DOI: 10.15825/1995-1191-2024-1-67-77

IMPLANTATION OF HEARTMATE III VENTRICULAR ASSIST DEVICES IN CHILDREN AFTER SURGICAL TREATMENT OF COMPLEX CONGENITAL HEART DEFECT: FIRST EXPERIENCE

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Background. There is quite a high number of patients with advanced heart failure (HF) who have undergone surgical treatment for complex congenital heart defects. Implantation of mechanical circulatory support systems is the only treatment option for patients with refractory end-stage heart failure. Only a few centers have experience in implantation of ventricular assist devices (VAD) in children, which is a major challenge for modern pediatric cardiac surgery. **Objective:** to present our first experience of implantation of HeartMate III VADs in patients after surgical correction of complex congenital heart defects. **Materials and methods.** From 2021 to 2022, at Bakulev Center for Cardiovascular Surgery, four HeartMate III systems were implanted in children with advanced HF, who had previously undergone surgery for a complex congenital heart defect. In one case, aortic valve implantation was carried out simultaneously with VAD implantation. **Results.** All patients were discharged from the center. One patient developed right-sided heart failure intraoperatively, which required the use of a right ventricular assist device (RVAD) for 8 days. There were no complications from the central nervous system, bleeding, pump thrombosis, or infection. **Conclusion.** HeartMate III can be implanted in patients with body weight ≥21 kg and BSA ≥0.88 m^2. Children's tolerance to physical activity increases, they are fully adapted socially, and can attend school.

Keywords: advanced heart failure, ventricular assist device, congenital heart defect.

INTRODUCTION

Implantation of mechanical circulatory support (MSC) systems is often the only treatment option for patients with refractory end-stage heart failure (ESHF). Heart transplantation (HT) options are limited by organ shortages that cannot be overcome. Globally, the number of implantations of such systems is increasing every year. Successful use of VADs in the treatment of ESHF in adults has led to industrial innovations in VADs with a focus on reducing their size and the incidence of potential complications. This has set the stage for the use of new generation devices in pediatric practice. The use of VADs in children has increased significantly over the past decade, and newer generation continuous-flow devices are now replacing the older pulsatile-flow devices that were previously the only option for young patients. Despite the increase in pediatric VAD implants, the number of patients remains relatively small. There have been reports on cases of implantation of HeartMate 3 VADs in children with dilated cardiomyopathy (DCM) and after hemodynamic correction of complex congenital heart disease (CHD) that ended with the Fontan procedure. In review articles, there are isolated cases of HeartMate 3 implantation in CHD children, but there is no data on which defects and whether they were corrected before implantation [1].

MATERIALS AND METHODS

In 2021–2022, four HeartMate 3 systems were implanted in children who had previously undergone multiple surgeries for complex CHD (single right ventricle, double outlet right ventricle (DORV), transposition of the great arteries, and aortic stenosis) and who developed critical heart failure in the long term after surgery. Given the severity of the children's condition, shortage of donors and peculiarities of the legislative framework in the Russian Federation, VAD implantation was used as an alternative to heart transplantation.

Demographics, previous surgeries, and INTERMACS level are presented in Table 1.

Preoperative examination

All patients were examined according to a single protocol, which included the following investigations: ECG, chest X-ray, echocardiography, angiocardiography and coronary angiography with measurement of central hemodynamics, contrast-enhanced chest CT scan, biochemical and hematological blood tests.

ECG revealed that three patients had sinus rhythm with a heart rate corresponding to the age norm. In one patient with an implantable triple-chamber cardiac resynchronization therapy pacemaker (CRT-P), no pacemaker dysfunction was detected.

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Chest X-ray examination showed that all patients had increased heart size, cardiothoracic ratio ranged from 52% to 75%.

Echocardiographic study was performed according to the protocol adopted in our center, Bakulev Center for Cardiovascular Surgery. All patients showed a sharp decrease in contractility of the left or systemic ventricle and a significant increase in its linear dimensions. Two patients had no significant stenosis or valvular insufficiency, one patient had satisfactory mitral and tricuspid valve functions. One patient had a high peak aortic graft gradient. Echocardiographic data are presented in Table 2.

During angiocardiographic study, coronary anatomy and heart anatomy were assessed, and pressure in the heart chambers was measured (Fig. 1). Central hemodynamic parameters were measured using a Swan–Ganz catheter; the corresponding data are presented in Table 3.

Table 1

Preoperative patient characteristics

Patient characteristics:	Patient 1	Patient 2	Patient 3	Patient 4
Age	11 years, 5 months	9 years, 4 months	13 years, 7 months	12 years, 10 months
Gender	male	female	female	male
Body weight (kg)	35	21	49	53
BSA (m^2)	1.23	0.88	1.52	1.5
Diagnosis:	Single right ventricle	Double outlet right ventricle (DORV)	Transposition of the great arteries	Aortic stenosis
Surgeries undergone:	1. Transluminal balloon atrial septostomy 2. BCPA, dilatation of IAC, ligation of main PA. 3. Embolization of MAPCA. 4. Fontan procedure	1. Definitive surgical repair of DORV. 2. MV implantation, subaortic membrane resection. 3. MV second implantation, TV implantation. 4. Implantation of a dual-chamber pacemaker. 5. Implantation of a triple-chamber pacemaker – CRT-P	1. Transluminal balloon atrial septostomy. 2. SPAS, constriction of the main PA, ligation of PDA. 3. Arterial switch surgery	1. Aortic valve plasty. 2. Aortic valve implantation, LCA trunk and AIA stenting. 3. LCA stenting
INTERMACS level	4	4	4	4

Note. BSA, body surface area; BCPA, bidirectional cavopulmonary anastomosis; IAC, interatrial communication; PA, pulmonary artery; MAPCA, major aortopulmonary collateral artery; MV, mitral valve; TV, tricuspid valve; CRT-P, cardiac resynchronization therapy pacemaker – a biventricular pacemaker; SPAS, systemic-to-pulmonary artery shunt; PDA, patent ductus arteriosus; LCA, left coronary artery; AIA, anterior interventricular artery.

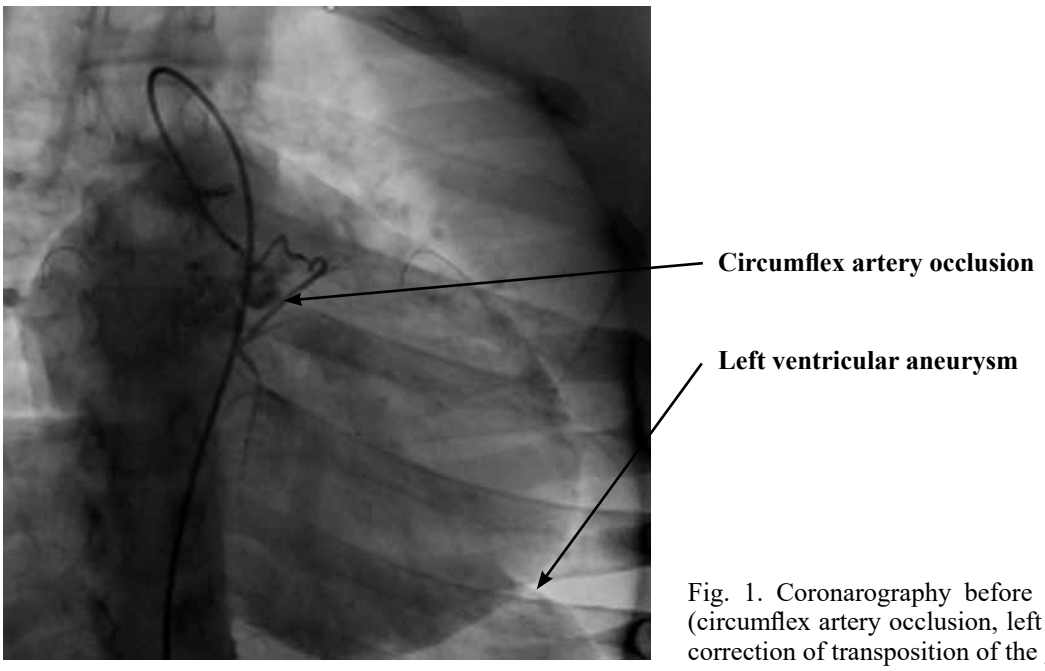

Fig. 1. Coronarography before HeartMate 3 implantation (circumflex artery occlusion, left ventricular aneurysm after correction of transposition of the great arteries)

Contrast-enhanced chest CT scan was performed in all patients to assess the possibility of placing a VAD in the pericardial cavity. A program was used to build a 3D model, which allowed to determine the location of the device – either completely in the pericardial cavity or partially in the left pleural cavity (Fig. 2).

This study also allowed to visualize the coronary anatomy more clearly.

Perioperative risk assessment system

Assessment of biochemical and hematological parameters before surgery allowed to prepare the patient more thoroughly for surgical intervention and assess the risk of adverse complications (Table 4). If these indicators went beyond the target values, the patient was awarded scores. Cardiotonic agents in the preoperative period, use of circulatory assist devices and duration of mechanical ventilation should also be considered, which is also reflected in the scores that are then summed up after which the risk of VAD implantation is determined.

If the patient scores from 0 to 8 points, VAD implantation risk is low; if from 9 to 16 points – medium risk; from 17 to 19 points – high risk of surgery; if >19 points – the patient's hemodynamic state should be first stabilized, blood parameters normalized, and then return to the question of VAD implantation. In our group, all children had a score of 15, meaning a medium risk of surgery.

Features of surgical interventions

All patients were accessed through median sternotomy. Considering that all children had previously undergone correction of complex heart defects, there was pronounced adhesion process in the pericardial cavity, which required a long and thorough cardiolysis due to the need to isolate not only the anterior surface of the

Table 2

Preoperative echocardiographic data

Indicators:	Patient 1*	Patient 2**	Patient 3	Patient 4***
Left ventricle:				
EDV (ml)	223	94	231	246
EDD (cm)	6.6	4.4	5.0	6.9
EF (%)	18	22–24	32–35	25–30
Right ventricle:				
EF/TAPSE		32/8	38/9	40/11
Mitral valve:				
regurgitation	No	Peak gradient 18 mmHg	No	No
stenosis	No	Grade 1	No	No
Tricuspid valve:				
regurgitation	No	Peak gradient 5 mmHg	Grade 1	Grade 1
stenosis	No	Grade 1	No	No
Aortic valve:				
regurgitation	No	No	Grade 1	Peak gradient 50 mmHg
stenosis	No	No	No	Grade 2
Pulmonary artery valve:				
regurgitation	No	No	Grade 1	Grade 1
stenosis	No	No	No	No

Note. EDV, end-diastolic volume; EDD, end-diastolic diameter; EF, ejection fraction; TAPSE, tricuspid annular plane systolic excursion; *, single right ventricle; **, mitral valve implantation and tricuspid valve implantation; ***, aortic valve implantation.

Table 3

Pre-operative evaluation of central hemodynamics in patients

Indicators	Patient 1	Patient 2	Patient 3	Patient 4
Pulmonary artery pressure:				
Systole	30	30	18	27
Diastole	23	12	11	18
Mean	24	20	14	15
PCWP (mmHg)	16	7	10	10
Cardiac index (l/min/m^2)	1.79	3.55	3.06	3.93
Stroke index (ml/m^2)	15.2	61.3	34	59.5
Total peripheral vascular resistance (DSm^2/cm^5)	3618	1867	1753	1140
Transpulmonary gradient (mmHg)		6	4	8

Note. PCWP, pulmonary capillary wedge pressure.

heart and great vessels, but also the left ventricular apex and posterior wall. In two patients, the pericardium was incised in the region of the left ventricular apex with a 2 cm longitudinal incision in order to increase the bed for implantation of the apical pump of the system. The VAD was then connected by separate cannulation of the vena cava and ascending aorta. The heart was dislocated from the wound and the apical cannula implantation site was determined under transesophageal echocardiography (TEE) at the left ventricular apex in the avascular zone. Placing the VAD correctly at its location is a prerequisite for adequate functioning of the VAD; it should clearly face the mitral valve and be equidistant from the interventricular septum and basal parts of the left ventricle. A "coupling" was fixed to the left ventricular myocardium to connect it to the inflow part of VAD. A hole in the LV apex was formed with a ring knife 12 for implantation of the apical cannula. The HeartMate 3 system was implanted with reinforced conduit #12 fixed to the left ventricle using a "coupling" (Fig. 3).

The conduit was placed in the pericardial cavity along the free wall of the right ventricle and right atrium. It is necessary to carefully measure the length of the conduit to avoid its kinks and lack of tension as the child grows (possible compression of the right heart chambers). The anterior wall of the ascending aorta, to which the distal end of the conduit was anastomosed end-to-side with

Table 4

Biochemical and hematologic parameters and risk factor assessment

Indicators (points)	Patient 1	Patient 2	Patient 3	Patient 4
Hemoglobin	95	98	101	107
Platelets ≤148 × 10^3 (7)	276	245	251	450
Albumin ≤33 g/l (5)	37	41	40	35
Hematocrit ≤34% (2)	30	31	28	30
Urea >51 (2)	2.7	3	7.8	7.2
INR >1.1 (4)	2.5	1.86	1.93	2.08
AST 45 (2)	29	20	26	42
Mean PA pressure ≤25 mmHg (3)	24	20	14	15
Vasodilators (4)	Yes	Yes	Yes	Yes
Artificial ventilation	–	–	–	–
ECMO/IABP	–	–	–	–
Cardiotonic therapy (2)	Yes	Yes	Yes	Yes

Note. INR, international normalized ratio; AST, aspartate aminotransferase; PA, pulmonary artery; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump.

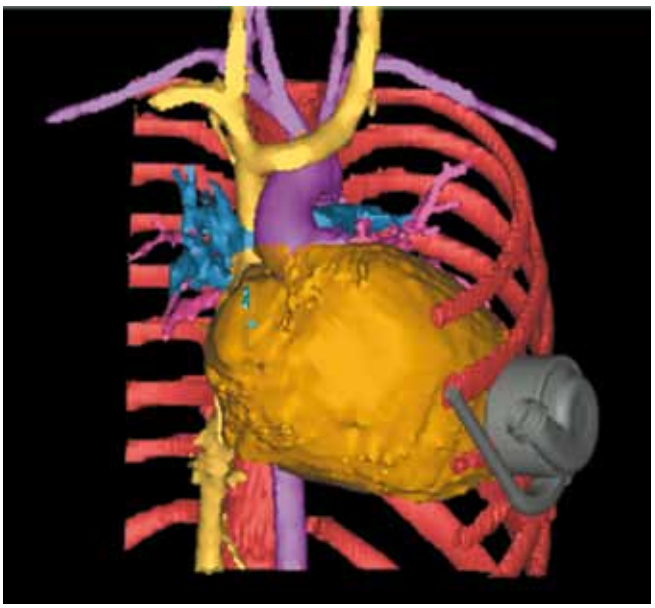

Fig. 2. 3D modeling of the location of the ventricular assist device in the pericardial cavity (location of HeartMate 3 in the pericardial cavity)

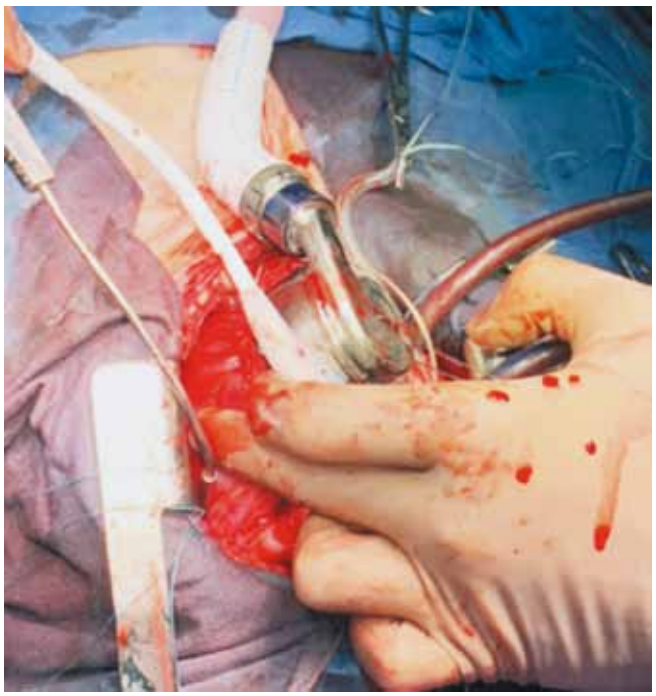

Fig. 3. Implantation of HeartMate 3

a continuous suture using Promilene 5-0 thread, was clamped at the anterior wall of the ascending aorta.

The pump drive cable was led through the contraincision to the anterolateral surface of the abdominal wall on the left side, the cord was placed in the subcutaneous fatty tissue in an S-shape. The HeartMate 3 pump was connected to the system unit through the cable and started working at 2000 rpm, maintaining a flow of 300–500 mL per minute. A control TEE was performed, which visualized the correct position of the apical cannula, absence of blood flow obstruction, and assessed the contractile and pumping function of the right and left ventricles.

When hemodynamic parameters were satisfactory, artificial circulation ended with increased pump operation.

In one patient, implantation of HeartMate 3 left VAD was combined with aortic valve reprotection. After aortic clamping and administration of cardioplegic solution Custodiol, the ascending aorta was opened by a transverse incision 2 cm above the fibrous ring. On revision of the aortic prosthesis, there was pannus buildup with wedging of one leaflet. The valve was excised, after which a sutureless aortic valve PERCEVAL 21 mm was implanted in the aortic valve position (Fig. 4).

Early postoperative period

The postoperative period was uneventful in three patients (75%). Length of hospital stay, hemodynamic, hematological, biochemical parameters, as well as the performance of HeartMate 3 left VAD are presented in Table 5.

The follow-up period in the long-term period was 1 year, 3 months, 4 months and 3 months, respectively. During this period, children's tolerance to physical activity increased, they fully adapted socially, and attended school.

Fig. 4. Implantation of aortic heart valve Perceval

In one patient with initially reduced right ventricular ejection fraction (preoperative RVEF 32%), refractory severe right ventricular failure developed intraoperatively (RVEF 18%, displacement of the interventricular septum into the left ventricular cavity, central venous pressure (CVP) 18 mmHg). It was decided to intraoperatively perform right ventricular bypass according to the "right femoral vein/pulmonary artery" scheme using a centrifuge pump without an oxygenator. A Medtronic 19 Fr venous cannula was placed into the right femoral vein by puncture. A 10-mm-diameter vascular prosthesis was sutured to the pulmonary artery trunk, which was brought to the anterior chest wall through the 5th intercostal space. Medtronic 17 Fr was inserted through the vascular prosthesis into the pulmonary artery trunk (Fig. 5).

The use of the right ventricular bypass lasted for 8 days. The patient's hemodynamic parameters, EchoCG data, right ventricular bypass performance and HeartMate 3 left VAD performance are presented in Table 6.

The right ventricular bypass system was removed on day 8 after surgery.

Artificial ventilation lasted for 20 days and 14 hours. The child was transferred to the ward on day 24. The patient completed a full course of drug and rehabilitation therapy (considering his asthenization). The follow-up period after the operation was 1 year, 1 month. The child gained weight, his tolerance to physical activity increased, and he fully adapted socially.

DISCUSSION

MSC is currently the main method of treatment for ESHF in adults [2, 3]. With the improved experience and success of VADs in the adult population, adoption and adaptation of these technologies for use in the pediatric population were the next steps.

CHD is the most common diagnosis in pediatric patients hospitalized for HF [4]. This patient cohort has a high lifetime risk of HF, especially in older adults and adults whose CHD was not corrected during the neonatal period or early childhood, and according to various authors, 10–20% of them require HT because of residual hemodynamic or anatomical anomalies and consequences of the course of the defect or previous surgery [5, 6]. This includes both pediatric CHD patients who have undergone surgery for CHD and are now older, as well as adult patients (over 19 years of age) diagnosed with CHD for the first time or who are under observation and receiving drug therapy. In a 2018 analysis, 25% of patients requiring MSC were diagnosed with CHD, compared to the previous PediMACs report from 2016, where 16–17.5% of patients with VAD had CHD at baseline [7]. Typically, these patients will be younger, smaller in stature, and have had previous cardiac surgery com-

pared to patients with cardiomyopathy, myocarditis, or complex cardiac arrhythmias [7].

Treatment of pediatric ESHF has improved significantly over the past decade with increased use of VADs [8]. According to the International Society for Heart and Lung Transplantation (ISHLT) International Thoracic Organ Transplant (TTX) Registry, more than one third of pediatric recipients are currently on VAD [9]. As the

Table 5

Postoperative period in 3 patients after HeartMate 3 implantation

Indicators	Patient 1	Patient 2	Patient 3
Mechanical ventilation duration (hours)	14	91	21
Cardiotonic therapy:	Levosimendan, 0.2 mcg/kg/min	Levosimendan, 0.2 mcg/kg/min; Dobutamine, 3.5 mcg/kg/min	Norepinephrine, 0.05 mcg/kg/min; Dobutamine, 4 mcg/kg/min
Length of hospital stay (days)	28	32	28
Hemoglobin	86	101	89
Hematocrit	27	28	26
Platelets	276	251	450
Albumin	40	41	35
Urea	2.7	4	7.2
AST	20	21	42
INR	2.8	2.7	2.2
Pump flow (liters)	5.3	3.4	3.8
Pump speed (rpm)	6050	4850	5100
Power	4.7	3.2	3.5
Pulse index	2.1	5.5	6.2
RVEF (%)	24	38	48
LVEF (%)	–	34	41
mAP (mmHg)	72	69	74
Heart rate	102	98	94
CVP (mmHg)	11	10	12
Prosthetic aortic valve function: Peak gradient Mean gradient	 –	 –	 8 3

Note. AST, aspartate aminotransferase; INR, international normalized ratio; RVEF, right ventricular ejection fraction; LVEF, left ventricular ejection fraction; mAP, mean arterial pressure; CVP, central venous pressure.

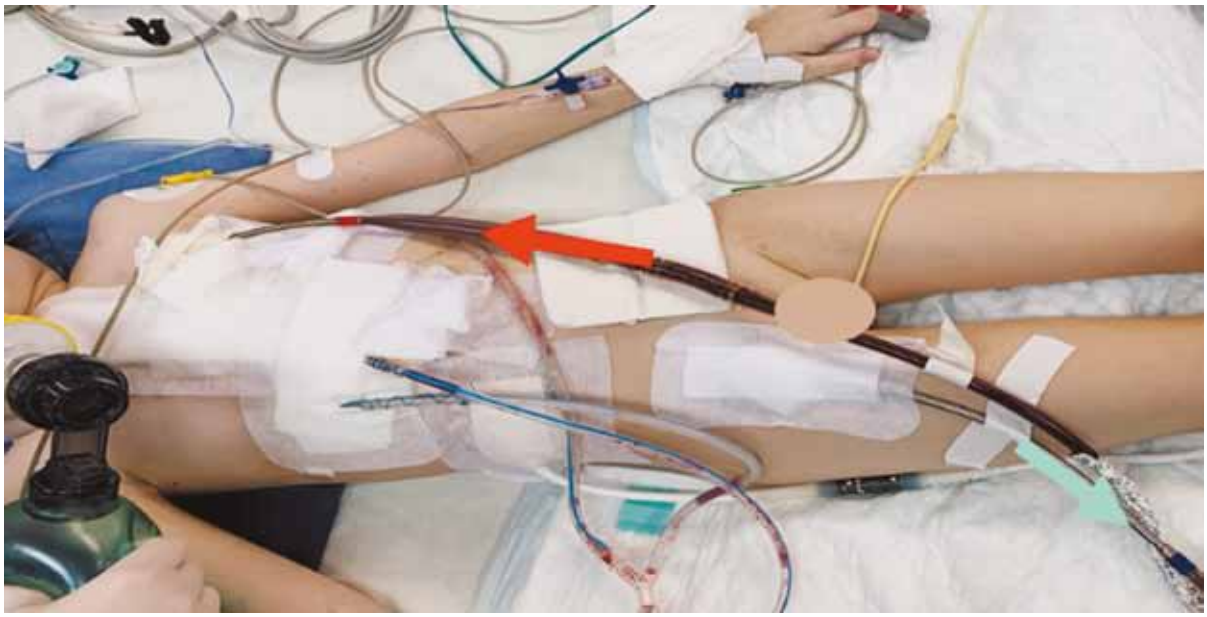

Fig. 5. Use of right ventricular assist device in the early postoperative period in a patient with right-sided heart failure after HeartMate 3 implantation

use of VADs to treat pediatric HF has increased, waiting list mortality has been halved since VAD implantation began [10]. Previously, strategies for mechanical support in the pediatric population were limited to venoarterial extracorporeal membrane oxygenation (VA-ECMO) or paracorporeal pulsatile-flow VADs (Berlin Heart), but continuous-flow VADs are now preferred due to improved survival and reduced side effects [2, 11–13]. Their use in pediatrics has been limited due to size constraints [14, 15]. Currently, long-term circulatory assist systems in the pediatric population are implanted for cardiomyopathy, but usage in the CHD population, especially in patients with complex congenital defects, is increasing [7, 16].

In the U.S. and European medical community, there are registries that collect aggregate data from clinics and summarize information on the use of long-term circulatory support systems, describing their outcomes, patient management tactics, and potential complications.

The Pediatric Interagency Registry for Mechanical Circulatory Support in North America (PediMACS) was created in 2012 and collects prospective data from pediatric VAD patients less than 19 years of age. PediMACS currently includes close to 600 patients with close to 750 implanted devices [13].

The European Registry for Patients with Mechanical Circulatory Support (EUROMACS) is a registry that collects data on both adult and pediatric patients on MCS across Europe [17]. As part of this registry, Pedi-EUROMACS operates to summarize and evaluate all clinical data collected from the pediatric population on MCS. In their second report, Pedi-EUROMACS outlined their findings since inception. A total of 353 patients with 398 implantable devices were included in the most recent analysis. One of their key findings was that survival in patients >10 kg was not significantly different between paracorporeal (pulsatile) and VADs (continuous) devices, indicating that perhaps VAD type is not a major risk factor for worse outcomes, and perhaps patient characteristics may play a more significant role, as patients with a BSA <1 m^2 had higher mortality than patients with a BSA >1 m^2, regardless of flow type.

Advanced Cardiac Therapies Improving Outcomes Network (ACTION) is a multicenter learning health system focused on improving critical pediatric heart failure. Utilizing ACTION, a study was conducted that outlined the outcomes of 35 pediatric and adult patients with complex congenital heart disease who were implanted with HeartMate 3 [13]. Most patients with CHD had Fontan circulation. This study provided the first evidence that HeartMate 3 can be used effectively in pediatric patients.

In our clinical practice, we implanted the HeartMate 3 system in four patients who had previously undergone several surgeries for complex congenital heart defects. While VAD implantation in patients who underwent the Fontan procedure has been described in reports, there are no such reports for implantation after correction of complex congenital anomalies [18].

The patient who underwent definitive correction of DORV and replacement of both atrioventricular valves with implanted CRT-P was resistant to drug therapy. VAD implantation was the only option to alleviate the patient's condition.

Patients after correction of transposition of the great arteries (TGA) and aortic valve replacement with left coronary artery (LCA) and left anterior descending (LAD) artery stenting had reduced left ventricular ejection fraction (LVEF) and were at risk of sudden death from impaired coronary blood flow and risk of developing complex cardiac arrhythmias.

Sutureless aortic valve PERCEVAL was chosen due to the ability to reduce the duration of artificial circulation, reduce the traumatic nature of the operation and prevent adverse events.

Bakulev Center for Cardiovascular Surgery has experience in implantation of various long-term circulatory support systems as a bridge to transplantation in children. Three patients with dilated cardiomyopathy,

Table 6

Postoperative period in a patient after implantation of HeartMate 3 right ventricular assist device

Indicators	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8
VAD:								
Flow	2.9	2.8	2.5	2.7	2.4	2.9	2.7	2.9
Pump speed	4800	4800	4800	4800	4800	4800	4800	4800
Pulse index	2.7	2.9	2.9	3.1	2.4	2.4	2.6	2.5
Power	5.0	4.8	4.3	4.7	4.2	4.8	5.0	4.3
RVAD:								
Flow (liter)	1.8	1.8	1.8	1.6	1.4	1.2	1.0	0.8
Pump speed (rpm)	4500	4600	4650	4200	3750	2860	2320	1900
mAP	64	68	71	70	67	74	68	70
CVP (mmHg)	4	11	13	9	7	12	10	10
LVEF	32	31	30	29	31	30	28	32
RVEF	18	32	37	40	47	45	46	51

Note. VAD, ventricular assist device; RVAD, right ventricular assist device; mAP, mean arterial pressure; CVP; central venous pressure; LVEF, left ventricular ejection fraction; RVEF, left ventricular ejection fraction.

postpartum cardiomyopathy and Uhl's anomaly, aged 16 to 17.5 years, and a BSA >1.5 m^2, were implanted with VAD Berlin Heart Excor and NasaDeBakey. They underwent HT within 8 months after implantation. One patient with dilated cardiomyopathy aged 7 years and a BSA <1.5 m^2 was implanted with the Berlin Heart Excor system. Due to the complex system for monitoring VAD and its large size, the child had to remain in the hospital under observation for 493 days.

Considering our experience with implantation of various circulatory assist systems, we concluded that the implantable HeartMate 3 system is compact, safe for small patients with minimal risk of possible adverse events.

CONCLUSION

HeartMate 3 can be implanted in patients with a body weight ≥21 kg and BSA ≥0.88 m^2. Children have increased exercise tolerance (they can walk for 2–3 hours), they fully adapt socially and can attend school. To prevent adverse events in the early and late period after VAD implantation, it is necessary to carefully approach the diagnosis and treatment of patients in the preoperative period.

The authors declare no conflict of interest.

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The article was submitted to the journal on 25.09.2023