 16.4%. Syndromic patients, hypokalemia, hypomagnesemia, longer bypass, and cross-clamp duration were the risk factors for JET. Patients with JET had significantly prolonged ventilation (*P* = 0.043), longer ICU (*P* = 0.004), and hospital stay (*P* = 0.034) than those without JET. JET was less frequent in amiodarone (8.5%) and dexmedetomidine (14.2%) groups compared to controls (24.7%) (*P* = 0.022). Patients receiving amiodarone and dexmedetomidine had significantly lower inotropic requirements, lower ventilation duration (*P* = 0.008), ICU (*P* = 0.006), and hospital stay (*P* = 0.05). Adverse effects such as bradycardia and hypotension after amiodarone and ventricular dysfunction after dexmedetomidine were not significantly different from controls.**

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Conclusion : **Prophylactic amiodarone or dexmedetomidine started before OHS is effective and safe for the prevention of postoperative JET.**

Keywords : Congenital heart disease, congenital heart surgery, prevention, tachyarrhythmia

INTRODUCTION

Junctional ectopic tachycardia (JET) is a common postoperative tachyarrhythmia caused by enhanced automaticity of the atrioventricular (AV) nodal tissues, often characterized by AV dissociation but rarely may have a 1:1 retrograde ventriculoatrial conduction.[1,2] The reported incidence of JET after pediatric cardiac surgery varies widely between 1% and 15% depending on an active look-out for this arrhythmia. It may increase up to 22% after certain high-risk surgeries.[3-5] Its morbidity is substantial and contributes to 3%–13.5% of surgical mortality.[6,7] Although its exact etiology is unknown, several associations and predictors are identified.[8,9] This arrhythmia is usually self-limited, but it warrants aggressive management as the accompanying postoperative myocardial depression, and loss of AV synchrony leads to hemodynamic collapse. Management strategies for JET in post operative intensive care unit includes general nonpharmacological measures, antiarrhythmic drugs, discontinuing inappropriate sympathomimetic infusions, specific pacing strategies and sometimes rarely extends to extracorporeal circulatory support in extremely sick patients.[1,10]

Considering the unpredictable clinical course following their occurrence, a few prophylactic medications such as amiodarone, magnesium, procainamide, ivabradine, beta-blockers, and dexmedetomidine have been tried to prevent this arrhythmia with varying success.[11-13] Identifying various pre-, intra and postoperative precipitating factors has improved the awareness of JET after high-risk surgeries in the current era, but its incidence has not reduced paradoxically due to increased recognition in the intensive care unit (ICU) from this heightened awareness. Among this current understanding, a prospective randomized trial comparing different prophylactic medications can assess their impact on morbidity and mortality associated with JET. Such a trial can also focus on the adverse drug effects.

METHODS

A prospective randomized controlled clinical trial comparing the role of two prophylactic drugs, namely amiodarone and dexmedetomidine was conducted at a tertiary cardiac care unit on pediatric patients undergoing open-heart surgery over a 2-year period. The institutional review board and ethical committee approved the study protocol.

The sample size was calculated based on a previous study that assessed the efficacy of prophylactic drugs in the prevention of postoperative JET after pediatric cardiac surgery.[14] The minimum sample size needed was 181 patients at a 95% confidence interval and assuming 80% power of the study. We included all children below 12 years of age who underwent surgery under cardiopulmonary bypass (CPB). Surgeries with low risk of JET, like atrial septal defect closure or Glenn shunt, patients with preexisting left ventricular dysfunction, and arrhythmias were excluded from the study. After parental consent, patients were randomized using an alternate sampling method into three groups. An alternate sampling method was adopted to ensure a nearly equal number of participants in each of the three groups.

Study groups

- Amiodarone group (A): Amiodarone was started at the induction of anesthesia without any bolus at a dose of 5–10 mcg/kg/min based on the hemodynamic parameters and continued for the next 48 hours
- Dexmedetomidine group (D): Dexmedetomidine was started at the induction of anesthesia at a dose of 0.2–0.5 mcg/kg/h based on the hemodynamic parameters and was continued for the next 48 hours
- Control Group (C): Routine postoperative care was provided, and treatment was initiated if there was the occurrence of JET.

Recognition of junctional ectopic tachycardia

A standard 12-lead electrocardiogram was done in all patients preoperatively and immediately after surgery to serve as a baseline and was repeated daily and whenever required during a close surveillance of the electrocardiogram monitor. Whenever a tachycardia was identified without a recognizable preceding P wave, atrial wire electrograms were very frequently recorded to decipher the atrial depolarization. In order to facilitate atrial wire recording, two epicardial temporary atrial pacing wires were used in all patients in this study. JET was defined as per standard guidelines as a supraventricular tachycardia at (i) a ventricular rate exceeding the maximum normal sinus rate for the patient's age, (ii) no preceding P wave or a retrograde P wave, and (iii) ventricular rate exceeding or equal to atrial rate. Adenosine was sometimes used to differentiate other arrhythmias as the drug did not alter the JET rate while slowing atrial rates and stopping retrograde P waves. Management after detection of JET includes general nonpharmacological measures, use of antiarrhythmic drugs and discontinuing inappropriate sympathomimetics, maintaining electrolyte balance, certain pacing strategies, and rarely extends to extracorporeal circulatory support in extremely sick patients.[1]

Data collection

The incidence of JET as well as the known pre-, intra and post-operative risk factors were collected. Preoperative factors included age, body weight at surgery, sex, nutritional status, syndromic associations, and underlying heart disease. Operative variables used in the analysis included duration of CPB and aortic cross clamp (ACC), type of surgery as well as the cardiac rhythm while patient is weaned off bypass. Postoperative parameters included serum electrolyte levels and inotrope use, duration of ventilation, ICU stay, and hospitalization. Vasoactive inotrope score (VIS) was calculated based on the type and dosage of the drug using the following formula designed to account for their relative potencies.[5] VIS = ([dopamine + dobutamine] in μg/kg/min × 1) + (Milrinone μg/kg/min × 10) + ([Epinephrine + Norepinephrine] in μg/kg/min × 100).

Statistical analysis

The data were analyzed using SPSS version 16.0 (IBM Corporation, Armonk, NY, USA). Descriptive analysis included calculating frequencies, proportions, mean and standard deviation, median, and range. The normality of continuous variables was tested. Chi-square tests and Fischer's exact were used for categorical variables. Continuous variables were tested using Independent *t*-test, ANOVA test, Mann–Whitney *U* test, and Kruskal–Wallis test. After a univariate analysis to identify predictors of JET, variables of significance were included in the multivariate logistic regression model. A $P < 0.05$ was considered statistically significant.

RESULTS

A total of 225 patients with a median age of 9 months (2 days to 144 months) formed the study group. One hundred and ninety-two patients (85%) were aged below 5 years. The median weight of the group was 6.3 kg (1.8–38 kg). 75% of the study population weighed below 10 kg. The two common lesions were ventricular septal defect (VSD) (42%) and Fallot's tetralogy (23%) [Table 1]. 63% of patients had malnutrition, as defined by the Indian Academy of Pediatrics.[15] Fourteen patients had syndromic features and Down syndrome was the most common association seen in 9 among them. The mean CPB and ACC times were 159 ± 81 min and 87 ± 50 min, respectively.

Incidence of junctional ectopic tachycardia

JET was diagnosed in 16.4% of patients. Age, sex, body weight, and presence of malnutrition did not find any significant association with JET [Table 2]. Syndromic patients had a significantly high risk for JET ($P = 0.045$). Longer CPB time ($P = 0.002$) and ACC time ($P = 0.014$) were also significantly associated with JET. While the presence of hypokalaemia ($P = 0.011$) and hypomagnesemia ($P = 0.008$) was significantly associated with JET, correlation with hypocalcemia was not significant. When these associations were analyzed by a multivariate analysis, hypokalemia and hypomagnesemia showed significance. Even though syndromic association, CPB and ACC duration showed significant association on univariate analysis, they did not show any significance on a multivariate analysis [Table 3]. Among the types of surgeries, VSD closure and tetralogy repair were the most common lesions presenting with JET in our study. JET was more often seen when the surgery was more extensive as in more complex forms of VSD and intracardiac repair, than in those where the surgery was relatively simple [Table 1]. Individual inotropic agents were not independently analyzed and a composite VIS

Table 1: Incidence of junctional ectopic tachycardia after different surgeries

Surgery	Total cases	JET incidence	Percentage
Simple VSD closure	73	6	8.2
Complex VSD closure	20	4	20
Simple ICR	21	2	9.5
Complex ICR	32	7	21.9
Other conotruncal anomaly repairs	26	6	23.1
Fontan completion	11	4	34.4
Cone repair of Ebstein anomaly	3	2	66.7
TAPVC repair	21	2	9.5
Mitral valve repair/replacement	8	2	25
Atrioventricular canal repair	7	1	14.3
Other surgeries	3	1	33
Total	225	37	16.4

JET: Junctional ectopic tachycardia, VSD: Ventricular septal defect, Complex VSD: Additional arch or valve repairs, ICR: Intracardiac repair of Fallot's tetralogy, "Complex": Transannular patch, conduit or unifocalization, TAPVC: Total anomalous pulmonary venous connection

Table 2: Demographic factors and junctional ectopic tachycardia

Variables	Presence of JET	Absence of JET	*P*
Weight (kg)			
≤5	12	68	0.648
>5	25	120	
Age (months)			
≤6	13	83	0.311
>6	24	105	
Malnutrition			
No	20	82	0.244
Yes	17	106	
Syndrome associations			
Yes	5	9	0.045*
No	32	179	
Gender			
Male	26	124	0.61
Female	11	64	

*Significant. JET: Junctional ectopic tachycardia score was assessed for each patient. The mean VIS was higher in those with JET compared to those without JET both in the operating room and in ICU. As soon as the diagnosis of JET was made, adrenaline and other sympathomimetic drugs were withdrawn if the other hemodynamic parameters permitted the withdrawal. Patients with JET had a longer ventilation time, ICU stay, and hospitalization compared to others [Table 4]. JET was not associated with higher mortality, possibly related to aggressive and effective ICU management.

Effect of prophylactic drugs

There were 70 patients each in amiodarone and dexmedetomidine groups and 85 patients in the control group. The three arms were comparable with respect to demographic factors such as age, malnutrition, syndromic associations and electrolyte abnormalities; however, the body weight of the control arm was less than the prophylactic arms [Table 5]. The incidence of JET was significantly lower ($P = 0.022$) in amiodarone (8.5%) and dexmedetomidine (14.2%) groups compared to controls (24.7%). The mean VIS was significantly lower in amiodarone and dexmedetomidine group compared to controls [Table 6]. Even though the duration of JET was not different between the three groups, the mean ventilation time, duration of ICU stays, and duration of hospital stay were significantly lower in amiodarone and dexmedetomidine groups compared to controls, thus simplifying the ICU management in the former groups. While the total duration of JET in the patients who had this arrhythmia was noted in the three groups, the average heart rates during JET were not individually analyzed between the groups as they markedly varied from time to time.

Drug adverse effects

Amiodarone had a higher incidence of bradycardia and hypotension than the other two groups, but it was not statistically significant ($P = 0.145$ and 0.27, respectively). The incidence of ventricular dysfunction was higher in the dexmedetomidine group but was not statistically significant ($P = 0.25$). There was no mortality in amiodarone group and 2.8% in the dexmedetomidine group as against 8.2% in the control group, but this did not reach statistical significance ($P = 0.128$). The majority of the patients with JET were treated with primary measures such as active cooling, correcting electrolytes, and minimizing inotropes. Sixteen patients needed atrial overdrive pacing for the control of JET rate. Two patients in the dexmedetomidine group and seven patients from the control group were treated with amiodarone for control of JET.

Table 3: Multivariate analysis of risk factors associated with junctional ectopic tachycardia

Factors	*t*	*P*
Presence of syndromic association	1.233	0.219
Presence of hypokalemia	3.127	0.002*
Presence of hypomagnesemia	2.805	0.005*
Cardiopulmonary bypass duration	–1.739	0.083
Aortic cross-clamp duration	1.006	0.316
Constant	4.044	0.000

**P*<0.05 - statistically significant

Table 4: Morbidity in patients with junctional ectopic tachycardia

Variables	Median (range)		*P*
	JET	No JET	
Ventilation duration in hours	45 (5-475)	25 (2-232)	0.043
Intensive care stay in hours	116 (17-1584)	87 (8-720)	0.004
Duration of hospital stay in days	11 (2-81)	9 (1-94)	0.034

Mann-Whitney *U*, *P*<0.05 is significant. JET: Junctional ectopic tachycardia

DISCUSSION

JET is the most common postoperative pediatric arrhythmia, often identified in the first 24–48 h after surgery and commonly begins during the rewarming

Table 5: Variables in the three randomized groups

Variables	Amiodarone	Dexmedetomidine	Control	*P*
Weight (kg)				
<5	19	22	39	0.041
>5	51	48	46	
Age (months)				
<12	39	42	60	0.152
>12	31	28	25	
Malnutrition				
No	34	35	33	0.306
Yes	36	35	52	
Gender				
Male	45	47	58	0.869
Female	25	23	27	
Electrolyte abnormality				
Yes	60	50	63	0.100
No	10	20	22	
CPB duration (min), median (range)	113.5 (52-318)	145 (60-373)	158 (49-543)	0.001
ACC duration (min), median (range)	64 (0-224)	78 (0-249)	88 (0-235)	0.006

CPB: Cardiopulmonary bypass, ACC: Aortic cross-clamp

Table 6: Comparison of outcomes in the three randomized groups

Variables	Amiodarone (*n*=70)	Dexmedetomidine (*n*=70)	Control (*n*=85)	*P*
Occurrence of JET in individual subgroups	6/70 (8.5)	10/70 (14.2)	21/85 (24.7)	0.022[@]
Median duration of JET in hours with range	27 (2-68)	18 (2-176)	25 (6-144)	0.979*
Mean and standard deviation	19.21±26.57	20.2±54.07	20.1±32.27	
Vasoactive inotropic score in the operating room	8.71±3.47	10.83±4.78	11.64±5.10	0.002[#]
Vasoactive inotropic score on the day of surgery	8.8±4.84	11.6±5.42	12.21±6.11	0.001[#]
Vasoactive inotropic score on the postoperative day 1	8.01±5.78	10.33±6.03	10.91±6.30	0.008[#]
Vasoactive inotropic score on the postoperative day 2	5.41±5.78	7.38±7.16	8.61±7.06	0.012[#]
Vasoactive inotropic score on the postoperative day 3	2.07±4.72	4.53±6.24	4.82±7.0	0.008[#]
Mean ventilation time in hours	29.31±24.92	52.01±63.84	53.29±46.13	0.008*
Median with range	22.5 (3-124)	43 (2-475)	42 (5-232)	
Mean intensive care stay in hours	85.2±59.71	121.49±189.2	127.4±105.3	0.006*
Median with range	72 (21-420)	93 (24-1584)	94 (8-720)	
Mean hospital stay in hours	11.56±8.33	13.69±13.87	13.55±8.55	0.050*
Median and range	9 (7-72)	9 (6-94)	10 (1-62)	
Bradycardia	9 (12.8)	4 (5.7)	6 (7.3)	0.145[a]
Hypotension	7 (10)	3 (4.3)	4 (4.6)	0.27[a]
Ventricular dysfunction	9 (12.8)	12 (17.14)	7 (8.5)	0.25[a]
Mortality within the group	0/70 (0)	2/70 (2.8)	7/85 (8.2)	0.128[a]

[@]Statistical test - Fisher's exact, *Statistical test - Kruskal-Wallis test, [#]Statistical test - ANOVA, [a]Statistical test - Chi-square test. JET: Junctional ectopic tachycardia

phase.[9] Enhanced automaticity of the perinodal tissues leads to junctional tachycardia without a preceding atrial contraction. Tachycardia-induced cardiomyopathy, reduced ventricular filling due to shortened diastolic duration, and lack of atrial kick contribute to low cardiac output leading to prolonged ventilation and ICU stay.[3] It is recognized as an unusually faster heart rate lacking a preceding P wave associated with irregular cannon waves on the central venous pressure trace. Unless atrial wires and Lewis leads are used as a part of active surveillance and look-out, the diagnosis is sometimes missed, especially with slower rates or those with 1:1 ventriculoatrial conduction. Hemorrhagic edema and inflammation around suture lines in perinodal tissue, local injury with direct damage to the node or longitudinal stretch during exposure of the VSD and infundibulum could lead to JET.[16] Systemic inflammation could be an additional reason in those patients where the perinodal tissues are not injured as in extracardiac conduit Fontan surgery.

The incidence of JET varies from 1% to 15% in different studies depending on the underlying heart disease and type of repair, occasionally increasing to 22% after tetralogy repair.[5] Incidence in our study was 16.4%, which was higher than a few others. Selection of high-risk patients, proactive lookout for tachyarrhythmia using atrial wires, and avoidance of loading doses of prophylactic drugs could be the possible reasons for the higher incidence. A similar high incidence was reported after high-risk surgeries such as tetralogy repair (35.7%), pulmonary outflow repair (28.6%), atrioventricular canals (18.8%), and VSD closure (17.4%).[17] The extent of the surgical repair correlated with the incidence of JET in our study. While simple VSD closure showed an incidence of 8%, it increased further when VSD closure was a part of atrioventricular canal repair. Incidence was lower after simple transatrial infundibular resection for tetralogy but increased after transannular patch or conduits. The risk was very high (25%) after mitral valve surgery, either repair or replacement.

While younger age and lower body weight were known risk factors, we did not find such a correlation. The inclusion of patients up to 12 years of age possibly introduced a wide variation of age and weight in the cohort and accounted for the lack of correlation.[4,6,18,19] Moreover, most of the patients in the study were very young and weighed less than 10 kg. Patients with JET had longer CPB and ACC times on univariate analysis, indicating inflammation and ischemia-reperfusion as a possible etiology.[20]

In our study, we observed JET in 8.5% of patients in the amiodarone group, 14.2% of patients in the dexmedetomidine group compared to 24.7% in the controls. Dexmedetomidine is a highly selective alpha-2 adrenoceptor agonist with antiarrhythmic properties without causing respiratory depression.[21] The incidence of JET was significantly lower in the dexmedetomidine group than in the controls. Amiodarone prophylaxis was even more effective compared to the other two groups. Two controlled studies using amiodarone prophylaxis showed similar efficacy of amiodarone prophylaxis.[22,23] Regarding the timing of starting amiodarone prophylaxis, early initiation had a significantly shorter time to rate and rhythm control, reduction in the dose needed for rhythm control and a significant reduction in ICU stay compared to late initiation.[22] The prophylactic drugs were started very early in our study, though without a bolus dose. Initial bolus dose increases adverse effects such as hypotension, bradycardia, and heart block.[23] The increase in the incidence of adverse effects after these prophylactic agents was not statistically significant in our study. Some of the newer prophylactic drugs, such as ivabradine, has also shown favorable response on the prevention of JET.[24]

The duration of the JET in the three groups was not statistically different. But the morbidity indicators such as VIS, ventilation duration, ICU, and hospital stay were significantly lower in the prophylactic group compared to controls. Even though the JET duration was similar, the prophylactic agents probably reduced the heart rates, thereby reducing the attendant morbidity. As there was a time-to-time variation in the heart rates in these patients with JET, our study did not record the differences in the average heart rates during JET between the three groups. This could explain the lack of difference in the duration of JET in the three groups, even though there was a reduced incidence of JET in both the drug arms.

Study limitations

This was a study from a single center with three surgeons and the results regarding the incidence of JET could not be generalized to other centers with different surgical teams. Although it is a randomized controlled study, in order to achieve an equal sample size in all three groups, we used an alternate sampling method. As explained earlier, the reduction in the morbidity indicators in the prophylactic groups compared to controls, despite the lack of difference in the duration of JET in the three groups, could have been explained if we had included the mean hourly heart rates during JET in the individual patients. However, this would have been a very cumbersome measurement. Similarly, a composite VIS score was used instead of individual inotrope hourly dosage to simplify the study.

CONCLUSIONS

Postoperative JET was commonly observed in syndromic patients. This arrhythmia was commonly associated with longer CPB and ACC times as well as electrolyte abnormalities such as hypokalemia and hypomagnesemia. More extensive surgery was associated with a higher incidence of JET. Occurrence of JET significantly increased inotropic requirement, ventilation hours, ICU, and hospital stay but was not associated with a higher risk of mortality. Prophylactic amiodarone and dexmedetomidine reduced the incidence of JET. They were associated with significantly lower inotrope requirements, ventilation hours, ICU, and hospital stay. When administered early as a steady infusion without a bolus dose, adverse effects such as bradycardia, hypotension, and ventricular dysfunction were not significantly increased.

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Conflicts of interest

There are no conflicts of interest.

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