J Extra Corpor Technol. 2019;51:153–9
The Journal of ExtraCorporeal Technology

Lactated Ringer's as a Base Solution for del Nido Cardioplegia

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Abstract: Unavailability of Plasma-Lyte A precludes the utility of traditional del Nido cardioplegia in many countries. This observational study aimed to evaluate myocardial preservation and clinical outcomes when using lactated Ringer's solution as the base solution for del Nido cardioplegia as compared with our institute's standard blood cardioplegia strategy. Eighty-nine adult patients underwent cardiac surgery for acquired heart disease from February 2017 to November 2017 either with del Nido cardioplegia (n = 44) or blood cardioplegia (n = 45). Clinical data and outcomes were compared. Patient characteristics were similar between groups. Troponin T release was lower in the del Nido group on postoperative day 1 (.632 [.437, .907] vs. .827 [.599, 1.388] ng/mL; p = .009) and day 2 (.363 [.250, .451] vs. .549 [.340, .897] ng/mL; p = .002). The del Nido group exhibited lower total volume of cardioplegia administered (1,075 [1,000, 1,250] vs. 3,400 [2,700, 3,750] mL; $p < .0001$), fewer doses (1.6 ± .7 vs. 4.6 ± 1.3; $p < .0001$), and a decreased incidence of ventricular fibrillation after aortic cross-clamp removal (9.09 vs. 31.11%; p = .01). The del Nido group had shorter intensive care unit stays (2 [1, 2] vs. 3 [2, 4] days; $p < .0001$), hospital stays (7 [6, 10] vs. 9 [7, 10] days; p = .0002), less vasopressor and inotropic support (1 [1, 1] vs. 1 [1, 2] days; p = .0001), and lower incidence of postoperative atrial fibrillation/flutter (25 vs. 46.7%; p = .033). No mortality occurred and clinical outcomes were similar. The use of traditional del Nido cardioplegia ingredients added to lactated Ringer's as the base solution provided either similar or superior myocardial protection than our blood cardioplegia strategy depending on the outcome measure analyzed. The use of lactated Ringer's as a base solution may be an option for centers that do not have access to Plasma-Lyte. Further investigation and follow-up are warranted after this observational study. **Keywords:** cardioplegia, adult cardiac surgery, myocardial protection. *J Extra Corpor Technol. 2019;51:153–9*

Del Nido cardioplegia has been used extensively in pediatric cardiac surgery for decades. Its unique characteristics include lidocaine that helps counteract potassium depolarization of the myocardial cell membrane, inhibition of intracellular calcium accumulation, preservation of intracellular high-energy phosphates, free-radical scavenging, and acid–base buffering (1). These qualities have proven to be very effective for myocardial protection during cardiac surgery for congenital heart disease. Traditional blood cardioplegia is commonly administered approximately every 20 minutes. By contrast, del Nido cardioplegia is typically administered in a single-dose fashion or with extended dosing intervals, which allows for fewer interruptions and improves surgical workflow. Recent studies have proven its safety, efficacy, and cost-effectiveness for myocardial protection in adult cardiac surgery (2–15). Theoretical benefits, as well as outcome studies, have led to the increased use of del Nido cardioplegia over the last decade.

The base solution for del Nido cardioplegia is normally Plasma-Lyte A (Baxter Healthcare Corporation, Deerfield, IL), which has an electrolyte composition similar to the extracellular fluid and is calcium free (1). Unfortunately, Plasma-Lyte A is unavailable in many countries, precluding many cardiac centers from using del Nido cardioplegia with its normal base solution. This is true at our institution. In an effort to access the benefits of del Nido cardioplegia for our patients, we use lactated Ringer's solution as the base solution. We report the results of this modified del Nido cardioplegia in an observational study evaluating myocardial protection and early clinical outcomes. Results are in line with our previous descriptive study (3).

Received for publication March 7, 2019; accepted June 2, 2019.
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The senior author has stated that the authors have reported no material, financial, or other relationship with any healthcare-related business or other entity whose products or services are discussed in this paper.

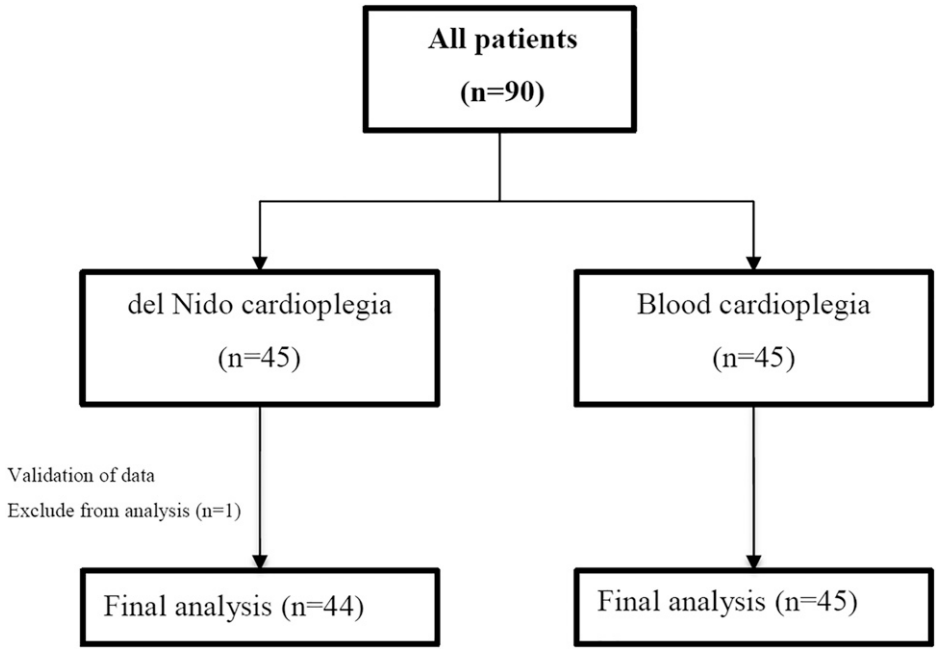

Figure 1. Enrollment flow diagram.

METHODS

Sample Size Calculation

Our sample size calculation was based on the difference between the 24-hour postoperative troponin levels in del Nido and St. Thomas cardioplegia, which were 4.2 ± 2.86 and 8.7 ± 6.21 ng/mL, respectively (16). Twenty-six patients in each group were required to detect the statistical difference in the two-sided test with 5% alpha error and 90% power. We decided to include more patients in this observational study to establish more reliable results with greater precision and power. A sample size of 45 patients was chosen for each group.

Patients

The study protocol was approved by the institutional review board (ref No. 016017). Informed consent was obtained from all patients before participation. The inclusion criteria included patients aged 18 years or older undergoing cardiac surgery for acquired heart disease, including isolated coronary artery bypass grafting (CABG), isolated valve surgery, combined valve surgery, or concomitant CABG and valve surgery. The exclusion criteria included lidocaine allergy and patients who refused to participate in the study. Between February 2017 and November 2017, 90 patients were enrolled. One patient was excluded during the final validation because of missing relevant clinical data (Figure 1). The final analysis included 89 patients (44 in the del Nido group and 45 in the standard blood cardioplegia group). This study was registered in the Thai clinical trial registry (ref No. TCTR20180124002).

Primary outcomes comprised assessments of myocardial injury, including the troponin-T level at immediate postoperative, postoperative day 1, and postoperative day 2.

Secondary outcomes comprised assessments of additional measures of myocardial protection (including creatinine kinase (CK) and CK-MB isoenzyme (CK-MB) levels at immediate postoperative, postoperative day 1, and postoperative day 2; incidence of ventricular fibrillation after aortic cross-clamp removal; postoperative left ventricular ejection fraction (LVEF) change; duration of inotrope/vasopressor requirement; and requirement for intra-aortic balloon pump (IABP) support), intraoperative outcomes (including total volume of cardioplegia, number of doses, total cardiopulmonary bypass [CPB] time, and aortic cross-clamp time), and clinical outcomes (including intensive care unit [ICU]) stay, hospital stay, incidence of postoperative atrial fibrillation or flutter with rapid ventricular response, mortality, postoperative complications, and red cell transfusion).

Patient characteristics and postoperative outcomes were as defined by the Society of Thoracic Surgeons (STS) Adult Cardiac Surgical Database. LVEF was assessed by transesophageal echocardiography before surgery and at the end of operation.

Cardioplegia and Delivery

The compositions of del Nido cardioplegia and our standard blood cardioplegia are shown in Table 1. It is

Table 1. Compositions of cardioplegia.

Modified del Nido Cardioplegia (1:4)		Standard Blood Cardioplegia (4:1)	
Lactated Ringer's solution	1,000 mL	Induction (20 mL/kg)	
Sodium bicarbonate 1 mEq/mL	13 mL	Acetated ringer's solution	500 mL
Mannitol (20%)	16.3 mL	DBL™	40 mL
Magnesium sulfate (50%)	4 mL	Sodium bicarbonate 1 mEq/mL	25 mL
Lidocaine (1%)	13 mL	Maintenance (10 mL/kg)	
Potassium chloride 2 mEq/mL	13 mL	Acetated ringer's solution	500 mL
		DBL™	20 mL
		Sodium bicarbonate 1 mEq/mL	25 mL
Dose 20 mL/kg with a maximum dose of 1,000 mL for patients weighing more than 50 kg		DBL™*	
		Water for injection	20 mL
		Magnesium chloride hexahydrate	16 mmol
		Potassium chloride	16 mmol
		Procaine hydrochloride	1 mmol

*DBL™ is a sterile cardioplegia concentrate, also known as St. Thomas' solution No. 1.

important to note that we found the ionized calcium level in the delivered del Nido cardioplegia to be .85 (±.03) mmol/L owing to the calcium contained in the lactated Ringer's solution. Our del Nido cardioplegia is prepared in a sterile manner by an in-house pharmacist. It is kept refrigerated at 2–8°C and used within 24 hours. It is delivered 1:4 with one part of oxygenated pump blood to four parts of cardioplegia solution (1,3). Del Nido cardioplegia can be delivered antegrade through an aortic root catheter, directly through the coronary ostia, or retrograde via the coronary sinus depending on the type of operation and degree of aortic valve insufficiency. Our protocol is to administer a single dose 20 mL/kg with a maximum dose of 1,000 mL for patients weighing more than than 50 kg. After 90 minutes of aortic cross-clamp time, the surgeon decides how much subsequent doses need to be administered (1–3). If coronary bypass grafting is required, 5–10 mL of del Nido cardioplegia is administered via the saphenous vein graft or the radial artery graft to test the distal anastomosis. In our circuit, del Nido cardioplegia passes through a non-recirculating cardioplegia set with a coil heat exchanger and a delivery temperature of 4°C. It is generally administered over 1–2 minutes with system pressure 100–200 mmHg.

DBL™ Sterile Cardioplegia Concentrate (Hameln pharmaceuticals GmbH, Hameln, Germany) is an important part of our institute's standard blood cardioplegia strategy. Its composition is similar to St. Thomas' solution No. 1. Our standard blood cardioplegia is delivered 4:1 with four parts of oxygenated pump blood to one part of cardioplegia solution. It is generally administered every 20 minutes at 4°C, with an initial dose of 20 mL/kg and maintenance dose of 10 mL/kg over 1–2 minutes with system pressure 100–200 mmHg. Before removal of aortic cross-clamp, 200 mL of warm blood is routinely administered through an aortic root catheter or a retrograde cardioplegia catheter. If coronary bypass grafting is performed, standard blood cardioplegia is also administered through the saphenous vein graft or the radial artery graft.

Statistical Analyses

Continuous data were reported as mean (SD) or median (interquartile range [IQR]) and compared by the independent sample *t*-test or the Mann–Whitney *U*-test. Categorical variables were presented as frequency (%) and analyzed by chi-squared or Fisher's exact test. All analyses were performed using STATA version 14 (StataCorp, College Station, TX). Statistical significance was defined as a p-value $< .05$.

RESULTS

Patient Characteristics

Patient characteristics were similar between groups, including age (64.5 [58.5–71.5] vs. 67 [59–72] years, $p = .739$), male gender (54.55 vs. 71.11%, $p = .106$), STS risk score (1.629 [.753, 2.891] vs. 1.206 [.718, 2.336], $p = .26$), CABG surgery (72.73 vs. 68.89%, $p = .714$), valve surgery (27.27 vs. 31.11%, $p = .678$), and comorbidities. Baseline patient characteristics are summarized in Table 2.

Primary Outcomes

Cardiac markers: Troponin-T levels were significantly lower in the del Nido group at postoperative day 1 (.632 [.437, .907] vs. .827 [.599, 1.388] ng/mL, $p = .009$) and postoperative day 2 (.363 [.250, .451] vs. .549 [.340, .897] ng/mL, $p = .002$) as shown in Figure 2. Levels for CK and CK-MB were similar at all time points. Cardiac markers are summarized in Table 3.

Secondary Outcomes

Intraoperative outcomes: Incidence of ventricular fibrillation after aortic cross-clamp removal was lower in the del Nido group (9.09 vs. 31.11%, $p = .01$). Postoperative LVEF changes were similar (0 [0, 1.70] vs. 0 [−8, 5], $p = .515$).

The total cardioplegia volume was significantly lower in the del Nido group than that in the standard blood

Table 2. Patient characteristics.

Variables	del Nido (n = 44)	Blood Cardioplegia (n = 45)	*p*-Value
Age, median (IQR)	64.5 (58.5, 71.5)	67 (59, 72)	.739
Gender, n (%)			
Male	24 (54.55)	32 (71.11)	.106
Female	20 (45.45)	13 (28.89)	
Body surface area (m^2), mean (±SD)	1.67 (±.2)	1.68 (±.21)	.866
STS risk score (%), median (IQR)	1.629 (.753, 2.891)	1.206 (.718, 2.336)	.260
Preoperative LVEF (%), median (IQR)	60 (49.5, 68)	55 (45, 65)	.230
Comorbidities, n (%)			
Diabetes	17 (38.64)	15 (33.33)	.602
Hypertension	36 (81.82)	36 (80)	.827
Dyslipidemia	27 (61.36)	33 (73.33)	.228
Dialysis	5 (11.63)	7 (15.56)	.563
Chronic pulmonary disease	1 (2.27)	0	.494
Chronic liver disease	0	1 (2.22)	.999
Cerebrovascular disease	6 (13.64)	1 (2.22)	.058
Atrial fibrillation	8 (18.18)	4 (8.89)	.199
New York Heart Association, n (%)			
Class I	5 (11.36)	10 (22.22)	.132
Class II	28 (63.64)	29 (64.44)	
Class III	7 (15.91)	6 (13.33)	
Class IV	4 (9.09)	0	
Operation, n (%)			
CABG surgery	32 (72.73)	31 (68.89)	.714
Isolated CABG	25 (56.82)	23 (51.11)	.589
CABG + valve	7 (15.91)	8 (17.78)	.814
Valve surgery	12 (27.27)	14 (31.11)	.678
Aortic	3 (6.82)	5 (11.11)	.714
Mitral	5 (11.36)	7 (15.56)	.563
Combine	4 (9.09)	2 (4.44)	.434

cardioplegia group (1,075 [1,000, 1,250] vs. 3,400 [2,700, 3,750] mL, $p < .001$). Similarly, the number of doses was lower in the del Nido group (1.6 [±.7] vs. 4.6 [±1.3], $p < .001$). The aortic cross-clamp time and total bypass time were similar. Intraoperative outcomes are summarized in Table 4.

Postoperative Outcomes

The duration of inotrope/vasopressor requirement was lower in the del Nido group (1 [1, 1] vs. 1 [1, 2] days, $p < .001$). The requirement for IABP support was similar between groups (4.55 vs. 11.11%, $p = .434$).

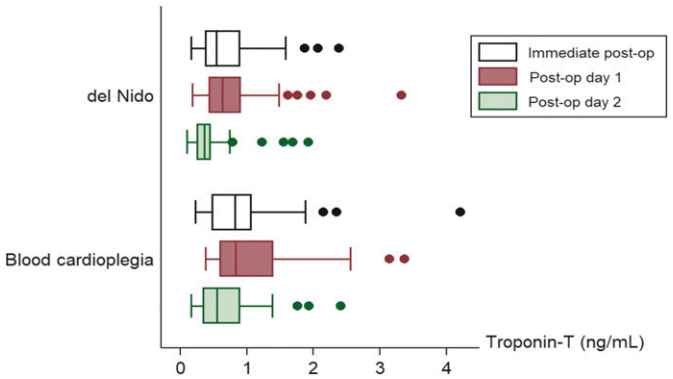

Figure 2. Postoperative troponin-T level of the del Nido group and blood cardioplegia group (day 0 = immediate postoperative).

Incidence of postoperative atrial fibrillation or flutter with rapid ventricular response was lower in the del Nido group (25 vs. 46.7%, $p = .033$). The del Nido group had a shorter ICU stay (2 [1, 2] vs. 3 [2, 4] days, $p < .001$) and hospital stay (7 [6, 8] vs. 9 [7, 10] days, $p < .001$). Complications and postoperative red cell transfusion requirements were similar between groups. The postoperative outcomes are summarized in Table 5.

DISCUSSION

This adult cardiac surgery study suggested better myocardial protection with our modified version of del Nido cardioplegia as compared with our institution's standard blood cardioplegia. Measures of myocardial injury, such as troponin-T levels, incidence of ventricular fibrillation after aortic cross-clamp removal, incidence of postoperative atrial fibrillation or flutter with rapid ventricular response, and duration of inotrope/vasopressor support showed favorable results with del Nido cardioplegia. Notably, values for postoperative LVEF, LVEF change, and clinical outcomes were similar between the cardioplegia protocols. In addition, the use of del Nido cardioplegia was associated with lower total cardioplegia volume, fewer doses, shorter length of ICU stay, and shorter length of hospital stay.

Myocardial injury, represented by troponin-T levels in this study, was lower in the del Nido group, whereas CK

Table 3. Cardiac markers.

Variables	del Nido (n = 44)	Blood Cardioplegia (n = 45)	*p*-Value
Troponin-T (ng/mL), median (IQR)			
Immediate postoperative	.541 (.376, .899)	.821 (.479, 1.065)	.063
Postoperative day 1	.632 (.437, .907)	.827 (.599, 1.388)	.009
Postoperative day 2	.363 (.250, .451)	.549 (.340, .897)	.002
CK (U/L), median (IQR)			
Immediate postoperative	.379 (.266, .471)	.334 (.273, .489)	.937
Postoperative day 1	.488 (.313, .665)	.493 (.321, .763)	.527
Postoperative day 2	.388 (.256, .480)	.394 (.210, .729)	.460
CK-MB (U/L), median (IQR)			
Immediate post-op	68 (55.5, 79.5)	67 (60, 87)	.370
Postoperative day 1	47 (35.5, 64)	48 (40, 63)	.761
Postoperative day 2	32 (24.5, 37.5)	32 (22, 40)	.937

Table 4. Intraoperative outcomes.

Variables	del Nido (n = 44)	Blood Cardioplegia (n = 45)	*p*-Value
Total cardioplegia volume (mL), median (IQR)	1,075 (1,000, 1,250)	3,400 (2,700, 3,750)	<.001
Number of doses, mean (±SD)	1.6 (±.7)	4.6 (±1.3)	<.001
Calcium level (mmol/L), mean (±SD)	.85 (±.03)	–	–
Cross-clamp time (minutes), mean (±SD)	116.4 (±39.5)	108.2 (±31.9)	.283
Total CPB time (minutes), mean (±SD)	145.8 (±42.7)	136.8 (±37.8)	.298
Ventricular fibrillation after aortic cross-clamp removal, n (%)	4 (9.09)	14 (31.11)	.01
Post-op LVEF (%), median (IQR)	60 (54.8, 66.5)	60 (50, 61)	.254
LVEF change (%), median (IQR)	0 (0, 1.70)	0 (–8, 5)	.515

Table 5. Postoperative outcomes.

Variables	del Nido (n = 44)	Blood Cardioplegia (n = 45)	*p*-Value
ICU stay (day), median (IQR)	2 (1, 2)	3 (2, 4)	<.001
Hospital stay (day), median (IQR)	7 (6, 8)	9 (7, 10)	<.001
Inotrope/vasopressor requirement (days), median (IQR)	1 (1, 1)	1 (1, 2)	<.001
Atrial fibrillation or flutter with rapid ventricular response, n (%)	11 (25)	21 (46.7)	.033
Renal failure, n (%)	0	0	–
Prolonged ventilation > 24 hours, n (%)	3 (6.82)	5 (11.11)	.479
Stroke, n (%)	2 (4.55)	0	.242
Reoperation for bleeding/tamponade	3 (6.82)	1 (2.22)	.361
Hospital death	0	0	–
IABP, n (%)	2 (4.55)	5 (11.11)	.434
Red cell transfusion (mL), median (IQR)	196.5 (0, 525.5)	487 (0, 760)	.067

and CK-MB levels were similar. Although myocardial injury can be measured by various cardiac biomarkers, previous reports comparing troponin-T with CK-MB after cardiac surgery demonstrated troponin-T has better correlation with clinical outcomes than CK-MB (17,18). Early del Nido cardioplegia studies demonstrated lower postoperative troponin levels than blood cardioplegia, but the difference did not reach statistical significance (5,6,8,15). Most of these studies were performed in low-risk patients with preserved left ventricular function, and they underwent procedures with aortic cross-clamp time usually lower than 90 minutes. In our report, the mean aortic cross-clamp time in the del Nido and standard blood cardioplegia groups were longer than other studies (averages of 116 and 108 minutes, respectively). The reason for longer aortic cross-clamp time is probably because we included a more complex procedure in our study (e.g., concomitant CABG/valve surgery and combine valve surgery). The prolonged aortic cross-clamp time in our study may have been sufficient to draw the significant difference in troponin release between both groups. Interestingly, despite the longer aortic cross-clamp times in the del Nido group, which were not statistically significant, myocardial protection was arguably superior. We could not definitely conclude that del Nido cardioplegia provides superior myocardial protection because very few data sets of prolonged aortic cross-clamp

times with del Nido cardioplegia in adult cardiac surgery were available. Therefore, this issue requires further investigation.

Another interesting finding in this report was the lower incidence of ventricular fibrillation after aortic cross-clamp removal in the del Nido group. Similar results were also observed in other studies (8,9,11,12). Although this finding may not impact the clinical outcomes, the spontaneous return of sinus rhythm after cardiac arrest with fewer requirements of defibrillation provides reasonable evidence of better myocardial protection. Postoperative atrial fibrillation and duration of inotrope/vasopressor requirement in the del Nido group were both lower in this study. The only randomized study by Ad et al. (15) also demonstrated fewer patients required inotropic support in the del Nido group than those who received Buckberg cardioplegia; however, their findings did not reach statistical difference . Reduced postoperative atrial fibrillation and duration of inotrope/vasopressor requirement were indirect signs of better myocardial protection and may have resulted in shorter ICU and hospital stay, as reported in our study. However, these findings had no clinical impact, as indicated by similar clinical outcomes.

A primary advantage of using del Nido cardioplegia is its longer redosing interval. Fewer interruptions during the surgical procedure facilitate improvement of surgical workflow. Its use is also associated with a reduction in the total volume of cardioplegia, CPB time, and aortic cross-clamp time (4,6,7,14). Although our study demonstrated no significant differences in the aortic cross-clamp time and total bypass time, these findings may have resulted from complexity and variety of operations (6). Reductions in total volume and redosing of cardioplegia has been consistently found in other del Nido cardioplegia studies and are consistent with our results. The reduction of the total volume of cardioplegia may result in less hemodilution and lower rate of red cell transfusion. Our study also demonstrated a trend to decreased requirement for red cell transfusion in the del Nido group, although this finding did not reach statistical significance. This finding has been reported in other studies (4,9,12).

The del Nido cardioplegia is originally designed to have no calcium in the base solution. The final calcium concentration in this cardioplegia on delivery can be considered as trace after mixing one part of oxygenated pump blood with the crystalloid component (1). Our modification to use lactated Ringer's as a base solution leads to different calcium concentrations in delivered cardioplegia because lactated Ringer's solution has calcium in a reported range between 1.5 and 3 mEq/L (19). The final calcium concentration in our modified del Nido cardioplegia was .85 (+.03) mmol/L (Table 4). This is different than the original del Nido cardioplegia, which has a calcium concentration of approximately .4 mmol/L (20). Although the calcium concentration was a concern for us, there was no evidence of impaired outcomes with our strategy. Theoretically, it may be more difficult for the sodium–calcium exchanger to pump calcium out of the cell with higher concentration of extracellular calcium. Increased intracellular calcium accumulation may result in poor myocardial relaxation and recovery. These effects were mitigated knowing that magnesium in the solution is a competitive antagonist for calcium and that lidocaine is a sodium channel blocker. We theorized that these additives compensated for the increased calcium level in the lactated Ringer's vs. Plasma-Lyte versions of del Nido cardioplegia.

Finally, our practice is to use in-house prepared del Nido cardioplegia within 24 hours of production. It is worth noting that del Nido cardioplegia with Plasma-Lyte A as the base solution has been shown to be stable up to 30 days when refrigerated (21). If stability testing verified similar results with lactated Ringer's as a base solution, it would help an institution's overall work flow in providing an inventory of del Nido cardioplegia.

LIMITATION

Although the prospective design and the patient characteristics in our study were commensurate, an inherent bias inevitably existed because of the nonrandomized nature of the study and individual surgeon's preferences. Our small sample size prevented us from controlling for potentially confounding factors, and thus our results are underpowered to make robust conclusions. Our study was designed to compare our modified del Nido cardioplegia with our institution's standard blood cardioplegia protocol. The results may not be applicable or generalizable to other cardiac centers because of variations in cardioplegia regimens. In many countries where Plasma-Lyte A is not available, our recommendation would be to use any normotonic solution which has low calcium and pH of approximately 7.4 as the base solution for del Nido cardioplegia. To validate our findings, a randomized trial to compare lactated Ringer's solution and Plasma-Lyte A as the base solution of del Nido cardioplegia is required.

CONCLUSIONS

Lactated Ringer's solution can be safely used to replace Plasma-Lyte A, the base solution of del Nido cardioplegia, with comparable outcomes in adult cardiac surgery. The use of del Nido cardioplegia was associated with better myocardial protection represented by troponin-T release, lower incidence of ventricular fibrillation after aortic cross-clamp removal and incidence of postoperative atrial fibrillation or flutter with rapid ventricular response, shorter

duration of inotrope/vasopressor support, and shorter length of ICU and hospital stay. Although our modified del Nido cardioplegia provided either similar or superior myocardial protection than our blood cardioplegia strategy depending on the outcome measure analyzed, further investigation and follow-up are warranted after this observational study.

ACKNOWLEDGMENTS

We would like to thank Dr. Pedro del Nido and Gregory Matte from Boston Children's Hospital for providing very useful information and guidance during the implementation phase of del nido cardioplegia at Ramathibodi Hospital. We also would like to thank our perfusion team for their support in the smooth transition to use this novel type of cardioplegia. Special thanks also go to Suraida Aeesoa for data collection and statistical analysis.

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