Original Article

The Comparison of Del Nido Cardioplegia and Crystalloid-Based Blood Cardioplegia in Adult Isolated Coronary Bypass Surgery: A Randomized Controlled Trial

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ABSTRACT

Background and Aim: In our study, patients who underwent isolated coronary artery bypass surgery (CABG) using Del Nido cardioplegia (DNC) and crystalloid-based cold blood cardioplegia (CBC) were compared. **Subject and Methods:** In this study, two groups of patients who underwent isolated CABG using DNC (n = 106) and CBC (n = 107) were prospectively randomized. Groups were compared in terms of many results such as troponin T, returning spontaneous rhythm, and cardioplegia volume. **Results and Conclusions:** Median troponin T levels of the DNC and CBC groups were compared for the 0th hour (baseline), 12th, 36th, and 60th hours. There was no statistical difference between groups in troponin T levels of the baseline 0th hour (18[33] vs. 22[27] pg/ml; P = 0.724). Troponin T levels at the 12th hour were less in the DNC group than the CBC group but no statistical difference between the groups (790[735] vs. 826[820] pg/ml; P = 0.068), respectively. Troponin T levels at 36th and 60th hours were higher in the CBC group compared to the DNC group, and a statistical difference was observed (580[546] vs. 650[550] pg/ml; P = 0.030) and (359[395] vs. 421[400] pg/ml; P = 0.020), respectively. After X-clamping, the spontaneous rhythm rate was statistically higher in the DNC group than the CBC group (72.60% vs. 37.40%; P < 0.001). There was no statistical difference between the groups in terms of postoperative arrhythmia, hospital stay, and mortality rates (P > 0.05). Based on data we acquired from the study, we think that DNC is at least as safe and effective as CBC in adult CABG cases.

KEYWORDS: *Del nido cardioplegia, isolated coronary artery bypass, return spontaneous rhythm*

INTRODUCTION

Myocardial protection is essential in cardiac surgery. Strategies designed for myocardial protection and avoidance of ischemic damage have been increasing intriguingly for about 70 years. Hypothermic hyperkalemic cardioplegic solutions have led to decisive advances in cardiac surgery. However, new investigations continue to provide cardiac protection in patient groups with prolonged operation times and diffuse coronary stenosis.[1] Crystalloid solutions and blood cardioplegia (BC) have been used in this area for many years. In recent years, the use of the Del Nido cardioplegia solution (DNC), which can provide myocardial protection for up to 90 min in a single dose, has become popular. DNC was first used in congenital cardiac surgery. Afterward, it was started to be used in adult cardiac surgery due to its facility of use and effectiveness. Many studies in this area have conducted research comparing BC and DNC groups.[2,3] Many of the studies comparing with other cardioplegia solutions have been enacted retrospectively. But prospective studies are limited.[4,5] In

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our study, patients who underwent isolated coronary artery bypass surgery (CABG) using DNC and crystalloid-based cold blood cardioplegia (CBC) were assessed prospectively. The study aims to compare the early results of two specific different cardioplegia strategies.

Material and Methods

Study design

The study was designed according to the updated Consolidated Standards of Reporting Trials (CONSORT) statement, the Declaration of Helsinki, and the Guidelines of Good Clinical Practice.[6] Enrollment CONSORT flow diagram is shown in Figure 1. This study was conducted at one center, the Bursa Yüksek Ihtisas Education and Research Hospital. This study was conveyed between July 2019 and February 2021 in a prospective randomized nature. Patients in both groups were randomly assigned to the clinic. (The study was finished with a delay due to the coronavirus pandemic situation.) This study was authorized by the Ethics Review Board of Bursa Yüksek Ihtisas Hospital (2019/06-17 2011-KAEK-25). Informed consent was obtained from all patients included in the study.

Patients

A total of 213 patients were included in the study. Patients were assessed in two groups.

Group 1: Del Nido cardioplegia (DNC group, *n*: 106).

Group 2: Crystalloid with blood cardioplegia (CBC group, *n*: 107).

Inclusion Criteria

Consecutive patients that undergo elective and isolated CABG over 18 years of age were included.

Exclusion Criteria

Patients who have any additional cardiac intervention, urgent surgery, or preoperative atrial fibrillation (AF) or atrial flutter and any device like cardiac pacemaker or defibrillator were excluded. Randomization was accomplished for study groups by selecting consecutive patients who applied to the cardiovascular surgery clinic for elective surgery. The patients were divided into groups according to their admission order without using any particular selection criteria.

Surgery and cardioplegia procedure

Conventional general anesthesia was applied in all patients. Standard cardiopulmonary bypass (CPB) with aortovenous two-stage cannulation and mild hypothermia (30–32°C) was performed after median sternotomy. Anticoagulation was achieved by administering heparin sulfate (300 IU/kg IV) and then adjusting to maintain an activated coagulation time >400 s. A single dose of 1000 ml was administered to the DNC group to achieve cardiac arrest. Subsequent DNC doses were administered at a dose of 500 ml at approximately the 60th minute to patients whose ischemic duration was thought to exceed 90 min. Application of DNC was prepared in a ratio of 1:4; blood: crystalloid, respectively. In the CBC group, the first cardiac arrest was achieved cold crystalloid cardioplegia (Selfleks Kardiyosol Cardiac 1000 ml, Haver Pharma, Istanbul, Turkey) (10–15 ml/kg). The cardiac arrest continued with BC (10 mEq KCL and 10 mEq $NaHCO_3$ for every 300 ml of CPB pump blood) 300 ml administered every 15–20 min. The cardioplegia characteristics are shown in Table 1. In both groups, the temperature of the cardioplegia solution was between 4°C and 10°C. Topical cooling with ice slush was used in all cases. Patients were delivered to the cardiovascular intensive care unit (ICU) after the operation. All patients received standard postoperative care. After hemodynamic stability, extubation was performed at the earliest possible stage.

Primary Outcomes: Troponin T levels, which are a marker of cardiac injury after surgery, the amount of inotropic agent, the rate of intra-aortic balloon use, and the rate of return to spontaneous rhythm after X-clamp.

Secondary Outcomes: X-clamp and CPB duration of patients in the intraoperative period, the number of anastomoses performed, and cardioplegia volume were determined. Cardiac rhythm monitoring in the ICU was determined as AF, ventricular tachycardia (VT), and ventricular fibrillation (VF). ICU and service length of stay were determined. Invasive arterial follow-up and arrhythmia confirmation with 12-lead ECG were a standard for the patients, and they were recorded when the patient delivered to ICU. In addition, the amount of drainage, revision requirement, stroke, and mortality rates were recorded. Mortality within the first 30 days was accepted as hospital mortality. Operative and postoperative outcomes are shown in Table 2. Blood was collected four times from the patients to perform serum troponin T assays. Troponin measurements were taken preoperatively (baseline) and postoperatively at 12th, 36th, and 60th hours. The laboratory uses a high-sensitivity troponin T-test (Cobas® 6000-Roche Diagnostics). The normal range of Troponin T was 3–14 pg/ml. Inotropic agent support was divided into single (dopamine or dobutamine), double (dopamine and dobutamine), or triple (adrenaline or noradrenaline in addition to the double inotropic agent) groups.

Arrhythmia Treatment: Amiodarone, lidocaine, or other antiarrhythmic agents were used in appropriate doses according to the type of arrhythmia in the patients. Moreover, treatments such as electrical cardioversion or defibrillation were used when necessary.

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Statistical analysis

Post-hoc power analysis was performed using the present findings of the study. The rate of spontaneous rhythm observed in the DNC was 72.60% and 37.40% in the CBC group. Using the relevant values and fixing the type I error at the level of 5%, the power of the study was determined as 95%. In the study, the compliance of continuous variables to normal distribution was examined using the Shapiro–Wilk test. According to normality test results, continuous and discrete variables in the study were expressed as median (interquartile range) and mean ± standard deviation values. Categorical variables are expressed in numbers and related percentages. Independent samples *t*-test, Mann–Whitney *U* test, Chi-square, and Fisher's exact test were used for comparisons between the DNC and the CBC groups. Analyzes of the study were performed in SPSS (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.) and G*Power v. 3, and the type I error rate was accepted as 5% in statistical comparisons.

Results

There was not any statistical difference between the patients in both groups in terms of age, gender, the body surface area level, and preoperative ejection fraction (EF) rates ($P > 0.05$). Also, there was not any difference between the groups in terms

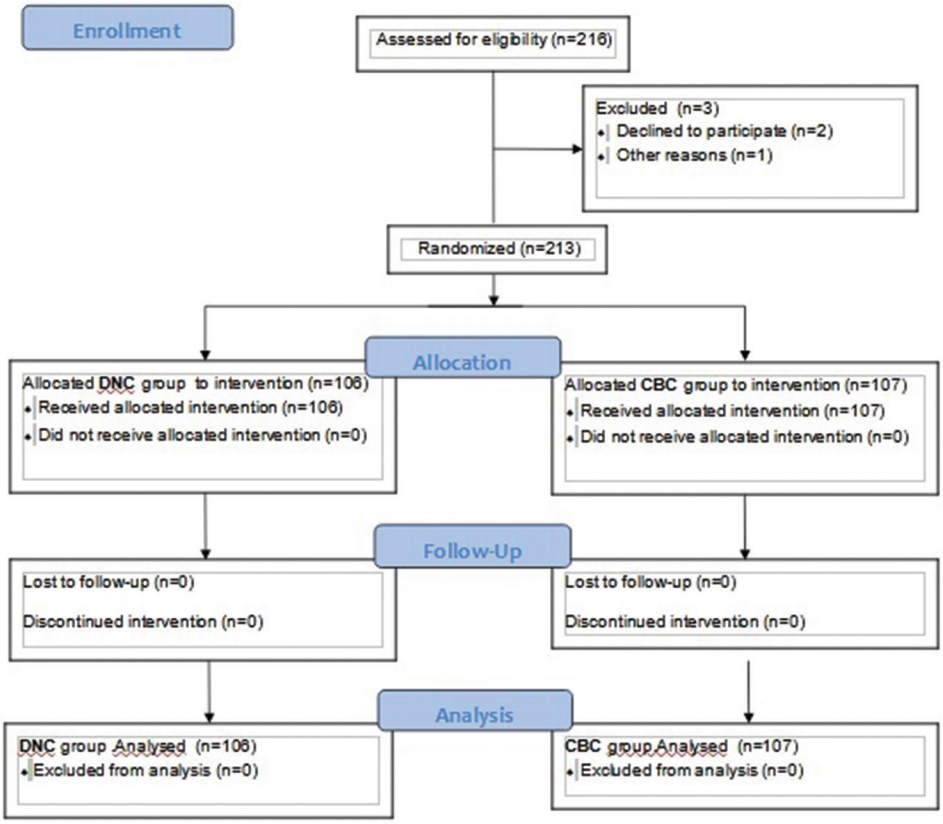

Figure 1: Enrollment CONSORT flow diagram

Table 1: Characteristics of cardioplegia

Components	Cristaloid cardioplegia	Del Nido cardioplegia	Blood cardioplegia
Base solution (ml)	Mix cristaloid (1000)	Isolyte-S (1000)	Blood (300)
Blood: cardioplegia ratio	-	1:4	Whole blood with titration
KCl (mEq)	16	26	8-10 mEq
8.4%, $NaHCO_3$ (ml)	10	13	10 mEq
20%, mannitol (ml)	0	17	-
2%, lidocaine (ml/mg)	0	6.5/130	-
15%, $MgSO_4$ (ml/g)	16	14/2	-
Ca (mmol/l)	2,4	-	-

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Table 2: Patient characteristics by DNC and CBC groups

	DNC group (*n*=106)	CBC group (*n*=107)	*P*
Age (years)	60.56±10.24	61.07±9.36	0.700[a]
Gender (F/M), *n*	27/79	19/88	0.171[b]
Body surface area	1.85 (0.15)	1.82 (0.21)	0.638[c]
Ejection fraction (%)	50 (20)	50 (15)	0.482[b]
Diabetes mellitus, *n* (%)	47 (44.30%)	38 (35.50%)	0.188[b]
Hypertension, *n* (%)	61 (57.50%)	66 (61.70%)	0.539[b]
Number of anastomosis, *n*	3 (1)	3 (1)	0.686[c]
X clamp (min)	62 (19.50)	68 (34)	0.050[c]
CPB (min)	97 (37)	95 (40)	0.936[c]
Cardioplegia (ml)	1000 (0)	1600 (300)	<0.001[c]
Postoperative			
AF, *n* (%)	25 (23.60%)	27 (25.20%)	0.779[b]
VT, *n* (%)	5 (4.70%)	8 (7.50%)	0.400[b]
VF, *n* (%)	1 (0.90%)	3 (2.80%)	0.621[d]
Return spontaneous rhythm, *n* (%)	77 (72.60%)	40 (37.40%)	<0.001[b]
Mortality, *n* (%)	2 (1.90%)	2 (1.90%)	>0.99[d]
ICU stay (days)	2 (1)	2 (2)	0.636[c]
Lenght of stay (days)	7 (3)	7 (2)	0.105[c]
Stroke, *n* (%)	5 (4.70%)	6 (5.60%)	0.769[b]
IABP, *n* (%)	9 (8.50%)	10 (9.30%)	0.827[b]
Infection, *n* (%)	16 (15.10%)	20 (18.70%)	0.484[b]
Smoke, *n* (%)	52 (49.10%)	53 (49.50%)	0.945[b]
İnotropic agent	1 (1)	1 (0)	0.875[c]
Drainage	250 (250)	250 (200)	0.519[c]
Revision, *n* (%)	2 (1.90%)	7 (6.50%)	0.170[d]

Data were presented as mean±St. deviation, median (interquartile range), and *n* (%). [a]Independent samples *t*-test, [b]Chi-square test, [c]Mann-Whitney *U* test, [d]Fisher's exact test, DNC: Del Nido cardioplegia, CBC: cristaloid with blood cardioplegia, CPB: cardiopulmonary bypass, ICU: intensive care unit, IABP: intra-aortic balloon pump

Table 3: Comparison of troponin T measurements

Troponin T pg/ml	DNC group (*n*=106)	CBC group (*n*=107)	*P*[a]
0	18 (33)	22 (27)	0.724
12th hour	790.50 (735)	826 (820)	0.068
36th hour	580 (546)	650 (550)	0.030
60th hour	359 (395)	421 (400)	0.020

Data were presented as median (interquartile range).
[a]Mann-Whitney *U* test

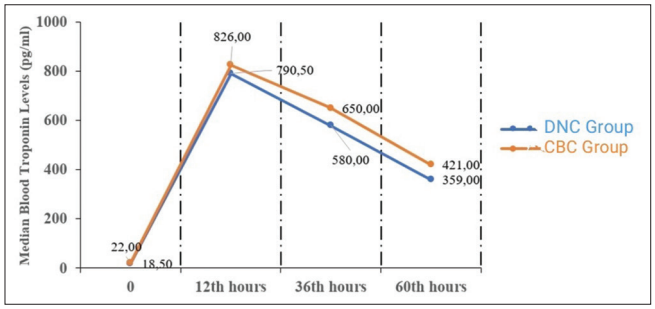

Figure 2: Change of troponin T levels in DNC and CBC groups according to the 0, 12th hour, 36th hour, and 60th hour

of diabetes mellitus, hypertension, and smoking rates ($P > 0.05$).

Primary Outcomes: Median troponin T levels of DNC and CBC groups for baseline, 12th, 36th, and 60th hours were compared [Figure 2]. It was determined that troponin T measurements of first, accepted as the baseline, did not differ between the two groups, respectively, (18[33] vs. 22[27] pg/ml; $P = 0.724$). When the troponin T values obtained at the 12th hour were examined, it was remarked that there is no difference between the groups according to the median troponin measurements, respectively (790[735] vs. 826[820] pg/ml; $P = 0.068$). According to the troponin T measurements obtained at the 36th and 60th hours, the median troponin T level was lower in the DNC group than CBC group, respectively (580[546] vs. 650[550] pg/ml; $P = 0.030$) and (359[395] vs. 421[400] pg/ml; $P = 0.020$). [Table 3]. After the X clamp was removed, the rate of returning spontaneous rhythm was higher in the DNC group than CBC group (72.60% vs. 37.40% [$P < 0.001$]). There was no difference between the groups in terms of IABP and inotropic agent usage rates ($P > 0.05$).

Secondary Outcomes: It was detected that the median X-clamp time in patients was lower in the DNC group than CBC group (62 vs. 68 min; $P = 0.050$). CPB

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duration and anastomosis numbers were similar between the groups, respectively (P = 0.936, P = 0.686). The median amount of cardioplegia in the CBC group was higher and statistically significant compared to the DNC group (1000[0] vs. 1600[300] ml; P < 0.001). There was no difference between groups in terms of postoperative AF, VT, and VF rates (P > 0.05). It was noted that the ICU and hospitalization times were the same in groups (P > 0.05). In addition, there was not any differentiation between the groups in terms of stroke and infection rate (P > 0.05). The amount of drainage and revision rates were also not different between the groups (P > 0.05). In addition, in-hospital mortality was the same between the groups (P > 0.05).

Discussion

Cardioplegia administration is a mandatory method for patients for whom the heart needs to be stopped. Numerous cardioplegia arrangements have been developed for many years. Melrose *et al*.[7] used the first crystalloid cardioplegia in 1955. In the following years, several crystalloid cardioplegias and CBC, which arose in the late 1970s, were popularly used in cardiac surgery.[8-10] Impeccable cardioplegia has still not been found in cardiac surgery. Researches in this area continue today. When the first Melrose solution was used to ensure cardiac arrest, myocardial necrosis was a major problem in patients. Besides, myocardial edema was an important problem in the later crystalloid cardioplegia. CBC was superior to crystalloid cardioplegia due to its properties such as oxygen-carrying capacity, inherent buffering capacity, endogenous antioxidants, and oncotic properties, minimizing myocardial edema.[7,11] In addition to the superiority of BC over crystalloid cardioplegia, it has some disadvantages. The main one is, the oxygen–hemoglobin dissociation curve shifts to the left due to hypothermia, and this may lead to less oxygen delivery with CBC than oxygenated crystalloid cardioplegia. Many studies on this interest compared blood and crystalloid cardioplegia. In particular, early postoperative complications such as mortality, myocardial infarction, or arrhythmia were evaluated, but the differences were not adequately revealed.[10,11]

Therefore, the search for the ideal cardioplegia still continues today. Amidst these researches, which consists of a mixture of blood and crystalloids, was brought to the agenda by Del Nido *et al*.[2] DNC has been using in pediatric patients for more than 20 years and in adult patients for approximately 10 years. Since the 1980s, St. Thomas Hospital's cardioplegic solution (STH) has been used. However, the study for new cardioplegia continued, especially because the infant myocardium has different physiological properties than the adult myocardium.[12] The research for novel and effective cardioplegia has developed as an alternative method of cardioplegia in cardiac surgery, providing approximately 90 min of arrest in a single dose.[2] DNC has a similar electrolyte concentration to the extracellular fluid. It is a blood-based solution that contains mannitol, magnesium, sodium bicarbonate, and potassium chloride. Additionally, it contains lidocaine, which provides long-term hyperpolarizing arrest by blocking sodium ion-channel.[13]

Del Nido *et al*.[2] highlighted the most distinctive features of novel type of cardioplegia solution, thus reduces energy consumption, blocks calcium entry into the intracellular environment, scavenges hydrogen ions, preserves high-energy phosphates, and promotes anaerobic glycolysis during the myocardial arrest. Del Nido *et al*.[2] stated that administration of this cardioplegia at a dose of 20–ml/kg at 8–12°C, and 1000 ml in patients over 50 kg. In various studies, DNC has been suggested to be safe and effective in adult surgical procedures. Nevertheless, the quantity of prospective randomized studies on this topic is remarkably inadequate.[14,15] Two major meta-analyses were evaluating DNC and BC in 2019 and 2020 made by An KR *et al*. and Misra *et al*. A total of 40 studies were evaluated in these two meta-analyses. However, only two of these studies are prospective, and one is a randomized controlled study.[5,16] One of these prospective studies was conducted by Niv Ad *et al*.[14] compared a total of 89 valve and CABG patients in DNC and BC groups. Sanetra *et al*.[17] conducted another randomized study; in this investigation, the aortic valve replacement patient group of 150 people was evaluated.

This implies that prospective studies in adults are not sufficient. Our study on isolated CABG patients may contribute to the literature due to its prospective and randomized nature. Today, crystalloid cardioplegia types are generally used at different temperatures or different electrolyte amounts. Different cardioplegia solutions were compared in many investigations in this area.[16] In our hospital, we have been using the initial dose of STH equivalent crystalloid cardioplegia in adult CABG patients for many years to guarantee cardiac arrest and cold BC for maintenance. In recent years, DNC has been routine in our clinic. In various clinics in the literature, it is known that the STH solution is used isolated or mixed with blood in different proportions.[18]

In our study, the CPB duration (P = 0.936) and the median X-clamp time were shorter in the DNC group (62 vs. 68 min; P = 0.050). In the literature, Niv ad *et al*.[14] reported that CPB and X-clamp time were less in the DNC group; no statistical difference was observed. In the study of Timek *et al*.,[19] CPB

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and X-clamp times were found less in the DNC group. Accordingly, we think that the CPB and X-clamp times of our patients are similar to the literature we examined. There was no statistical distinction between the groups in terms of the inotropic agent support in our patients ($P = 0.875$). However, the return to spontaneous rhythm was higher in the DNC group than in the CBC group (72.60% vs. 37.40%; $P < 0.001$). Kavala *et al*.[20] also reported in their study that inotropic agent support was similar between the groups and the return to spontaneous rhythm was statistically higher in the DNC group. In Niv Ad *et al*.[14] study, the Del Nido group showed higher return to spontaneous rhythm (97.7% vs. 81.6%; $P = 0.023$) and fewer patients required inotropic support (65.1% vs. 84.2%; $P = 0.050$). Our results are similar to the studies of Niv Ad *et al*.[14] and Kavala *et al*.[20] in terms of inotropic agent support and return to the spontaneous rhythm.

We found that the total cardioplegia volume used in our study was statistically less in the DNC group than in the CBC group (1000 vs. 1600 ml; $P < 0.001$). In the study of Niv Ad *et al*.,[14] the total cardioplegia volume was found less in favor of DNC group (1746 vs. 5077 ml; $P < 0.001$). Over, in the studies of Sanetra, Kavala, and Timek *et al*., that was emphasized that less cardioplegia was used in the DNC group.[17,19,20] The cardioplegia volume used in our study was less in the DNC group, similar to the literature we examined. Postoperative arrhythmias in different cardioplegia groups have been examined in many studies in the literature. One of these, Shu *et al*.[21] found less postoperative ventricular arrhythmias in the DNC group compared to the STH group (12.4% vs. 17.4%, $P = 0.040$) and AF (17.39% vs. 15.94%), respectively, but no statistical difference was found.

On the other hand, in the study of Sanetra *et al*.,[17] postoperative AF rates were observed in the DNC and BC groups (24% vs. 28% $P = 0.710$); there was no differentiation between the groups. In our study, no statistical difference was observed between the AF ($P = 0.779$), VT ($P = 0.400$), and VF ($P = 0.621$) groups in terms of postoperative arrhythmia rates. In terms of postoperative arrhythmia, our results are similar to the literature we have reviewed. Postoperative troponin levels, which are a very important parameter in determining heart injury, are very important in terms of the effect of the cardioplegia used. Some studies have been made on troponin levels in the literature.[14,17,19]

Sanetra *et al*.[17] declared that troponin levels were lower in the DNC group, but there was no statistically significant difference. In the study of Niv Ad *et al*.,[14] troponin levels were lower in DNC group, but no statistical difference was found. On the other hand, in Timek *et al*.'s[19] retrospective series of 851 cases, postoperative median troponin T levels were lower for patients receiving DNC group. In our study, no statistical difference was observed between the groups in terms of median troponin T levels at the 12th hour, although the DNC group was fewer values (790 vs. 826 pg/ml; $P = 0.068$).

Nevertheless, troponin T levels were significantly lower in the DNC group at the 36th hour (580 vs. 650 pg/ml; $P = 0.030$) and 60th hour (359 vs. 421 pg/ml; $P = 0.020$). The postoperative troponin levels in our study are similar to the study of Timek *et al*.[19] However, they are partially similar to the troponin levels in the Niv Ad and Sanetra *et al*. studies.[14,17] In a meta-analysis reviewed in 2020, it was emphasized that DNC and BC had similar results. In particular, DNC had a shorter CPB and X-clamp duration and lower cardioplegia volumes. The postoperative cardiac troponin T rate (reduced troponin release) was lower in the DNC group. In addition, stroke, AF, length of ICU, and hospital stays were equal.[5] In the literature, Yerebakan *et al*.[22] declared that length of stay, infection, stroke, and revision rates were similar in the patient groups; they underwent CABG using DNC and BC groups.

In a retrospective study in which Schutz *et al*.[23] evaluated 863 patients divided into the DNC and BC groups, there was no statistical difference in terms of complications such as permanent stroke and length of stay, and overall complications and mortality were similar. It was reported that hospital 30-day mortality was similar in many studies in the literature.[19,22] In our study, no difference was observed between the DNC and CBC groups in terms of ICU and length of stay ($P = 0.636$, $P = 0.105$), rates of infection ($P = 0.484$), drainage ($P = 0.519$), and revision ($P = 0.170$). Finally, 30-day mortality was also similar between groups (2 vs. 2 $P > 0.99$).

Our study found that there were much less cardioplegia volume, shorter Xclamp time, and lower postoperative troponin T levels in the DNC group. In addition, postoperative inotrope need, postoperative complications, and mortality rates were found similar. X-clamp time was statistically shorter in the DNC group. However, there was no superiority between the groups in total CPB duration. Postoperative arrhythmias were minor in the DNC group, but it was not statistically notable. A statistically significant difference was observed in the rate of returning to spontaneous rhythm after X clamp in the DNC group. We found that troponin levels were statistically lower in the DNC group.

Limitations and strengths

This study has several limitations. Although the main one is the same surgical procedure, surgical procedures are performed by different surgeons. Emergency, cardiac

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arrhythmia, or patients using pacemaker were excluded from the study. In addition, it can be considered not to do postoperative EF. This study has some strengths in our opinion. These are, respectively, including elderly patients in the study. The relatively high number of patients enrolled in the study, the follow-up of troponin levels for more than 48 h, and the inclusion of all patients without any limitation in CPB and X-clamping times.

Conclusion

As a result, shorter X-clamp time, less cardioplegia volume, higher spontaneous rhythm, and lower troponin levels are advantageous aspects of DNC. The groups were generally not superior to each other in terms of mortality, CPB duration, arrhythmia, infection, drainage, and revision. Based on these data, we think that DNC may be more advantageous than CBC and can be used safely in isolated CABG cases. We think that the superiority of these two methods to each other can be revealed more unquestionably with large and randomized studies to be managed in the future.

Statement of Ethics: This study was conducted in accordance with the World Medical Association Declaration of Helsinki. This study was authorized by the Ethics Review Board of Bursa Yüksek Ihtisas Hospital (2019/06-17 2011-KAEK-25). Informed consent was obtained from all patients included in the study.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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