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INTRODUCTION

Aortic arch surgery is the most difficult because of the peculiarities of perfusion, need for a “dry” surgical field and adequate neuroprotection (1). The main protective approaches in surgical treatment of congenital aortic arch diseases are antegrade cerebral perfusion (ACP) and deep hypothermic circulatory arrest (DHCA) (1, 2). Previous randomized studies found no superiority of any technique regarding neuroprotective effect (3). Despite a significant decrease in the incidence of severe neurological complications in recent years, transient disorders are common causes of complicated course of early postoperative period (1). Imoto Y. et al. (4) proposed full-flow perfusion with double aortic cannulation (DAC) to reduce the incidence of cerebral complications and damage to visceral

Cerebral perfusion protection in newborns after surgical correction of aortic coarctation with aortic arch hypoplasia

Abstract

Aim: To compare the rate of neurologic complications in infants with aortic coarctation and aortic arch hypoplasia undergoing aortic arch repair under deep hypothermic circulatory arrest or full-flow perfusion with double arterial cannulation.

Material and Methods: This pilot single-center simple blinded prospective study assessed the early postoperative outcomes in infants with aortic arch obstruction. Patients underwent on-pump repair under deep hypothermic circulatory arrest (I group, 20 patients) or full-flow perfusion with double arterial cannulation (II group, 20 patients).

Results: In-hospital mortality was 5% (1 patient) in each group ($p>0.05$). Neurologic complications occurred in 14 (70%) patients of the 1st group and 6 patients (30%) of the 2nd group ($p=0.025$). The only significant risk factor was head tissue saturation according to near-infrared spectroscopy. Each percent decreased the risk of neurologic event by 6%.

Conclusion: Aortic arch repair under full-flow perfusion reduces the rate of neurologic events in infants compared to deep hypothermic circulatory arrest. Head tissue saturation was the risk factor of neurologic complications. Each percent decreased the risk of neurologic event by 6%.

Keywords: Coarctation of the aorta, deep hypothermic circulatory arrest, full-flow perfusion, double arterial cannulation

organs. Nevertheless, there are still no prospective randomized studies devoted to neuroprotective properties of this technique.

The objective was to compare the rate of neurologic complications in infants with aortic coarctation and aortic arch hypoplasia undergoing aortic arch repair under deep hypothermic circulatory arrest or full-flow perfusion with double arterial cannulation.

MATERIAL AND METHODS

Study Design

This pilot single-center simple blinded prospective study assessed the early postoperative outcomes in infants with aortic arch obstruction. Patients underwent on-pump repair under deep hypothermic circulatory arrest (I group, 20 patients) or full-flow

perfusion with double arterial cannulation (II group, 20 patients) (Figure 1). All patients underwent surgery between 2018 and 2020 at the Meshalkin National Medical Research Center. The local ethics committee approved this clinical study.

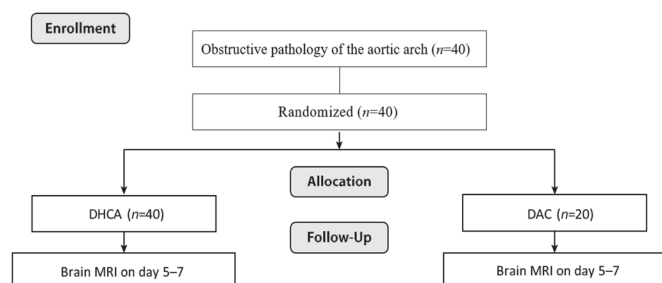


Figure 1. DAC — double arterial cannulation, DHCA — deep hypothermic circulatory arrest, MRI — magnetic resonance imaging

Inclusion criteria

- infancy (children under 1 year old);
- congenital aortic arch abnormality requiring on-pump repair.

Exclusion criteria

- local coarctation of the aorta with moderate aortic arch hypoplasia (z-score of aortic arch > -2.0);
- complex heart defects (common arterial trunk type IV, Shone syndrome, atrioventricular communication, critical valvular stenosis, transposition of the great vessels, etc.);
- univentricular defects;
- left ventricular dysfunction (ejection fraction < 40%);
- organic brain lesions;
- deep prematurity (gestational age < 32 weeks);
- refusal of parents to participate in the study.

Primary endpoint was MRI-confirmed freedom from adverse neurological events in early postoperative period.

Secondary endpoints were in-hospital mortality, cardiopulmonary bypass (CPB) time, inotropic index.

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Methods

In-hospital mortality was assessed within 30 days after surgery or until discharge (if length of hospital-stay was over 30 days).

In postoperative period, we routinely assessed neurological status; MRI of the brain was performed in 5-7 days after surgery (5, 6). Seizures, transient motor disorders, paresis or plegia of extremities with MRI-confirmed focal brain lesion (ischemia, leukomalacia, hemorrhage) were defined as neurological complications.

Inotropic support index was calculated as maximum volume of daily inotropic support throughout 3 postoperative days.

Inotropic score (IS) was calculated according to Gaies M. et al. (7):

$$\begin{aligned}
 \text{IS} = & 1 \times \text{dopamine } (\mu\text{g} / \text{kg} / \text{min}) \\
 & + 1 \times \text{dobutamine } (\text{mcg} / \text{kg} / \text{min}) \\
 & + 100 \times \text{adrenaline } (\text{mcg} / \text{kg} / \text{min}) \\
 & + 10 \times \text{milrinone } (\mu\text{g} / \text{kg} / \text{min}) \\
 & + 100 \times \text{norepinephrine } (\text{mcg} / \text{kg} / \text{min}) \\
 & + 10 \times \text{mesatone } (\mu\text{g} / \text{kg} / \text{min}).
 \end{aligned}$$

We used cerebral spectroscopy for intraoperative evaluation of tissue perfusion. To measure brain tissue saturation, we fixed sensor to the forehead.

Baseline assessment of aortic arch dimensions and concomitant congenital cardiac malformations was performed using transthoracic echocardiography and contrast-enhanced CT. Degree of aortic arch narrowing was analyzed using z-scores (CT). These values were calculated using the Petterson calculator (8).

Demographic data

Baseline and demographic characteristics of patients in both groups are summarized in Table 1.

There were significant between-group differences in patient weight (higher in the DAC group), as well as z-score of descending aorta (higher in the DHCA group). Other variables were similar.

Surgical procedure

General combined anesthesia was performed in all patients with aortic coarctation. Induction of anesthesia included sevoflurane 6-7 vol. %, pipecuronium bromide 0.06 mg/kg, fentanyl 5-6 $\mu\text{g}/\text{kg}$. Subsequent anesthesia was maintained using fentanyl 5-7 $\text{mcg}/\text{kg}/\text{h}$, sevoflurane 1-1.5 vol. %, pipecuronium bromide 0.03 $\text{mg}/\text{kg}/\text{h}$.

Surgical approach was median sternotomy. Skin incision was made along the midline from jugular notch to xiphoid process base using a scalpel No. 20. Subcutaneous adipose tissue was dissected using a diathermic knife with parallel hemostasis of surgical wound. Sternum was transected longitudinally using a sternotome. Periosteal edges were cauterized, and spongy bone of the sternum was treated with wax. We totally resected thymus or excised its right lobe. Pericardium was dissected and fixed using stay-sutures. We used Dideco Lilliput I systems (Sorin, Italy) for cardiopulmonary bypass. Primary filling volume for extracorporeal circuit (200-220 ml) included donor erythrocytes (hematocrit > 30%), fresh frozen plasma 10 ml/kg, 20% albumin 5 ml/kg, sodium bicarbonate 4%, mannitol and heparin. Bicaval cannulation was performed after heparin injection (3 $\mu\text{g}/\text{kg}$). Blood pressure monitoring was carried out through femoral and radial arteries. Perfusion rate was 150 ml/kg. Body temperature was measured either in the nasopharynx or rectum during patient

cooling. Blood gas composition was maintained according to pH-stat or α -stat strategy depending on the preference of perfusion specialist. Aortic occlusion was performed as soon as the target temperature was achieved. Bretschneider cardioplegia 40 ml/kg (Custodiol Dr. Franz Kohler Chemie, Alsbach-Hahnlein, Germany) was injected into aortic root. The main surgical stage was performed either under full-flow perfusion with DAC or under DHCA. Full-flow perfusion was performed under mild hypothermia (30-32°C), DHCA — at a temperature of 18-23°C.

In case of full-flow perfusion, innominate artery and both venae cavae were cannulated first. As soon as cardiopulmonary bypass was established, we transected posterior layer of the pericardium, raised the apex of the heart and cannulated descending thoracic aorta. Aortic arch repair was performed using one of the following methods: 1) aortic arch enlargement via pulmonary autologous patch augmentation (9); 2) “extended” anastomosis

(10); 3) ascending sliding procedure proposed by E. McKenzie et al. (11).

Statistical analysis

Distribution normality was tested using the Shapiro-Wilk test. Continuous variables are presented as median (25 and 75 percentiles), unless otherwise indicated. Categorical data are presented as absolute values and percentages. The Mann-Whitney, Chi-square, or Fisher's exact tests were used for between-group analysis. Binary logistic regression was used to study the likelihood of neurological complications in both groups. For multivariate logistic regression analysis, we used a stepwise procedure with p-value 0.20 cutting-off to develop the final regression model. Differences were significant at two-sided p -value < 0.05. Statistical analysis was performed using Stata 14 software for Mac OS (StataCorp LP, College Station, TX, USA).

Table 1. Baseline and demographic preoperative characteristics of patients

Variable	DHCA (n=20)	DAC (n=20)	p-value
Age, days	8.5 (6.5; 17.5)	11.5 (5; 30)	0.97
Weight, kg	3 (2.5; 3.3)	3.5 (2.9; 4)	0.045*
Low birth weight, n (%)	5 (25)	1 (5)	0.18
Height, cm	50.5 (49; 52.5)	52 (50; 54.5)	0.15
Male, n (%)	10 (50)	14 (70)	0.33
Body surface area, m ²	0.21 (0.19; 0.23)	0.23 (0.2; 0.25)	0.07
Newborns, n (%)	17 (85)	13 (65)	0.27
Premature infants, n (%)	2 (10)	4 (20)	0.66
Critical patients, n (%)	6 (30)	5 (25)	0.99
Ductus arteriosus dimension, mm	6 (2; 7.7)	3 (1.5; 5)	0.16
Z-score of proximal aortic arch	-1.75 (-2.65; -1.37)	-3.1 (-4; -2.1)	0.11
Z-score of distal aortic arch	-3.1 (-4; -2.2)	-2.9 (-3.7; -2.4)	0.82
Z-score of descending aorta	1.25 (0; 1.8)	0 (-0.5; 0.6)	0.01*
Left ventricular ejection fraction, %	73 (68; 76)	74 (67; 78)	0.81
LV EDVI, ml/m ²	22 (18; 25)	21 (18; 25)	0.79
PaO ₂ , mm Hg	102 (98; 134)	106 (94; 142)	0.45
PaCO ₂ , mm Hg	36 (33; 40)	37 (34; 39)	0.57
Saturation, %	98 (97; 100)	99 (98; 100)	0.94
Lactate, mmol/L	1.5 (1.2; 1.9)	1.8 (1.5; 2)	0.88
Preoperative cerebral spectroscopy, %	88 (79; 92)	85 (76; 91)	0.69
Concomitant diseases:			
ASD, n (%)	4 (20)	3 (15)	0.99
VSD, n (%)	5 (25)	6 (30)	0.99
VSD+ASD, n (%)	10 (50)	9 (45)	0.99
Isolated aortic arch hypoplasia, n (%)	1 (5)	2 (10)	0.99

Note. Here and in Tables. 2-4: * - $p < 0.05$; LV EDVI - left ventricular end-diastolic volume index; ASD - atrial septal defect; VSD - ventricular septal defect.

RESULTS

There was no intraoperative mortality. However, 1 (5%) patient died in each group ($p > 0.05$) in early postoperative period due to necrotizing enterocolitis.

Intraoperative characteristics are summarized in Table 2.

There were significant between-group differences in body

temperature and cerebral spectroscopy data during the main surgical stage. CPB and aortic cross-clamping time, cerebral spectroscopy data after the main surgical stage, oxygen and carbon dioxide partial pressure, saturation and lactate were similar in both groups.

Perioperative characteristics are presented in Table 3.

Table 2. Intraoperative characteristics of patients

Variable	DHAC (n=20)	DAC (n=20)	p-value
CPB time, min	109.5 (101; 132)	102 (76; 117)	0.09
Aortic cross-clamping, min	41 (33; 49)	35.5 (24; 43)	0.18
Circulatory arrest, min	23 (20.5; 29)	—	—
Body temperature, C°	24 (20; 25)	31 (25; 32)	0.001*
Cerebral spectroscopy during the main surgical stage, %	47.5 (42; 68.5)	80 (75; 90)	0.0007*
Cerebral spectroscopy after the main surgical stage, %	89.5 (81; 92.5)	91 (84.5; 95)	0.23
PaO ₂ , mm Hg	225 (198; 276)	222 (176; 269)	0.31
PaCO ₂ , mm Hg	34 (33; 37)	35 (34; 38)	0.45
Saturation, %	99.5 (99; 100)	99.3 (99; 100)	0.93
Lactate, mmol/L	6 (2; 8)	4.5 (2; 6.5)	0.06

Table 3. Perioperative characteristics of patients

Variable	DHCA (n=20)	DAC (n=20)	p-value
Z-score of proximal aortic arch	1.6 (1.25; 1.9)	1.44 (1.12; 1.75)	0.21
Z-score of distal aortic arch	2.05 (1.65; 2.25)	1.92 (1.56; 2.1)	0.17
Sternal diastasis, n (%)	12 (60)	12 (60)	>0.99
Sternal diastasis time, days	2 (1; 5)	1 (1; 2)	0.11
LV ejection fraction, %	69 (61; 72)	67 (61; 73)	0.62
LV EDVI, ml/m ²	22.7 (20; 26)	22 (19; 25)	0.71
Ventilation time, hours	5 (4; 8)	4.5 (2; 6)	0.37
ICU-stay, days	8 (6; 11)	7 (5; 9)	0.39
Inotropic support, days	6 (5; 9)	5.5 (4; 9)	0.27
Maximum inotropic score after 24 hours	12.6 (10.5; 19.75)	7 (5; 12.5)	0.012*
Maximum inotropic score after 48 hours	11 (6.6; 25.75)	8.5 (5.5; 10)	0.018*
Maximum inotropic score after 72 hours	9.5 (6; 14)	5.5 (2.5; 8)	0.019*
MRI-confirmed neurological complications, n (%):	14 (70)	6 (30)	0.025*
Ischemic Foci	4 (28.6)	0	0.26
Leukomalacia	5 (35.7)	0	0.25
Subdural Hematoma	2 (14.3)	3 (50)	0.13
Intraventricular Hemorrhage	2 (14.3)	1 (16.5)	0.99
Subarachnoid Hemorrhage	1 (7.1)	2 (33.5)	0.20
Hospital-stay, days	26 (19; 37)	19.5 (15; 32)	0.06

We found significant between-group differences in maximum inotropic scores after 24, 48 and 72 hours, as well as neurological complications. Incidence of adverse neurological events was higher in the DHCA group. Other variables were similar in both groups.

Risk factors for any neurological event are summarized in Table 4.

In multivariate analysis, the only risk factor was cerebral spectroscopy during the main surgical stage. Each unit of this variable reduced the risk of neurological event by 6%. According to ROC analysis, cerebral spectroscopy during the main surgical stage has good prognostic properties for any neurological event (area under ROC curve 0.23 (95% CI 0.08 — 0.37), cut-off value 46% with sensitivity 78% and specificity of 69%) ($p = 0.03$) (Figure 2).

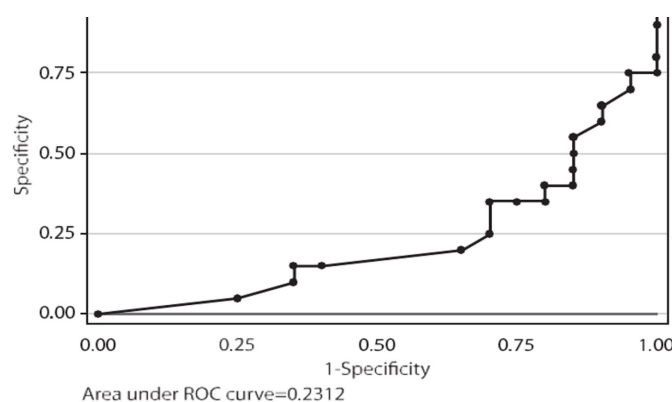


Figure 2. ROC analysis of cerebral spectroscopy data during the main surgical stage for any neurological event

Table 4. Univariate and multivariate regression analysis for any neurological event

Variable	Univariate analysis		Multivariate analysis	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Time of circulatory arrest	1.06 (1.01-1.12)	0.022	1.07 (0.89-1.3)	0.435
DAC group	0.18 (0.04-0.71)	0.014	3.02 (0.14-6.28)	0.684
Cerebral spectroscopy during the main surgical stage	0.95 (0.9-0.98)	0.007	0.94 (0.90-0.99)	0.046*
Intraoperative PaO ₂	1.11 (1.02-1.23)	0.047	1.22 (0.98-1.45)	0.06

DISCUSSION

The first neuroprotective technique (hypothermic circulatory arrest) was applied in cardiac surgery more than 60 years ago. Nevertheless, this method of cerebral protection is still popular even half a century later (1,12). This method slows down all metabolic processes and ensures short-term “safe” circulatory arrest for surgical correction (1). For a long time, aortic arch surgery routinely implied DHCA (13). Modernization of medical equipment and development of new drugs and methods of aortic arch repair made it possible to significantly reduce mortality in pediatric patients. However, incidence of postoperative complications was still high (14). Comprehensive analysis of DHCA identified weak aspects of this technique. It was found that DHCA has a high risk of neurological complications and multiple organ failure despite simplicity of this technique (1,12-14). Neurological complications not only affect early postoperative period, but also have long-term consequences (need for redo surgery, disability, deterioration in the quality of life, long-term rehabilitation) (15).

The need to resolve this problem made it possible to introduce alternative methods of cerebral protection and improve early and longterm postoperative outcomes in patients with aortic arch

diseases. For example, Asou T. et al. (16-18) first used selective antegrade cerebral perfusion (ACP) in 1996. This technique was followed by excellent results and widely used in many cardiac surgery centers. A detailed study of ACP as a neuroprotective strategy made it possible to effectively and safely use this method without deep hypothermia (up to 26°C) and reduce CPB time and morbidity following deep hypothermia (blood loss, capillary leak syndrome, hemolysis) (18,19). However, recent prospective studies have not revealed the advantages of ACP over deep hypothermic circulatory arrest despite multiple retrospective studies reporting less risk of neurological complications after ACP (3).

DAC was a result of modification of ACP technique.

The purpose of DAC was maintaining the complete perfusion of the upper and lower half of the body. In 2001, Imoto

Y. et al. (4) described double aortic cannulation, when the second arterial cannula was inserted into descending aorta through posterior pericardium or directly into the lumen of the transected aorta. Hammel J. et al. (20) actively popularize this technique and report the advantages of DAC under hypothermia 32°C vs. deep hypothermic circulatory arrest during aortic arch repair in patients with coarctation or interruption of the aortic arch and in newborns with univentricular hemodynamics. Currently, full-

flow perfusion is used only in a few number of pediatric cardiac surgery centers. However, data of retrospective studies suggest its high neuroprotective properties even in comparison with ACP (4, 20, 21).

Like in many other hospitals, mortality rate did not exceed

5-10 % in our study (22,23). Neonatal necrotizing enterocolitis caused an unfavorable outcome in both cases. The last one could be caused by prolonged intake of prostaglandin E1, its high dose, critical coarctation of the aorta with long-standing bowel ischemia, insufficient hypothermic protection or poor visceral perfusion and hyperperfusion after aortic arch repair (1, 10,21,24,25). In our sample, both patients admitted with critical coarctation of the aorta and high dose of prostaglandin E1. These two reasons are most likely in development of neonatal necrotizing enterocolitis.

Postoperative period was significantly more favorable after DAC compared to DHCA, as evidenced by inotropic score.

Hammel J. et al. (20) reported similar data. The authors emphasized lower inotropic support after double aortic cannulation compared to deep hypothermic circulatory arrest. They also note that continuous visceral perfusion reduces the risk of multiple organ failure and subsequent inotropic support. In our study, ICU-stay was similar in both groups despite the lower inotropic score in the DAC group.

The main feature of our study was MRI-based identification of neurological complications. Many authors analyzed neurological complications after reconstructive surgery considering clinical data only (for example, seizures or limb paresis). After that, they only confirm the diagnosis by MRI or CT (1,12,26). Algra S. et al. (3) showed that MRI is valuable to detect neurological lesion, initiate early therapy and improve quality of life even in asymptomatic patients. In our case, we performed MRI after 5-7 postoperative days that was determined by lower probability of false-positive results associated with anesthesia and a more detailed picture of neurological lesion (5,6).

Like in multiple studies devoted to aortic arch repair, deep hypothermic circulatory arrest was followed by high risk of neurological complications (1,12,14,18). In our study, we observed focal damage to central nervous system in 70% of patients after deep hypothermic circulatory arrest. There is a common stereo- type that DHCA is often accompanied by ischemic brain lesion. However, we found similar foci only in 2/3 of patients while other ones had hemorrhagic foci.

Neurological complications also occurred in 30% of patients after double aortic cannulation. It was previously described that most patients had hemorrhagic lesions after cerebral perfusion. In our sample, we found similar lesions in all patients (1,18).

Causes of neurological complications are a fairly discussed issue in reconstructive surgery of aortic arch in children (15). Some authors associate neurological events with α -stat strategy (27).

Other ones emphasize the role of temperature (1,15), duration of cerebral perfusion or circulatory arrest (28), high partial pressure of oxygen during patient warming (12) or technique of cerebral protection (1). Our study showed that the only risk factor of neurological complications was low brain tissue oxygen saturation according to cerebral spectroscopy data. We also found that oxygen saturation increment by 1% above the target value of 46% reduced the risk of neurological complications by 6% with a sensitivity of 70%.

Study limitations

It is a single-center study. Therefore, sample size of 20 patients in each group can limit significance of data. No intraoperative transcranial Doppler ultrasound data can also limit the value of data regarding postoperative complications.

CONCLUSION

- Aortic arch repair under full-flow perfusion reduces the rate of neurologic events in infants compared to deep hypothermic circulatory arrest.
- Head tissue saturation was the risk factor of neurologic complications. Each percent decreased the risk of neurologic event by 6%.

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Conflict of Interests: The author declares that there are no conflict of interests.

Financial Disclosure: There are no financial supports.

Data Availability Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethics committee approval : All patients underwent surgery between 2018 and 2020 at the Meshalkin National Medical Research Center. The local ethics committee approved this clinical study.

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