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Original Article

Comparison of Myocardial Protection Between Del Nido and St. Thomas Cardioplegia in Paediatric Patients during Surgical Repair of Congenital Heart Disease

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Key Words: *Myocardial Protection, Del Nido Cardioplegia, St Thomas Cardioplegia, Congenital Heart Disease.*

Abstract

Background: *Myocardial protection is a critical component of surgery in congenital heart disease (CHD). Since the commencement, several cardioplegia solutions have been developed to accomplish the goal. This study was aimed to compare the myocardial protection provided by Del Nido cardioplegia and St. Thomas cardioplegia solution in paediatric patients undergoing surgical repair for CHD.*

Methods: *This comparative cross-sectional study was carried out with a total of 30 paediatric patients who underwent elective cardiopulmonary bypass surgery for repair of congenital heart disease were included. They were divided into two groups: group-A (15 patients, who received Del Nido cardioplegia solution) and group-B (15 patients, who received St. Thomas cardioplegia solution). After surgery of all patients, biochemical markers (Troponin-I and Creatine Kinase MB) was done at 6th hour and 24th hour postoperatively and Vasoactive Inotropic Score (VIS) was taken immediately and at 24th hour postoperatively. pre and post operative left Ventricular Ejection Fraction (LVEF) was evaluated. Post operative events (Mechanical ventilation time, postoperative CICU stay period, postoperative hospital stay and complications) were recorded.*

Results: *The mean age, height, weight and body surface area were not statistically significant in both groups (p>0.05). Group-B patients had significantly higher cardiopulmonary bypass time (83.8±20.39 vs 106.87±31.33, p=0.022) and aortic cross clamp time (40.66±10.68 vs 50.73±12.10, p=0.020) than that of group A patients. Group-A patients had significantly lower value of Troponin-I (33.68±20.80 vs 268.15±297.48, p=0.005) and CK-MB (17.98±7.57 vs 49.66±52.32, p=0.035) after 24 hours of surgery. There was significantly higher number of patients in Group B, who had their Troponin-I (20% vs 73.33%, p = 0.003) and CK- MB (13.33% vs 60%, p = 0.008) at 24th postoperative hour in comparison to Group A. Besides, value of postoperative vasoactive inotropic score was significantly lower in group-A than group-B during immediately postoperative (11.81±3.03 vs 15.01±3.40, p=0.011) and at the 24th postoperative hour (9.1±2.73 vs 12.82±2.26, p<0.001).*

Conclusion: *Better myocardial protection is provided by Del Nido cardioplegia in comparison to St. Thomas cardioplegia in paediatric patients who underwent surgical repair for congenital heart disease. So, the application of Del Nido cardioplegia can minimize the morbidity and mortality with early postoperative recovery of the paediatric patients.*

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Introduction

The prevalence of congenital heart diseases is 4 to 10 per 1000 live births. Paediatric cardiovascular surgery is being performed by cardiac surgeons for about 8 decades. An advance in definition, diagnosis, and surgical techniques

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used in repair of the CHD is continuously increasing in the number of patients undergoing surgical repair for CHD.[1]

Most heart surgeries are carried out on arrested heart. Cardioplegia solution is a pharmaceutical therapy given during heart surgery for deliberately and temporarily arresting the heart. The majority of congenital heart surgeries are performed by creating diastolic cardiac arrest as one of the strategies to maintain adequate myocardial protection.[2]

Cardioplegia solutions and strategies vary among cardiac surgeons, countries, and institutions but the overall goal is to stop the heart so the surgeon can operate in a motionless and bloodless field and to preserve myocardial function. Different commercial and self-made cardioplegia solutions are used in cardiac surgical practice. There is still ongoing debate to select the superior one over the other. Among various types of cardioplegia solutions, St. Thomas cardioplegia and Del Nido cardioplegia are the most commonly used in congenital heart disease operations.[2]

St. Thomas cardioplegia solution is an extracellular cardioplegia. It contains high potassium concentration, which acts predominantly by depolarizing the cell membrane. This method of arrest involves perfusing repetitive multiple dosing of cardioplegia once every 20 30 min. Repetitive multiple dosing may interrupt the operation and may hamper adequate myocardial protection if the timing of cardioplegia is not appropriately followed.[2]

Myocardial protection is an essential tool during the surgical repair of congenital heart defects when the heart needs to be arrested. In the early 1950's Dr. Melrose tried first cardioplegia solution during cardiopulmonary bypass. Since the 1950s, research and strategies have been developed to continuously improve myocardial protection and prevent further ischemic injury. The main aim of myocardial protection is to arrest the heart creating a bloodless surgical field to facilitate cardiac repair in a relaxed state while preserving myocardial function with minimizing myocardial metabolism during this ischemia. One of the most important elements of cardiopulmonary bypass is cardioplegia solution which reduces myocardial oxygen consumption by cooling the heart and making it arrested.[3]

The immature myocardium of infants and children is different structurally, physiologically and metabolically to that of adults. Therefore, constant researches are conducted to find a cardioplegia solution that more specifically addresses the needs of the immature heart. Promotion of anaerobic glycolysis, scavenging of oxygen-free radicals and prevention of intracellular calcium accumulation are probably the keys to myocardial protection during the period of arrest. Cardioplegia solutions generally rely on metabolic arrest in addition with hypothermia to address these concerns.[4]

In the early 1990s, a team led by Dr. Pedro del Nido at the University of Pittsburgh developed a cardioplegia solution (CPS) aimed specifically at protecting the immature myocardium. This formula was perceived as a single dose and modified depolarizing solution. After several modifications, the end result was a solution now commonly used and referred to as Del Nido cardioplegia solution.[5]

The Del Nido cardioplegia solution is made by mixing the patient's blood with a crystalloid base of Plasma- Lyte A (Baxter Healthcare Corporation, Deerfield, IL.) at a 1:4 blood to crystalloid ratio that needs to be used in single dose 20 ml/kg through ante-grade at 8-12 degree centigrade and retrograde at 4 degree centigrade in most of the congenital heart repair surgeries. Del Nido cardioplegia solution seems to reduce cross clamp time as single dose is effective for 90 minutes. Del Nido is almost 60 ml solution and is composed of KCl, Mannitol, Lidocaine, MgSO4 and bicarbonate mixed with the crystalloid and blood.[6] KCl is a water-soluble component and causes rapid arrest at depolarizing state and prevention of hypokalemia. An osmotic diuretic, Mannitol has ability of scavenging free radicals and preventing tissue oedema production.[5,6] Magnesium Sulfate (MgSO4) and Lidocaine are added for prevention of the accumulation of sodium and calcium within the cell by polarizing the cell membrane,[7] which is important as paediatric hearts are more sensitive to calcium-induced injury during ischemia due to immature calcium regulatory mechanisms. Bicarbonate scavenges hydrogen ion and thus helps to maintain the body's acid-base

(pH) balance. Decreasing postoperative ventricular arrhythmias and reduction of ICU stay is another importance of bicarbonate. For cardioplegia delivery, a common practice is to reduce metabolic rate with hypothermia. Hypothermia is done during cardioplegia solution is delivered as it reduces metabolic rate by reducing oxygen and phosphate usage. Electrolytes play an important part in cellular metabolism. It is also used in transformation of energy and regulation of membrane potential. Severe arrhythmias can occur by reduction of these electrolytes. Use of diuretics and hemodilution are the main cause of greater electrolytes reduction. Moreover, there is increased risk of hypoglycaemia in association with hypokalemia. Maintaining normal electrolytes level during cardiopulmonary bypass (CPB) is very important. Del Nido cardioplegia solution has ions like K+ (potassium), Ca++ (calcium), Na+ (sodium) and Mg++ (magnesium). They are used for decreasing contractility and also used for preservation of myocardium.[3,6,7]

The del Nido cardioplegia solution which has been developed through considering the aforementioned physiologic conditions, is currently one of the most preferred cardioplegia solution by cardiac surgeons for congenital heart disease surgery in paediatric group and has been adopted by one third paediatric cardiac surgeons.[8] This comparative cross- sectional study aimed to compare the myocardial protection between two different cardioplegia solutions in paediatric patients who underwent cardiovascular surgery for CHD as they have immature myocardium which is vulnerable to ischemic arrest of the heart during operation.

This study aimed to compare the myocardial protection between Del Nido cardioplegia and St. Thomas cardioplegia solutions in the paediatric patients who underwent surgical repair of congenital heart disease in our institution. However the comparison of myocardial protection by effects and outcome measures of Del Nido cardioplegia and St. Thomas cardioplegia solutions in surgical procedures for congenital heart diseases in paediatric patients has not yet been studied in Bangladesh. So, the study findings helped us to minimize the complications of congenital heart surgeries and ensure better early postoperative outcome of the congenital heart disease patients.so Research hypothesis was Del Nido cardioplegia solution provides better myocardial protection than St. Thomas cardioplegia solution in paediatric patients undergoing surgical repair for congenital heart disease.

Methods

This comparative cross-sectional study was carried out in Department of Cardiac Surgery, Bangabandhu Sheikh Mujib Medical University, Dhaka, from August 2021 to September 2023. A total of 30 paediatric patients who underwent elective cardiopulmonary bypass surgery for repair of congenital heart disease were included and divided into two groups: group-A (15 patients, who received Del Nido cardioplegia solution) and group-B (15 patients, who received St. Thomas cardioplegia solution). General objective was to compare the myocardial protection between Del Nido and St. Thomas cardioplegia in paediatric patients undergoing surgical repair for congenital heart disease. Markers of myocardial injury were-biochemical markers (Troponin-I and CK-MB), vasoactive Inotropic Scores (VIS) and LVEF. Peroperative events related to variables were: number of cardioplegia doses given volume of cardioplegia solution, cardiopulmonary bypass (CPB) time, aortic cross clamp (ACC) time, time taken to restore spontaneous regular rhythm. Postoperative events related to variables were: Mechanical ventilation time (hours), postoperative CICU stay (days) and postoperative hospital stay (days). Postoperative complications related to variables were: Renal failure- serum Creatinine, Low Cardiac Output Syndrome (LCOS), Respiratory failure- ABG Post operative bleeding requiring re-sternotomy, post operative ventricular systolic dysfunction mortality all were other independent variables.

Inotrope Score (IS) = Dopamine dose (μg/kg/min) + Dobutamine dose (μg/kg/min) + 100× Epinephrine dose (μg/kg/min) VIS = IS + 10× Milrinone dose (μg/kg/min) + 10000× Vasopressin dose (U/kg/min) + 100× Norepinephrine dose (μg/kg/min)

Data was analyzed by statistical analysis Statistical analyses were performed using

windows-based computer software devised with Statistical Packages for Social Sciences (SPSS-26) (SPSS Inc, Chicago, IL, USA). Descriptive and inferential statistical methods were applied to analyze data. In descriptive statistics, continuous data were summarized by mean ± SD and categorical data were summarized as frequency distribution and percentage. To make comparison between groups and draw conclusions on data, several inferential statistics were used including Chi-square (÷2) test for qualitative data and independent sample t-test for quantitative data. All comparisons were made between variables of myocardial protection between Del Nido and St. Thomas cardioplegia in paediatric patients underwent surgical repair for CHD. For all analytic tests, the statistical significance threshold was set at 5% and a p value of ≤0.05 was considered statistically significant.

Results:

The age distribution between the two groups was statistically similar, with the majority of patients in both groups being aged 5-8 years. The mean age for Group A was 6.87±3.76 (SD) years, while for Group B it was 7.4±3.67 (SD) years. No difference in mean age between the two groups was observed. Both groups had a higher proportion of male patients, but the gender distribution was not significantly different between the two groups. Regarding distribution of anthropometric measurement There were no significant differences between the two groups in terms of weight, height, and body surface area (BSA) of studied children. The distribution of types of CHD was statistically similar between the two groups with Atrial Septal Defect (ASD) being the most common type followed by Ventricular Septal Defect (VSD) and Tetralogy of Fallot (TOF). Group B patients received a significantly greater (p<.05) number of cardioplegia doses compared to Group A. The mean number of doses for Group B was also statistically higher (p<.05) than that of group A patients. A significantly higher (p<.05) volume of cardioplegia solution was used in Group B patients in comparison to group A. The mean volume for Group B was also statistically higher (p<.05) than that of group A.

The CPB time and ACC time were significantly shorter (p<.05) for Group A patients compared to Group B patients. Time taken to restore spontaneous regular rhythm was statistically same for both groups (p≥.05).

Table-I

Comparison of the number of cardioplegia doses and volume of cardioplegia used between two groups of patients (N=30).

	Group A n=15 n (%)	Group B n=15 n (%)	p value
Number of doses			
<2	13 (86.7)	1 (6.7)	<0.001*[s]df= 1
≥2	2 (13.3)	14 (93.3)	
Total	15 (100)	15 (100)	
Mean±SD	1.13±.35	2.20±.67	<0.001**[s]df= 28
Volume (mL)			
150 – 400	13 (86.7)	1(6.7)	
401 – 800	2 (13.3)	9 (60)	0.002*[s]
801 – 1200	0	4 (26.7)	df= 3
1200 – 1500	0	1 (6.7)	
Total	15 (100)	15 (100)	
Mean±SD	356.66±99.76	750±307.64	<0.001**[s]df= 28

Group A: Patients undergoing CHD repair bypass surgery using Del Nido cardioplegia solution
Group B: Patients undergoing CHD repair bypass surgery using St. Thomas cardioplegia solution
p value was determined by chi-square test* and independent student t test**
df= degrees of freedom
s= Significant

Regarding Distribution of preoperative and postoperative LVEF between two groups of patients There was no significant difference in the preoperative and postoperative LVEF between the two groups. Mean value of Troponin-I level was higher in Group B patients at both the 6th and 24th postoperative hours while the difference was statistically significant at the 24th hour (p<.05), which indicates the level of myocardial injury was significantly higher among group B patients at 24th hour of CHD repair surgery. Also there was higher number of patients (20% vs 73.33%, p = 0.003) in Group B, who had their Troponin-I higher than normal value (0-60.4 pg/mL) at 24th postoperative hour.

Mean value of another cardiac injury marker, CK-MB level was also higher in Group B patients at both the 6th and 24th postoperative hours while the difference was statistically significant at the 24th hour (p<.05) and there was higher number of patients (13.33% vs 60%, p = 0.008) in Group B, who had their CK-MB higher than normal value (7-25 U/L) at 24th postoperative hour.

The mean value of postoperative VIS was significantly higher (p<.05) in Group B patients both during immediately postoperative and at the 24th postoperative hour.

Comparison of mechanical ventilation time, postoperative CICU stay, postoperative hospital stay and complications between two groups of patients - mechanical ventilation time, postoperative CICU stay and postoperative hospital stay were statistically similar (pe".05) in both groups. Only 1 patient from each group

Table-II

Comparison of cardiopulmonary bypass time, aortic cross clamp (ACC) time and time taken to restore spontaneous regular rhythm between two groups of patients (N=30)

	Group A n=15 Mean±SD	Group B n=15 Mean±SD	Total N=30 Mean±SD	p value
CPB time (minutes)	83.8±20.39	106.87±31.33	95.33±28.60	0.022*s
ACC time (minutes)	40.66±10.68	50.73±12.10	45.7±12.32	0.020*s
Time taken to restore spontaneous regular rhythm (minutes)	3.13±1.24	3.33±1.11	3.23±1.16	0.646*nsdf= 28

Group A: Patients undergoing CHD repair bypass surgery using Del Nido cardioplegia solution
Group B: Patients undergoing CHD repair bypass surgery using St. Thomas cardioplegia solution
p value was determined by independent student t test*
df= degrees of freedom; ns= Not significant; s= Significant

Table-III

Comparison of postoperative Troponin-I between two groups of patients (N=30)

	Group A n=15 Mean±SD n (%)	Group B n=15 Mean±SD n (%)	p value
6th hour	314.11±206.09	489.13±318.22	0.085*ns
0-60.4	0 (0)	0 (0)	df= 28
>60.4	15 (100)	15 (100)	
Total	15 (100)	15 (100)	
24th hour	33.68±20.80	268.15±297.48	0.005*s
0-60.4	12 (80)	4 (26.67)	0.003*s
>60.4	3 (20)	11 (73.33)	df= 1
Total	15 (100)	15 (100)	

Group A: Patients undergoing CHD repair bypass surgery using Del Nido cardioplegia solution
Group B: Patients undergoing CHD repair bypass surgery using St. Thomas cardioplegia solution
p value was determined by chi-square test*
df= degrees of freedom; ns= Not significant; s= Significant

Table-IV

Comparison of postoperative CK-MB between two groups of patients (N=30)

	Group A n=15 Mean±SD n (%)	Group B n=15 Mean±SD n (%)	p value
6th hour	133.98±123.04	181.86±142.95	0.334*ns
7-25	0 (0)	0 (0)	df= 28
>25	15 (100)	15 (100)	
Total	15 (100)	15 (100)	
24th hour	17.98±7.57	49.66±52.32	0.035*s
7-25	13 (86.67)	6 (40)	0.008*s
>25	2 (13.33)	9 (60)	df= 1
Total	15 (100)	15 (100)	

Group A: Patients undergoing CHD repair bypass surgery using Del Nido cardioplegia solution
Group B: Patients undergoing CHD repair bypass surgery using St. Thomas cardioplegia solution
p value was determined by chi-square test*
df= degrees of freedom; ns= Not significant; s= Significant

Table-V

Comparison of postoperative vasoactive inotropic score (VIS) between two groups of patients (N=30)

Postoperative VIS	Group A n=15 Mean±SD	Group B n=15 Mean±SD	Total N=30 Mean±SD	p value
Immediate postoperative VIS	11.81±3.03	15.01±3.40	13.41±3.56	0.011*s
VIS at postoperative 24th hour	9.1±2.73	12.82±2.26	10.96±3.11	<0.001*sdf= 28

Group A: Patients undergoing CHD repair bypass surgery using Del Nido cardioplegia solution
Group B: Patients undergoing CHD repair bypass surgery using St. Thomas cardioplegia solution p value was determined by independent student t test*, df= degrees of freedom, s= Significant

experienced postoperative complication: Postoperative bleeding requiring re-sternotomy was reported in group A and postoperative respiratory failure was reported in group B.

Discussion:

Over the years, various cardioplegic solutions and techniques have been developed to optimize myocardial protection and among them Del Nido and St. Thomas cardioplegia have emerged as two prominent solutions in paediatric cardiac surgeries for repair of congenital heart disease.[9] This comparative cross- sectional study aimed to assess and compare the level of myocardial protection provided by Del Nido cardioplegia and St. Thomas cardioplegia solution. A total of 30 patients with congenital heart disease were enrolled in this study where 15 patients were taken under Group A who had CHD repair surgeries using Del Nido Cardioplegia solution and 15 patients were taken under Group B who had CHD repair surgeries using St. Thomas Cardioplegia solution. The data were collected, compiled and compared with data of similar studies reported in various international literatures. In this study, Mean±SD age of the participants in Group A and Group B was 6.87±3.76 years and 7.4±3.67 years respectively with majority of them (12 patients) were aged between 5 to 8 years in both groups. Among the patients, male predominance was found in both Group A and Group B (63.3% vs 36.7%, p=0.705). Similar age and gender pattern was observed in a previous trial conducted by.[10] Age group

distribution, mean age and gender were statistically similar in both groups. Different types of cardioplegia solutions, their dosing strategies and regimens cause different level of myocardial protection in different age groups.[11] Regarding other baseline characteristics like anthropometric measurements; height, weight and body surface area were statistically similar in both groups. This study included only patients with a confirmed diagnosis CHD based on exclusive selection criteria to rule out the probability of selection biases. Majority of the children were diagnosed with atrial septal defect (53.3%) which followed by a decreasing order by ventricular septal defect and tetralogy of Fallot.

A significantly higher number of cardioplegia doses in Group B suggests that St. Thomas cardioplegia may require more frequent dosing to maintain cardiac arrest during surgery compared to Del Nido. Similar findings were reported by other studies.[7,12] It has been speculated that single or lesser dose cardioplegia offers better myocardial protection than does multiple-dose cardioplegia.[13] A multivariable logistic regression analysis of 27,215 patients undergoing cardiac surgery demonstrated that Aortic Cross Clamp time was an independent predictor of perioperative mortality. In addition, CPB time has been shown to be an independent risk factor for postoperative death; pulmonary, renal, and neurologic complications, multiorgan failure, reoperation and blood transfusion.[14] In this study, CPB time and ACC time were shorter for Del Nido group. Studies also observed a shorter CPB and ACC time associated with the use of Del Nido cardioplegia solution comparing St. Thomas cardioplegia solution.[2,10,15,16] But the retrospective study by Floh et al. found longer CPB and ACC time in Del Nido cardioplegia group and the clinical relevance of the findings was unclear, which differs with this study.[17] There was no difference in time taken to restore spontaneous regular rhythm after weaning of CPB between the two groups in this study. Panigrahi et al. found that the time taken to recover spontaneous regular rhythm after release of the Aortic Cross Clamp was significantly shorter in the Del Nido group.[12] But, Haranal et al., reported no difference in case of time taken to recover spontaneous regular rhythm in both groups which is similar to this study.[18] Surprisingly, change in LVEF, which is a marker of perioperative myocardial injury, did not show any significant difference period between the groups. Haranal et al. and Pourmoghadam et al. also found no changes of LVEF of pre and post operative patients in their studies.[18,19] This could suggest that despite the biochemical markers indicating more myocardial injury in Group B, it didn't translate to a significant functional difference in the immediate post-operative period. Biochemical markers of cardiac injury, Troponin-I and CK-MB were significantly lower among patients at the 24th postoperative hour who underwent CHD repair bypass using Del Nido cardioplegia solution indicating lesser myocardial injury in comparison to the other group. Similarly, Isildak et al. and An et al. found that Del Nido cardioplegia leads to lower Troponin-I concentrations than St. Thomas blood cardioplegia at postoperative 24th hour in their studies. Panigrahi et al. and Haranal et al. found no time-related changes in Troponin-I and there turn to baseline was also similar.[12,18]

In this study, there was significantly higher number of patients in Group B, who had their Troponin-I higher than normal value and CK- MB higher than normal value at 24th postoperative hours in comparison to Group A. This also shows that biochemical markers of most of the patients who underwent surgeries using Del Nido cardioplegia comes back to the normal limit within 24 hours of surgery. So, it is an indicator of less ischemic injury and better myocardial protection provided by Del Nido cardioplegia. Another indicator observed in this study was Vasoactive Inotropic Score (VIS) which is an index used to determine the amount of inotropic support a patient needs after performing the surgery. A significantly higher VIS scores was observed in Group B patients both immediately postoperatively and at the 24th postoperative hour. This finding indicates a higher need for inotropic support in the St. Thomas group, pointing again to possibly better myocardial protection by Del Nido cardioplegia. Mohammed et al. and Pourmoghadam et al. also reported a significantly higher VIS score following neonatal congenital heart surgery among patients who received St. Thomas cardioplegia in comparison to patients who received Del Nido cardioplegia.[2,19]

But the use of inotropes and vasoactive supports do not cause adverse postoperative outcome. A high VIS can be said as a surrogate marker of illness severity after cardiac surgery.[20] Mechanical ventilation time, days stayed by the patients in CICU and Hospital after their surgeries found statistically similar in this study. One patients of each group experienced postoperative complications which was managed accordingly.

Based on the findings demonstrated by this study, Del Nido cardioplegia seems to offer superior myocardial protection in paediatric patients undergoing CHD repair compared to the St. Thomas cardioplegia solution. The findings suggest fewer myocardial damage, lower inotropic requirement, administration of fewer doses, a lesser volume of cardioplegia solution and Shorter CPB and ACC time with Del Nido compared to St. Thomas cardioplegia. The strength of the study was controlling certain confounders such as age, gender, and type of CHD, there may still be other unknown variables that could have influenced the results. Additionally, the small sample size of 30 participants in this study might not be entirely representative of the broader population, which is the weakness of the study. However, further studies with larger sample sizes and different patient cohorts are essential to generalize these findings and ensure comprehensive myocardial protection in various clinical settings so that, morbidity and mortality of the paediatric patients can be minimized after congenital heart disease repair surgeries using the best cardioplegia during operation.

Conclusion:

Based on the findings demonstrated by this study, Del Nido cardioplegia seems to offer superior myocardial protection in pediatric patients undergoing CHD repair compared to the St. Thomas cardioplegia solution. The findings suggest fewer myocardial damage, lower inotropic requirement, administration of fewer doses, and a lesser volume of cardioplegia solution requiring shorts operation time with Del Nido compared to St. Thomas cardioplegia. However, further multi-centered study with a larger sample size in recommended to corroborate the research findings.

Limitations of the study

All surgeries were not performed by the same surgical unit. Different units may imply different surgical techniques. Again, in case of same performer there may be chance of biasness regarding the echocardiographic findings. Sample was taken purposively. It was a single center study with relatively small sample size. Long term follow-up (to asses hospital readmission due to post-operative heart failure, thromboembolic events or mortality) was beyond the scope of the study.

Conflict of Interest - None.

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