To Evaluate The Effectiveness Of Del Nido Cardioplegia In Adult Cardiac Surgery At A Tertiary Care Centre

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Key words

Cardiac surgery, cardioplegia, del Nido, myocardial hibernation, stunning, reperfusion injury.

Abstract

Del Nido cardioplegia has emerged as a promising myocardial protector in adult open heart surgeries after it's initial success in Paediatric open heart surgeries, specially in immature myocardiums. To conclude, del Nido as an effective cardioplegic agent among the adult open heart surgeries one must compare it's advantages and disadvantages with other cardioplegic agents.

Methodology

This is a retrospective study where about 200 patients were studied who were adults with first time CABG, Valve Surgery, interventions for Aneurysms etc requiring CPB. After obtaining the institutional ethical committee approval the study was conducted. Primary outcomes were assessed for spontaneous cardiac rhythm, requirement of Shocks(defibrillatory) Troponin levels compared with baseline, after 1,2 hours after the CPB (pump off), ventilatory duration, length of ICU stay, requirement of Insulin, glycaemic indices, overall hospital stay, mortality etc several of these factors were studied.

Results

Pre-operative criteria were almost similar between groups including age, society of thoracic surgeons risk score, for CABG and valve procedures

There was no significant difference on CPB time (98 vs 104 minutes) and cross clamp time(68 vs 79.8 minutes: p=0.019).

The Del Nido group showed higher return to spontaneous rhythm(97. 8% vs 81.7%

p= 0. 022 and fewer patients required inotropic support (65.1% vs84. 32%) but did not reach the statistical significance.

Conclusions

From this study it may be inferred that del Nido cardioplegia may be used safely for adult cardiac surgeries with streamlined surgical workflow. Troponin should be checked baseline and at time bound manner to prove the Superiority of the cardioplegia.

Introduction

Abbreviations & Acronyms

CABG-Coronary Artery Bypass Grafting, CPB -Cardio Pulmonary Bypass, CVICU-Cardio Vascular Intensive Care Unit, Society of Thoracic Surgeons Score (STS), TEE-Trans Esophageal Echocardiography

Historical aspects

Optimal myocardial protection during complex cardiac surgery is the key component of successful outcome of a cardiac surgery. Since 1950 studies and research work is an ongoing entity to discuss all the pros and cons and how to improve the myocardial protection over further ischemia and reperfusion injury. The hypothermic and hyperkalaemia solutions become the clinical standard in almost all cardiac centres of excellence all over the world. However there lies the ambiguity and lack of clear consensus on composition, temperature, PH route of administration and over all technique

A novel cardioplegia for paediatric cardiac surgeries with immature myocardium was developed in 1955 which was patented as single dose modified depolarizing solution which is none other than del Nido cardioplegia, mainly contributed by Pedro del Nido and his team at the university of Pittsburgh. This blood mixed with crystalloid is known to give better and longer duration of myocardial protection by the virtue of preserving intracellular high energy phosphate molecules, PH and preventing influx of calcium ions during and after ischemic arrest and thus decreasing the reperfusion injury, myocardial stunning and thus causing only a temporary myocardial hibernation.

Materials and Methods

STUDY DESIGN- RETROSPECTIVE STUDY

STUDY SAMPLE- Total Number of Patients 200

STUDY PERIOD: From January 2018- December 2021

INCLUSION CRITERIA

Body surface area~1.9m2

Male and females of age groups >18 years and<70 years of age

ASA Grade upto IV

200 adult patients who underwent open heart surgeries who were put on CPB were considered for del Nido cardioplegia, administered as single short.

EXCLUSION CRITERIA

ASA Grade beyond V

Age <18 years & > 70 years

Redo Cardiac Surgeries.

PRIMARY OUTCOME:

Primary outcome was measured as myocardial preservation by return to spontaneous rhythm, defibrillation requirement, inotropic requirement and Troponin levels at 4 time points viz

1 baseline, (at the induction of anaesthesia),

2. Two hours after the pump off

3. Twelve hours Post=operative CVICU

4. Twenty Four hours after the admission to CVICU

SECONDARY OUTCOMES

1.Safety and workflow

2.CPB time

3.Cross-clamp time

4.Cardioplegia redosing, blood transfusion, EKG changes 1 day after Surgery.

Post-operative clinical outcomes defined by the STS, Pre operatively and adult cardiac surgical overall outcome Post operatively.

TEE-to assess LVEF prior to and after pump off where also consider.

CPB AND CARDIOPLEGIA DELIVERY SYSTEM

Terumo advanced system, extracorporeal perfusion system, Terumo RX series Oxygenator, hardshell reservoir, an AF -125 arterial filter, 3/8-inches arterial and venous tubings.

HEPARIN DOSAGING:

Standard dosaging calculated per BMI, acute normo volemic haemodilution and retrograde autologous prime were performed on all patients deemed to be haemodynamically stable to donate and able to maintain the CPB haematocrit of 21%, target hypothermic temperature on CPB support were maintained between 32^0C to 35^0 C. The use of cardiotomy pump suction was limited to intracardiac blood collected during heart valve surgery.

The del Nido and whole blood cardioplegia formulas were delivered, to all patients enrolled in the study received 1.0 Liter del Nido cardioplegia after the Aortic cross clamp was applied to the Ascending Aorta, an additional 500ml was administered for those whose LVH was documented prior to the surgery or on operating chief surgeon's discretion. When a retrograde dose of cardioplegia through the coronary sinus was demanded by the operating surgeon, the calculated dose of cardioplegia was split equally for anterograde and Retrograde routes. Subsequent dosaging was not required unless the procedures expected to run beyond 90 minutes or when heart resumed on spontaneous electrical activity during the Aortic cross clamp in situ.

Figure 1 : Cardioplegia Delivery System

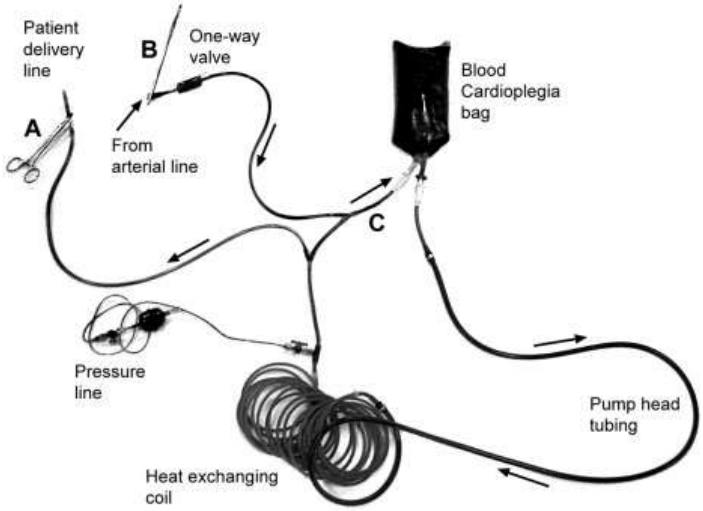


Figure 2: Composition of Cardioplegia in Comparison

Table 1: Composition of cardioplegia solutions

Group A		Group B	
Blood Cardioplegia in St. Thomas solution		Del Nido cardioplegia	
Blood: Crystalloid 4: 1		Blood: Crystalloid 1: 4	
Ringer's lactate	320 ml	Plasmalyte-A	500 ml
Mannitol	20 ml	KCl (2 meq/ml)	6.5 ml
Bicarbonate	20 ml	$NaHCO_3$	6.5 ml
St. Thomas solution	40 ml	Lidocaine 2%	3.25 ml
KCl 16 mmol		Mannitol	8.15 ml
$MgCl_2$ 16 mmol		$MgSO_4$ 50%	2 ml
Procaine 1 mmol			

KCl – Potassium chloride, $MgCl_2$ – Magnesium chloride, $MgSO_4$ – Magnesium Sulfate, $NaHCO_3$ – Sodium bicarbonate

Patients in the control group received whole blood cardioplegia according to the institutional protocol, no additional crystalloid was added, potassium chloride and magnesium sulphate were titrated into the blood delivery. Induction dose for whole blood cardioplegia was in the range of 1-2 Liters with subsequent doses were time bound as alarmed by the perfusionist say for about every 20-25 minutes, temperature of the cardioplegia was maintained at 8-10^{0}C. Prior to the removal of Aortic cross clamp Amino Acid enriched warm blood cardioplegia with monosodium aspartate and glutamate, a systemic bolus of 1% lidocaine(2mg/kg) were given, TEE was performed to check the LVEF. Postoperative inotropic support was based on the discretion of both the surgeon and anaesthesiologist.

Serum Troponin Assessment,; at 4 standard junctures 1. induction of Anaesthesia, 2.Two hours after the discontinuation of the CPB, 3. Twelve hours after the admission to CVICU . 4.twenty four hours after the admission to CVICU

Figure : Myocardial Ischemia Pathogenesis

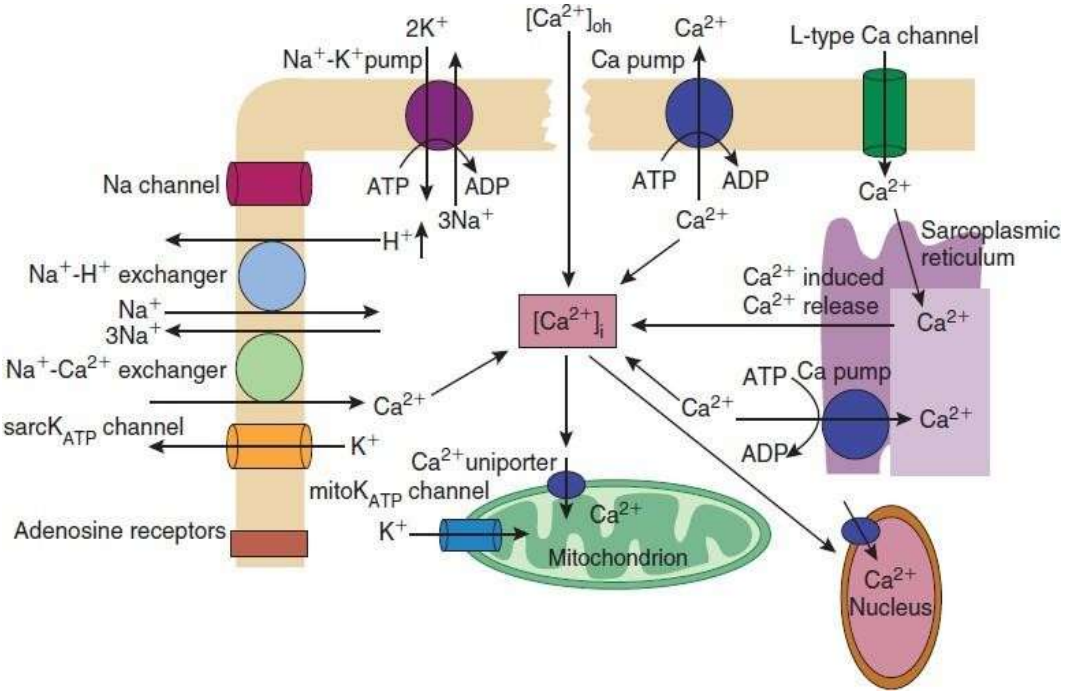
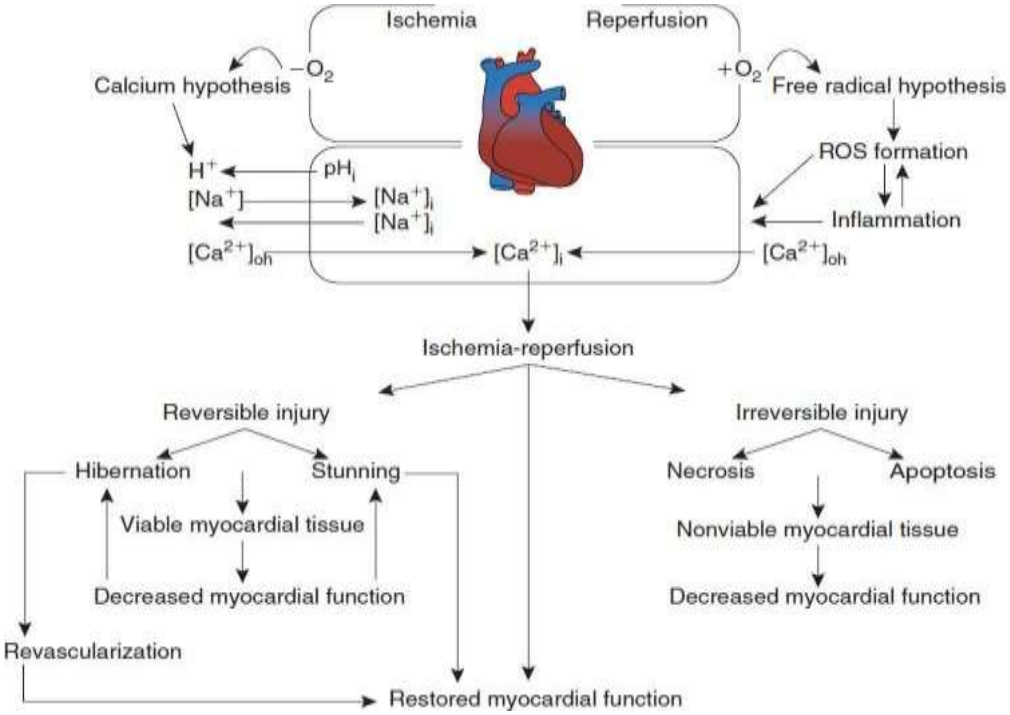


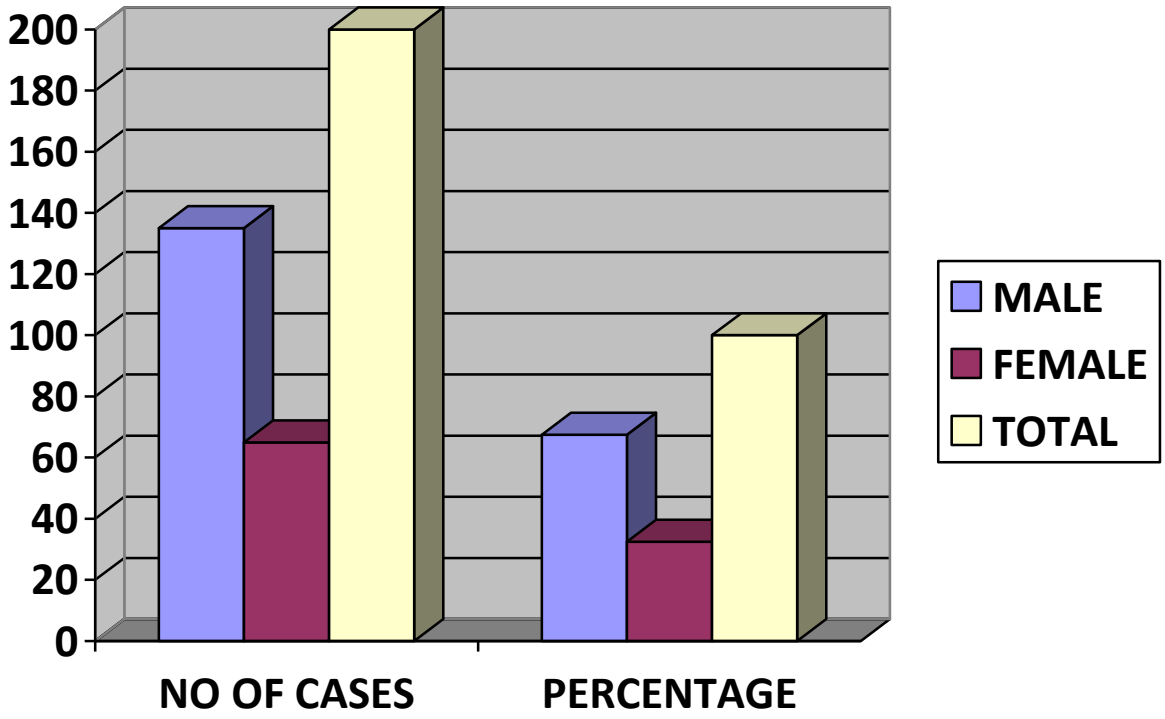
Figure: Reperfusion Injury Hypothesis



STATISTICAL ANALYSIS

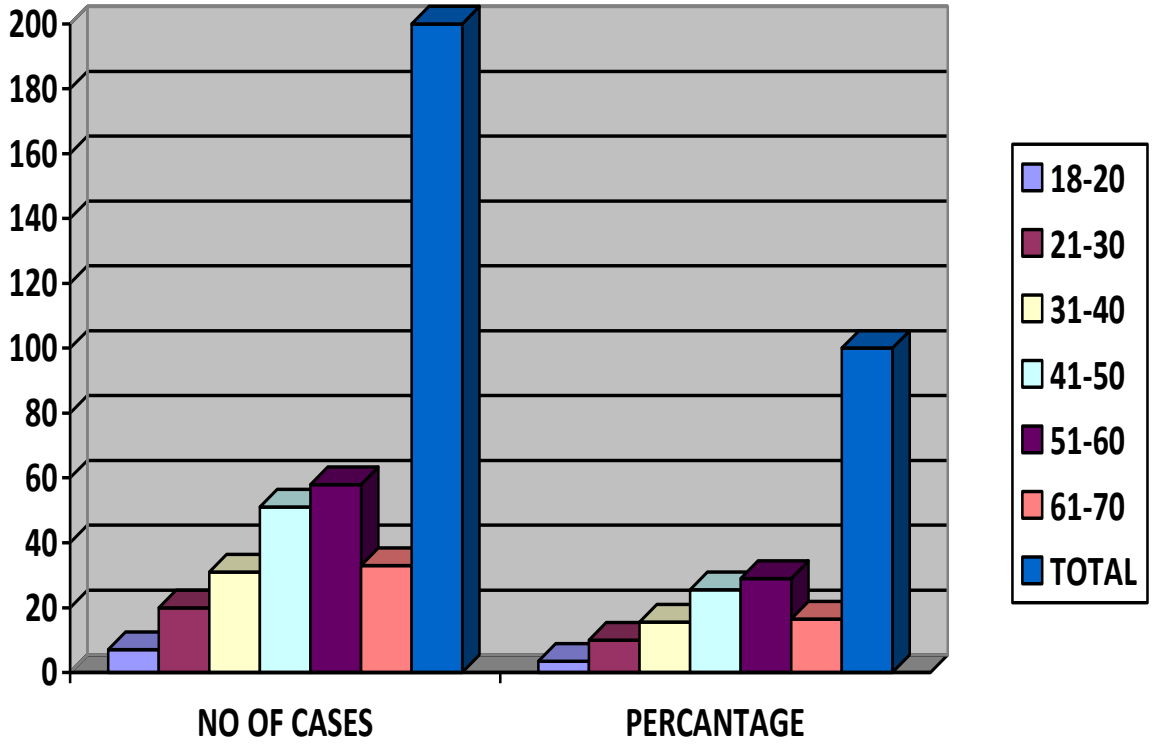
SEX DISTRIBUTION: TABLE 1

SEX	NO OF CASES	PERCENTAGE
MALE	135	67.5
FEMALE	65	32.5
TOTAL	200	100



Age Distribution:

AGE GROUP	NO OF CASES	PERCANTAGE
18-20	7	3.5
21-30	20	10
31-40	31	15.5
41-50	51	25.5
51-60	58	29
61-70	33	16.5
TOTAL	200	100



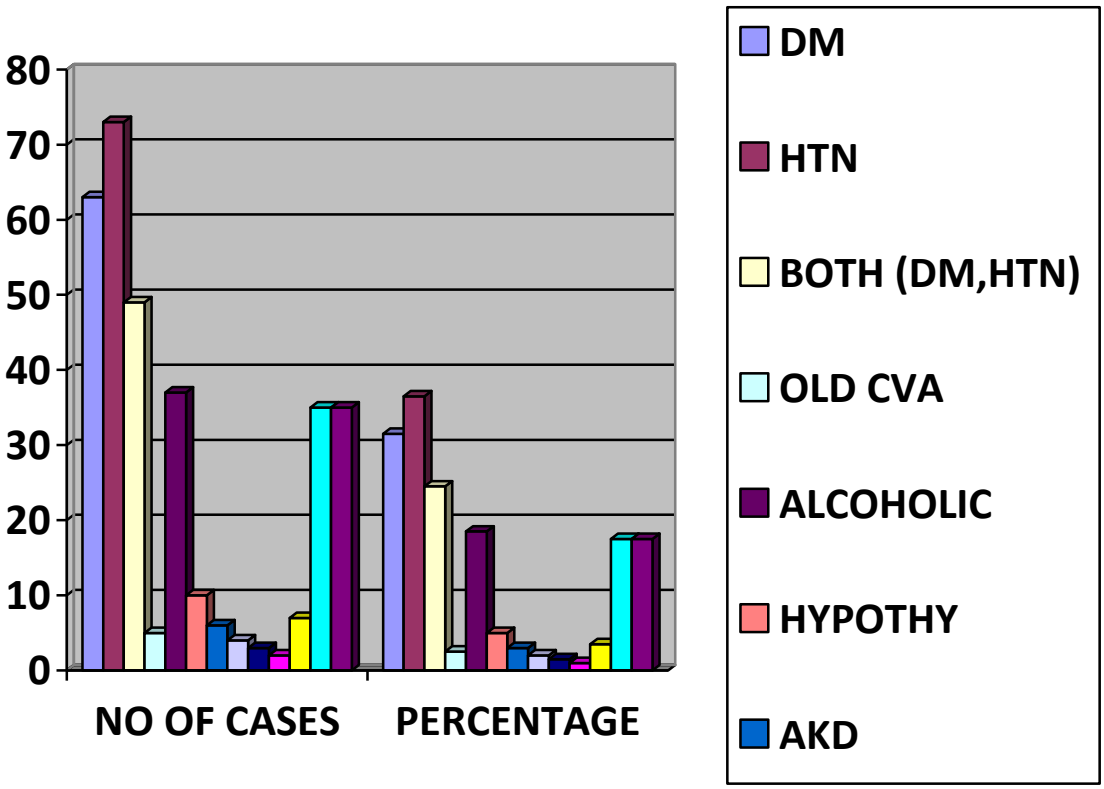
Diagnosis Percentage:

DIAGNOSIS	NO OF CASES	PERCENTAGE
SVD	5	2.5
DVD	9	4.5
TVD	60	30
LMCA	32	16
MVR	22	11
AVR	6	3
DVR	4	2
REDO SURGERIES	10	5
OTHERS	40	20
ASD	12	6
TOTAL	**200**	**100**

Comorbidities :

COMORBIDITIES	NO OF CASES	PERCENTAGE
DM	63	31.5
HTN	73	36.5
BOTH (DM,HTN)	49	24.5

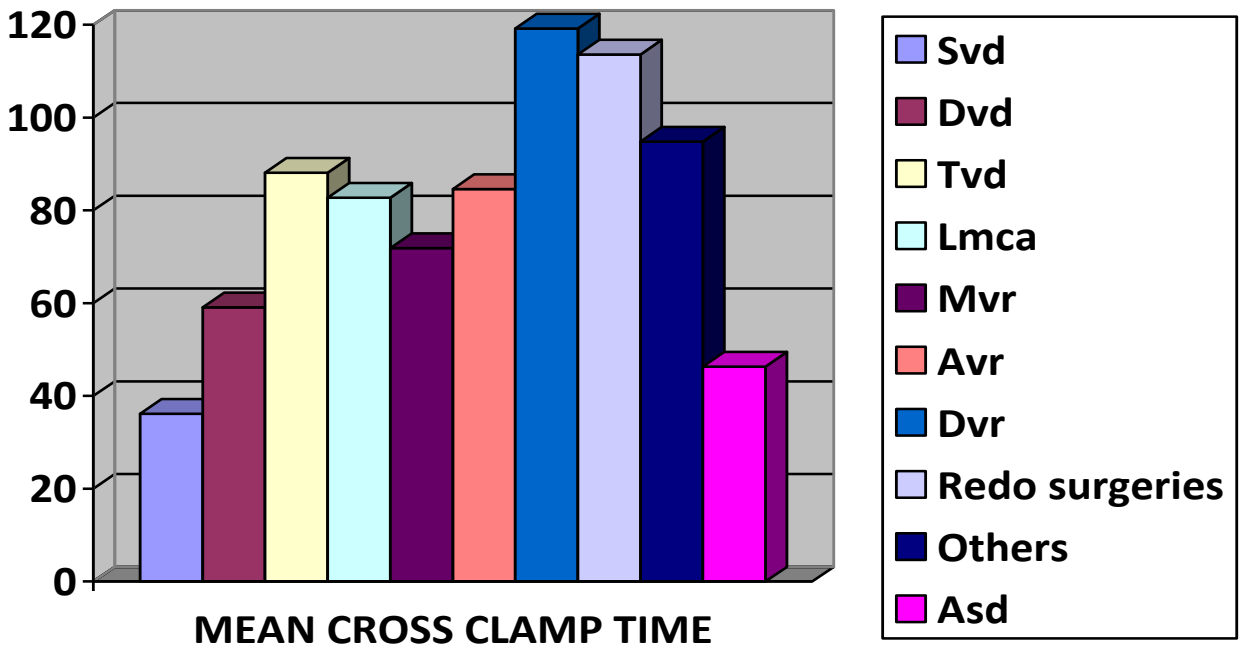
OLD CVA	5	2.5
ALCOHOLIC	37	18.5
HYPOTHY	10	5
AKD	6	3
CKD	4	2
VARICOSE VEINS	3	1.5
PVD	2	1
CAROTID STENOSIS	7	3.5
COPD	35	17.5
SMOKER	35	17.5



Mean Cross-Clamp Time:

DIAGNOSIS	MEAN CROSS CLAMP TIME
Svd	36.2
Dvd	59.1
Tvd	88.1
Lmca	82.7
Mvr	71.9
Avr	84.6
Dvr	119.2
Redo surgeries	113.6
Others	94.8

Asd	46.3

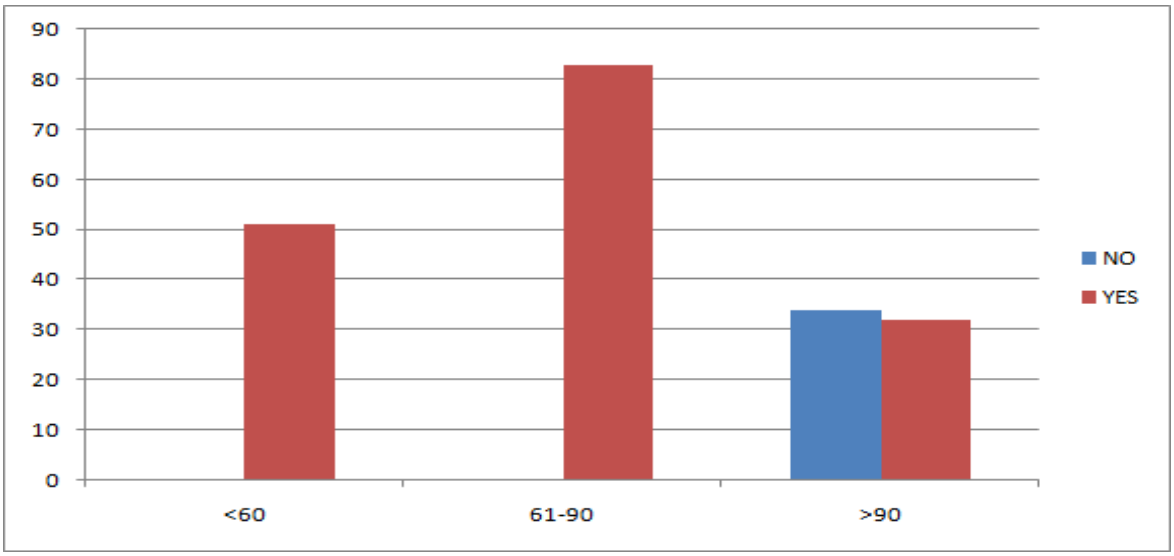


Total of 200 patients data were analysed, continuous data by mean, median and standard deviation, categorical data where presented as frequency(%). Analysis comparing patients characteristics and outcomes of treatment group included independently by -sample t tests or the Main Whitney u test for continuous variables Fisher exact tests for categorical variables

Troponin analysis at 4 points analysis done by variance testing, for patients with missing Troponin deletion was employed. Ejection fraction at the termination CPB were evaluated by linear regression.

RESULTS

ACXTIME	SPONTENEOUS RHYTHM		TOTAL
	NO	YES	
<60	0	51	51
61-90	0	83	83
>90	34	32	66
TOTAL	34	166	200



PRIMARY OUTCOMRS

The del Nido group had a greater proportion of patients who returned to spontaneous heart rhythm than the control group(Literature).

Number of defibrillator shocks were same for both the groups..

Fewer patients in the del Nido group required inotropic support. Troponin levels at all 4 time points revealed that levels dint increase in the del Nido groups much as for control group though it did not attain Statistical significance.

Troponin levels after 24 hours of admission to CVICU were higher to control groups compared to del Nido group.

GLYCEMIC INDICES: During the post operative period where better and controlled for del Nido group in comparison to conventional blood cardioplegia group.

SECONDARY OUTCOMES

There were no significant differences between the del Nido and control groups as far as CPB time was concerned., however Aortic cross clamp time was shorter for del Nido group compared to control group, though dint attain statistically significant value. TEE measurement of LVEF before and after the surgery were of not much difference by regression analysis

The composite outcome of any STS defined complications appeared lower for del Nido group, although analysis dint reach statistical significance.

Requirement of blood transfusions were almost similar in both the groups.

No new Q waves in EKG except the one in control group with ST- segment elevation(Literature).

The total volume of cardioplegia solution was significantly lower in the del Nido group in comparison with control group. The amount of crystalloid used was calculated by 1:4 ratio of blood to crystalloid, additives were 44 ml of potassium chloride, 40 ml of magnesium sulphate and 30 ml of monosodium aspartate and monosodium glutamate. Number of doses of cardioplegia for del Nido were lesser than control group and control group required 200% extra dosaging whereas for the del Nido group only 26% required extra dosaging of cardioplegia

DISCUSSION

Findings from the above study indicates that del Nido cardioplegia can be safely used for adult CABGs and valve replacement surgeries which yields significant benefits in surgical workflow. Although there are several cardioplegia formulas and techniques reported in scientific literatures only few studies compare the effects in a prospective controlled study design. Previous studies are mainly randomized control trials in myocardial protection have been limited to multidose and depolarizing cardioplegic solutions. A prospective randomized study is yet to be performed on single dose, modified depolarizing strategies. The purpose of this current study was to compare the use of del Nido cardioplegia delivery to our current whole blood-based delivery protocol(literature) with the initial hypothesis that del Nido would be non-inferior to the conventional strategy in myocardial protection, postoperative recovery and reduction in reperfusion injury. This study did prove it and also suggests better surgical workflow, shorter CPB time , shorter Aortic Cross Clamp Time and single or fewer doses of cardioplegia.

The del Nido group received lesser volume of cardioplegia and was there no need of retrograde cardioplegia delivery.

Yerebaken et al found no difference between del Nido and whole blood cardioplegia, in prospective study however they concluded that CPB duration and Aortic cross clamp time were significantly reduced in del Nido group

Timek et al also compared the outcome in del Nido group and the conventional whole blood cardioplegia, del Nido provided equivalent myocardial protection as single antegrade dose compared to the multiple dosing, larger volume and routes if administration (both antegrade & retrograde) in conventional whole blood cardioplegia.

When it comes to Multivessel coronary artery disease there may be maldistribution and penetration of the del Nido due to severe disease, calcifications and hence doubtful myocardial protection, uniform hypothermia and hence may require retrograde cardioplegia to assure the same. Topical ice lavage may assure uniform hypothermia.

Troponin levels: is a matter of discussion as it showed significantly lower levels in del Nido group, but the results were not consistent as there no many prospective studies and hence cannot be commented much and Troponin release in the first 24 hours post operatively is Multifactorial. The lower haematocrit value may help in better micro circulation. As temperature decreases the viscosity of whole blood increases and that further results in sluggish micro circulation.

Lidocaine may also influence on tissue vaso- activity and microvascular response through action potential inhibition and an increase in local Nitric Oxide release and better coronary Vaso-dilatation and better myocardial perfusion.

Lidocaine may also preserve intracellular PH and prevent calcium influx and thus is a cell protector. Magnesium sulphate would have done the synergistic action as a natural calcium antagonist and hence better myocyte preservation.

In conventional whole blood cardioplegia lidocaine was not an additive, it was administered as systemic bolus of 1% (2ml/kg Body weight) prior to the removal of Aortic cross clamp.

By inhibiting the influx of intracellular protons through sodium channel blockade and buffering agents as carbonic anhydrase, intracellular glycogen stores may be better preserved and provide additional ATPs during crisis period of ischemia and myocardial hibernation.

However, we believe that more stringent prospective studies with larger population is required to draw firm conclusions.

A stringent preoperative synopsis including an Echocardiography just prior to surgery and intraoperative TEE and follow up echocardiography on day 1,2,3,4,5 post operatively is a mandate.

Assessment of subendocardial function in the format of global longitudinal strain 24hours before and 24,48,72 hours after the surgery. Global longitudinal strain is a very sensitive marker for subendocardial functional status.

Mean Aortic cross clamp time was shorter in del Nido compared to the conventional multi dosaging as the surgeon needs to stop intermittently several times for the delivery of cardioplegia, these results are consistent with the single dose crystalloid cardioplegia like Custodial. Reduction in CPB time however did not reach statistical significance.

LIMITATIONS

Ours was a retrospective study and study design involved only 200 patients a smaller sample size.

Our findings may not be generalizable to the broader surgical community. as it is difficult to get comparable results in various cardioplegia techniques.

Other del Nido comparative studies in the literature are those with Buckberg cardioplegia controls.

Surgical team blinding in a prospective study may remove the bias.

Indication for inotropes was not standardized in this study and therefore may not be a unbiased indicator of myocardial protection.

Peak Troponin levels in 24 hours in control group were not confirmed, we are unable to determine the long-term outcomes based on Troponin levels, additionally our study excluded high risk cardiac patients, re do surgeries, patients requiring mechanical(IABP) and pharmacological (Multiple Inotropes) support preoperatively, older than 80 years of age all were excluded in the eligibility criteria.

We are unable to substantiate the effects of del Nido for prolonged periods of arrest of beyond 2 hours.

However, we give a strong opinion that these findings in conjunction with previous retrospective literature and various studies serve as a pivotal data to support an undertaking of a larger randomised controlled prospective trials with the expansion of patient population and surgical procedures and blinding of the surgeons two for the conclusive opinion on the best cardioplegia and technique of methodology.

CONCLUSIONS

Evidence from this study and previous literature indicates that del Nido cardioplegia can be used as a safe agent in adult cardiac surgeries routinely which is safe and can improve the surgical workflow and streamline the entire open cardiac procedures for better outcome.

Troponin studies may be further investigated over a longer postoperative period as it may reflect the myocardial protection associated with del Nido versus blood cardioplegia regarding selective cardiac vasodilation and microvascular circulation.

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Conflict of the Interest Statement:

All the authors have nothing to disclose with regard to commercial aspects and financial benefits.