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DEL NIDO CARDIOPLEGIA: A 'MAGIC BULLET' FOR CARDIAC SURGEON- A MULTIVARIATE PROSPECTIVE COMPARATIVE STUDY

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Abstract

Introduction-

Cardioplegia remains an essential component of myocardial protection during cardiac surgeries.

Main purpose-

This is a single centre prospective study that compares the better cardioprotective effect between del Nido(DN) and modified St. Thomas(mST) cardioplegia solution during intra-operative and immediate post-operative period.

Method-

This is a prospective randomised double blind study conducted over a period of one year from among the patients admitted for different cardiac surgeries. The selected patients were divided into two groups. Surgical procedures included in this study: coronary artery bypass graft(CABG)(multiple graft), mitral valve repair / replacement+ tricuspid ring annuloplasty (MVR+TVR), mitral + aortic valve replacement (DVR), ventricular septal defect(VSD)

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repair, intra-cardiac repair for Tetralogy of Fallot (TOF). Surgical procedures excluded in this study were: isolated mitral valve replacement, aortic valve replacement (AVR), atrial septal defect (ASD), CABG (single graft). Primary end point was to compare the cardioprotective factors in DN and mST group.

Result-

In comparison to modified St Thomas group, del Nido group had lesser cardiopulmonary-bypass time(76.50 min vs 67.16 min), aortic cross clamp time(60.60 min vs 53.52 min) and comparatively lesser rise in post-operative Troponin T level (1.027 ng/dl vs 0.719 ng/dl) and earlier appearance of first cardiac rhythm after removal of aortic cross clamp(39.88 sec vs 29.52 sec) and lesser incidence(n=8) of re-dosing of cardioplegia administration, lower rate of post-operative defibrillation(six vs twenty) and lower post-operative complication rate (three vs ten).

Conclusion-

Our study demonstrated that by using del Nido cardioplegia, there is in better myocardial protection and improved cardiac output in comparison to other standard cardioplegic solutions along with improved haemo-concentration. Hence, the del Nido cardioplegia can be a 'magic bullet' for cardiac surgeons.

Keywords: del Nido, modified St Thomas, cardioplegia, cardiopulmonary bypass, magic bullet

Manuscript

Introduction-

Cardioplegia is an essential component of myocardial protection for patients undergoing cardiac surgeries. Out of different methods to reduce the myocardial oxygen consumption, hyperkalemic cardioplegic solution remains the most acceptable modality for myocardial preservation. An ideal cardioplegic solution should preserve the myocardium during ischemia, reduce the reperfusion injury, buffers the electrolyte and osmotic imbalance as well as preserve the myocardium and its contractility.

Cardioplegic solutions are categorised as either intracellular or extracellular based on their composition and cellular environment. Custodial HTK solution is an intracellular solution while St. Thomas , Buckberg and del Nido solutions are extracellular solutions[1]. Cardioplegia may further be classified based on polarisation of the resting membrane of the myocytes. del Nido, St. Thomas, Buckberg,Plegisol are diastolic depolarising solution and they act by addition of potassium ion, where as Bretschneider, Custodial HTK polarise the cell membrane by removing sodium ion their by avoiding an action potential; Adenosine, Adenocaine, Pinacidil act as hyperpolarising agent by filling the extracellular space with potassium channel opener their by avoiding an action potential[2].

Out of different commercially available cardioplegic solutions, blood based solutions are associated with less reperfusion injury and better myocardial preservation and reduction in perioperative cardiac enzyme levels. Out of these, St. Thomas cardioplegia solution was developed by Braimbridge at London in 1975 and latter modified to St. Thomas solution II (mST) is wildly used in different centres[3]. del Nido cardioplegia (DN) was developed by Pedro del Nido at the University of Pittsburg in 1990 and initially meant for paediatric

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cardiac surgery and latter used in adult cardiac surgery[4]. These crystalloid solutions (mST and DN) have basic solutions and different components (Table I).

Aim

This is a single centre prospective study that compares the better cardioprotective effect between del Nido(DN) and modified St. Thomas(mST) cardioplegia solution during intra-operative and immediate post-operative period.

Material and Method

A) Study design-

This is a prospective randomised double blind study conducted over a period of one year from April 2021 to March 2022 from among the patients attending the OPD posted for cardiac surgeries. The admitted patients were assigned a number sequentially by an allocator who was not associated with this study. The 'even numbered' and 'odd numbered' patients were subjected to modified St Thomas and del Nido cardioplegia solution respectively during their cardiac surgeries. The allocator, operative surgeons as well as the patients were not aware about the nature of cardioplegia used during procedures.

Surgical procedures included in this study: coronary artery bypass graft(CABG)(multiple graft), mitral valve repair / replacement+ tricuspid ring annuloplasty (MVR+TVR), mitral + aortic valve replacement (DVR), ventricular septal defect(VSD) repair, intra-cardiac repair for Tetralogy of Fallot (TOF). Surgical procedures excluded in this study were: isolated Mitral valve replacement, aortic valve replacement (AVR), atrial septal defect (ASD), CABG (single graft).

B) Method –

After Institutional Ethical Committee approval, informed consent from individual patient was taken. All patients were operated under general anaesthesia in mild hypothermia (32^0 - 34^0C). Standard midline sternotomy done in each case. Cardioplegia administered in ante-grade manner in most cases except in DVR and CABG, where cardioplegia administered through direct coronary ostias and proximally anastomed venous grafts respectively. The initial dose of cardioplegia calculated as 20ml/kg body weight of the patient and subsequent dose administered at a dose of 10 ml/kg body weight after every 20-25 minutes of duration in case of mST group and after 60 minutes duration in case of DN group. Arterial blood gas (ABG) done at different points during surgery (before procedure, 10-15 minute after cardioplegic arrest, during rewarming phase of cardioplegic arrest). "Hotshot" given and de-airing done meticulously in each case. The cardiopulmonary bypass (CPB) time, aortic cross clamp (ACC) time recorded. The CPB time is the extracorporeal circulation time in which the circulatory and respiratory support is provided by the pump along with the temperature management. The ACC time is the time period between apply of aortic cross clamp to its removal. The time duration between appearance of first heart beat from the time of ACC removal noted. Internal defibrillation applied when there was fibrillation of heart and which were not responding to intravenous lignocaine. After the procedure, the patient monitored in cardio thoracic intensive care unit (CTVS ICU) under inotropes and fluid support. The

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patients were weaned from ventilator support after one to two days of surgery. Post operative serum Troponin -T (quantitative) (Trop-T) estimation was done on second post-operative day in each case. Post-operative complications like bleeding, reduced cardiac output, surgical site infection etc. were recorded, duration of hospital stay and mortality if any noted in each case.

C) Statistics

The primary end point is to compare the cardio-protective factors like- CPB time, ACC time and post-operative Trop-T level measurement in del Nido as well as modified St Thomas cardioplegia solution. The secondary end points are cardioplegia single dose/ multiple dose, surgical interruption, post-operative defibrillation, calcium and potassium level in re-warming ABG, return of cardiac rhythm from time of aortic cross clamp removal, post-operative complications, duration of hospitalisation and hospital mortality.

Statistical analysis done using SPSS (version 21) software using Mann-Whitney U test and Pearson Chi Square test.

Results

Out of total 100 patients included in this analysis with 50 in each group, in DN group, 24 male patients and 26 female patients participated where as in mST group, there were 20 male patients and 30 male patients. Both the groups were almost similar in their preoperative variables like age and disease distribution pattern. (Table IIa, IIb).

The outcome of various variables between DN group and mST group described in Table IIIa, IIIb.

The CPB time in DN group with mean of 67.16 minutes(SD-26.68) is significantly lower than mST group with mean value of 76.50(SD-21.76) (p value 0.008). Similarly, ACC time is 53.52 min(SD-23.28) in DN group which is significantly lower than mST group, where it's 60.60min(SD-19.56)with p value of 0.021.

The re-warming ABG showing Calcium level in DN as well as mST group is not statistically significant. But in contrast to this, the Potassium level in DN group is significantly lower than mST group (p= 0.021).

The time between appearance of cardiac rhythm after removal of ACC is significantly lower (p=0.001)in case of DN group(mean of 29.52second , SD-16.08) than mST group(mean of 39.88 second, SD-14.80).

Post operative Trop T level lie within normal range in case of DN group (mean 0.719 ng/dl) , where as in mST group , its beyond normal range(mean-1.027, SD-0.40) with p value of 0.001.

Similarly, cardioplegia single dose(n=42) and multiple doses (n=8)administered in DN group, which is statistically significant (p=0.001) and in mST group multiple doses administered in all cases(n=50).

There is surgical interruption in all cases of mST group (n=50) and in eight number of cases in DN group (p=0.001)

Post operative defibrillation done in six number of cases in DN group, where as 20 number of cases in mST group, which is statistically significant (p=0.001).

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Average duration of hospital stay for both groups are almost similar; but post operative complications like arrhythmia, bleeding, surgical site infection seen in three patients in DN group and ten patients in mST group, which is statistically significant(p= 0.03). Hospital mortality seen in two patients in DN group, where as five in mST group which is statistically insignificant (p= 0.23)

Discussion

Myocardial protection by cardioplegia not only provides a static and bloodless field, but also preserves the myocardial function. The quest to find ideal candidate of cardioplegia having longer duration of myocardial protection there by reducing the re-dosing and hence the surgical interruption time , ACC time, CPB time as well as reducing the re-perfusion injury, has lead to development of various cardioplegic solution till now. Global survey conducted by Ali JM described in their study that blood cardioplegia is most commonly used cardioplegia in most cardiac centres [5].

In our study, single dose of DN cardioplegia administered in 42 number of patients(84% in the group) and multiple doses in eight number of cases(16% in the group);but in mST administered in all cases (n=50)(Chi Square Test P value 0.001); similar result was there in case of George G study(1.13 Vs 2.35, P < 0.001)[6]. Zwolinski R in their study of mitral valve surgery concluded that single dose of DN cardioplegia is better than multiple doses of St. Thomas Hospital solution, as there is decrease in crystalloid load resulting in decrease in the haemodilution and decrease in frequent blood transfusion postoperatively[7].

Due to single dosing or less frequent dosing in case of DN, there is decrease in overall surgical time and hence the degree of contamination.

In our study, the ACC time was 53.52 min(SD 23.28) and 60.60 min(SD 19.56) in DN and in mST group respectively(P =0.021). The CPB time was 67.16 min(SD 26.68) and 76.50 min (SD 21.76) in DN and mST group respectively (P=0.008). These duration are lesser than study of Prasant M where, the ACC time was 110.15min (36.84) and 133.56 min(35.60) in DN and mST group respectively[8]. Whereas, HuiShi could not find any difference between the ACC time and CPB time comparing the DN group and blood cardioplegia group (P = 0.957,when ACC time ≤ 90 min and P=0.068, when ACC time > 90 min)[9]. The smaller the duration of ACC time and the CPB time, there is better myocardial preservation and better cardiac output and decrease in surgical exposure time.

Serial ABGs were done at different points during and after CPB. Although primarily it measures the pO2 and pCO2 during different phases of surgery, it also measures the calcium (Ca^{2+}) and potassium (K^{+}). In our study, we measured the extracellular Ca^{2+} and K^{+} level at rewarming phase of cardioplegic arrest, as they reflect the load of above ions in the cardiac myocyte indirectly. Although in our study, there was no significant difference of level of Ca^{2+} in DN group (1.21(SD 0.31)) and mST group (1.2(SD 0.23)) (P= 0.904), but there was significant difference of level of K^{+} in DN group (3.17(SD 0.58)) between mST group (3.72(SD 0.43)) (P= 0.001).This difference may be due to low level of K in DN group (26 mEq in DN vs 36 mEq in mST). Normal influx of calcium inside cardiac myocyte initiates contraction but decreases relaxation. Ongoing accumulation of calcium leads to interruption of relaxation and increase in diastolic stiffness with poor recovery of ventricular

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function. Magnesium being the natural calcium channel blocker, its presence in the DN cardioplegia solution improves the ventricular function in presence of low calcium[10].

In our study group, return of spontaneous cardiac rhythm was significant earlier in case of DN group in comparison to mST group (P= 0.001) which is similar to study by Debasish P group (P< 0.0001)[11]. In contrast to this, Kallol D studied that spontaneous cardiac rhythm returned earlier in ST group(34 sec, SD 5.09) than DN group(70 sec, SD 12.06)[12]. According to Linda B. Mongero, return of spontaneous rhythm is longer both in DN as well as in ST group because in DN group, presence of lignocaine causes arterial vasodilatation and in ST group, 4:1 cardioplegic solution with higher hematocrit causes microvascular obstruction during hypothermia induced sludging there by increase duration in the return of spontaneous rhythm [13].

Post-operative defibrillation rate was significantly lower in DN group than mST group in our study (P= 0.001). Similar results found in study group of Kallol D [12] and Shane TB[14]. Our study further supported by Buel ST study, where there is six fold decrease in defibrillation rate following ACC removal [15]. But according to Gladdy G and Sadeghi, there was no significant difference in rate of defibrillation in their study[6,16]. The decrease in the rate of defibrillation in DN group may be due to better myocardial protection as a result of decrease in ACC time. Lower rate of defibrillation rate associated with lesser degree of cardiac injury.

In our study group troponin-T level on second post-operative day was elevated in both DN as well as mST group, but DN group had significantly lesser rise than mST group(0.719ng/dl (SD 0.37) vs (1.027 ng/dl (SD 0.40)(P=0.001). This is supported by PBM Lama study, where they had measured creatin kinase-MB(CPK-MB) on second post-operative day (59.91 SD31.62) in DN group and (73.82 SD 37.25) in mST group(P=0.03)[17] and Zeki T group where they had measured the post operative cardiac enzymes like CPK-MB and Troponin-I, which were significantly low in DN group in compared to mST group(P= 0.0034)[18]. Zwolinski R explained that postoperative Troponin levels were not significantly differ in both the groups but lower in DN group (P=0.358) due to shorter overall ACC time in the latter group [7]. Satyajeet M in their systemic review and meta-analysis found that there were lower release of cardiac Troponin-T in DN group (SMD -0.51;95CI,-0.98 to-0.05, P=0.03) with significant heterogeneity (I^2> 90%)[19]. Niv Ad in his editorial commentary concluded that cardiac enzymes levels are although surrogate markers of myocardial preservation, other parameters like cardiac output, myocardial performance by echocardiography and peri-operative outcome should be taken into account to quantify myocardial preservation [20]. With respect to duration of stay in hospital and mortality incidence both groups have similar outcome but with respect to early post-operative complication, DN group has better outcome than that of mST group .

Conclusion

Our study demonstrated that by using del Nido cardioplegia in various cardiac surgical procedures in comparison to other standard cardioplegic solutions, there is shorter duration of aortic cross clamp time, cardiopulmonary bypass time and lower rise in Troponin-T level. This results in better myocardial protection. There is also reduced incidence of post-operative

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defibrillation and hence, reduced cardiac injury which leads to improved cardiac output post-operatively. Apart from these, there is less number of repeated dosing of cardioplegia which lead to better post-operative haemo-concentration and reduced surgical time and lower incidences of contamination rate in del Nido cardioplegia. Hence, the del Nido cardioplegia can be a 'magic bullet' for cardiac surgeons.

Limitations

Being a single centre study, is one of the limiting factors. Profound conclusion might have been drawn if multi centre study would have been done and homogenous cohort study would have been selected.

Declaration:

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2. **Declaration of Conflicting interests:** There is no conflict of interest.
3. **Ethical approval:** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Ethical committee of the institution approved the study. (IEC application no-883)
4. **Consent to participate:** Informed consent was obtained from all individual participants included in the study
5. **Consent to publish:** Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.

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Table I. Composition of cardioplegia solution with their basic role

Composition	**Modified St. Thomas Solution (mST)**	**del Nido solution (DN)**	**Role of each constituent**
Carrier solution	Ringer Lactate	Plasmalyte A(1000ml)	Basic (Plasmalyte A: Na-140 mmol/L, K-5 mmol/L,Mg- 3 mmol/L, pH7.4
Blood to crystalloid ratio	4:1	1:4	Blood in cardioplegia improves coronary perfusion, preserves myocardial metabolism, lessens ischemic stress and reperfusion injuries
Potassium chloride (KCl) (mEq)	36	26 (13 ml)	Diastolic arrest. (myocardial depolarisation)
Procaine hydrochloride (1 mmol/20 ml= 272 mg)	544mg	nil	
Lignocaine (1%)	nil	13 ml	Sodium channel blocker Counteracts negative effect associated with poor myocardial recovery due to intracellular Na^{+} & Ca^{++} accumulation during arrest
Magnesium (gm)	6.4 gm (16 mmol/L)	50% (2 gm) (4 ml)	Natural calcium channel blocker and thereby reduces diastolic stiffness and improves ventricular recovery in hypothermic cardioplegic solution when coupled with low calcium level
Sodium bicarbonate 8.4% (mEq)	27 mEq	13 mEq (13 ml)	Buffers to scavenge excess H^{+} Mantains intracellular pH Carbonic anhydrase of RBCs with bicarbonate

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			scavenges H^+ and generates CO2 and H2O
Mannitol 20%	nil	16.3 ml (3.26 gm)	Scavengers of free radical and reduce myocardial cell edema

Table IIa.
Numbers of patients in del Nido and modified St Thomas groups according to age groups

Age group in year	Numbers of patients in DN group(n=50)	Numbers of patients in mST group(n=50)
0-10	1	2
11-20	10	8
21-30	2	1
31-40	5	5
41-50	15	14
51-60	16	18
61-70	1	2

DN- del Nido, mST- modified St Thomas

Table IIb.
Numbers of patients in del Nido and modified St Thomas groups according to surgical procedure done

Surgical procedure done	Numbers of patients in DN group(n=50)	Numbers of patients in mST group(n=50)
VSD repair	9	6
TOF ICR	2	4
MVR+ TVR	4	2
DVR	11	11
CABG	24	27

VSD- ventricular septal defect, TOF ICR- tetralogy of Fallot intracardiac repair, MVR- mital valve repair/replacement, TVR-tricuspid valve ring annuloplasty, DVR- double valve (aortic and mitral) replacement, CABG- coronary artery bypass graft
DN- del Nido, mST- modified St Thomas

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Table IIIa.

Comparison of different variables between del Nido and modified St Thomas groups using Mann-Whitney U test

Variables	del Nido(DN) group (n=50)(SD)	Modified St. Thomas(mST)group (n=50) (SD)	P value
CPB time (in minute)	67.16 (26.68)	76.50(21.76)	0.008
ACC time (in minute)	53.52 (23.28)	60.60(19.56)	0.021
Calcium level(Rewarming ABG)	1.21 (0.31)	1.2(0.23)	0.904
Potassium level(Rewarming ABG)	3.17 (0.58)	3.72(0.43)	0.001
Return of rhythm from time of aortic cross clamp removal(in second)	29.52 (16.08)	39.88(14.80)	0.001
Post operative Trop-T (ng/dl)	0.719 (0.37)	1.027(0.40)	0.001

CPB-cardiopulmonary bypass, ABG- arterial blood gas, SD-standard deviation

Table IIIb.

Comparison of different variables between DN and mST groups using Chi Square Test

Variables	del Nido (DN) group (n=50)	Modified St. Thomas (mST) group (n=50)	P value
CP Single dose	42	0	0.001
CP Multiple dose	8	50	
Surgical interruption (yes)	8	50	0.001

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Surgical interruption (no)	42	0	
Post op defibrillation (yes)	6	20	0.001
Post op defibrillation (no)	44	30	
Post operative complication	3	10	0.03
Mortality	2	5	0.23

CP-cardioplegia,