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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

# First Polish analysis of the treatment of advanced heart failure in children with the use of BerlinHeart EXCOR® mechanical circulatory support

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## Abstract

**Background:** The treatment of advanced heart failure (HF) in children and infants poses a serious management problem. Heart failure in that patient group is usually of congenital aetiology. The treatment schedules for paediatric patients are in most cases adapted from the guidelines for treatment of adults. Up to 2009, the treatment of that extremely difficult group of patients was limited to pharmacological therapy and occasional heart transplantations. Constantly increasing problems with recruiting donors, especially for the paediatric group, contribute to the fact that mechanical support with the use of ventricular assist devices is for many children the only chance of surviving the period of waiting for a heart donor.

**Aim:** The aim of the study was to analyse the outcomes of circulatory support in Poland and to assess the advisability of this method for treatment of children with severe HF.

**Methods:** This treatment of paediatric patients is currently used in three Polish centres. From December 28, 2009 to August 1, 2015, 27 implantations of BerlinHeart EXCOR® mechanical circulatory support system were performed in children aged from one month to 16 years (10 patients below one year of age; 37%). Left ventricular assist devices were implanted to 21 patients, whereas the remaining children received biventricular support. The most common reason for using this method was HF developed in the course of cardiomyopathy. In one case, HF after Fontan operation was the indication.

**Results:** The duration of the circulatory support period ranged from six to 1215 days. It was followed by successful heart transplantations in 10 (37%) patients, in five (18.1%) it resulted in regeneration of the heart, enabling explantation of the device, whereas three children are still waiting for transplantations. Nine (33%) children died during the therapy because of thromboembolic complications.

**Conclusions:** As follows from our data, circulatory support utilising the BerlinHeart EXCOR® system is an effective and promising method used as a bridge to cardiac transplantation, or for regeneration of the myocardium in paediatric patients. In the group of the youngest and the most difficult patients, the method requires close cooperation of the medical and nursing personnel.

**Key words:** heart failure, mechanical circulatory support, heart transplantation

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## INTRODUCTION

The treatment of advanced heart failure (HF) in infants and children is a huge management issue. Heart failure in such patients is usually of congenital aetiology. The treatment schedules for paediatric patients are in most cases adapted from the guidelines developed for adult patients. However, while left ventricular failure with extremely depressed systolic function is predominant in adults, in the case of children a variety of disorders affecting both the left and the right ventricle, often involving also myocardial diastolic function, is encountered [1, 2]. On the basis of a prospective study conducted in the United Kingdom, the number of new severe HF cases in children can be estimated at ca. one case per 100,000 population per year [3], which accounts for 380 children in the case of the Polish population. In addition, British data indicate that 1/3 of children with HF die or require a transplant within a year. By 2009, the treatment of this extremely difficult group of patients in Poland was limited to pharmacotherapy and occasional heart transplantation. Constantly increasing problems with recruiting donors, particularly for the paediatric group, contribute to the fact that mechanical circulatory support systems with pneumatic chambers enabling support for the left/right or both ventricles have become the only chance for many children to survive the period of waiting for a heart donor.

Based on the available literature and medical data it was decided to apply the BerlinHeart EXCOR® system for cardiac support in children and infants, as the sole system registered in the world for this group of patients, while having the full logistic background [4, 5].

The first implantations performed in Poland were based on individual consent for financing from the health insurance fund. The use of ventricular assist devices is currently registered as a new procedure settled in a monthly mode, including the implantation or replacement of the chamber/chambers. Change of the financing mode has enabled the development of a circulatory support programme, especially for the youngest patients.

This technique is currently used in three Polish centres:

1. Silesian Centre for Heart Diseases, Paediatric Cardiac Surgery Unit, Chair and Clinical Department of Cardiac Surgery, Transplantation, Vascular, and Endovascular Surgery, Silesian Medical University (SUM) — 15 patients;
2. University Children's Hospital, Department of Cardiac Surgery and Cardiac Intensive Care — seven patients;
3. Children's Memorial Health Institute, Department of Cardiac Surgery — five patients.

## METHODS

In this paper we present a retrospective analysis of paediatric patients with HF treated with the use of the BerlinHeart EXCOR® external pneumatic pump system.

### *Qualification for EXCOR system implantation*

The qualification for implantation of mechanical circulatory support is based on the international seven-grade Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) scale (Fig. 1), assuming that patients who meet grade 2 criteria or, provisionally, grade 3 after exclusion of other possibilities for haemodynamic stabilisation are in optimal condition for implantation [6, 7]. The implantation performed at the optimal time contributes to the reduction of mortality and minimises complications in the perioperative period.

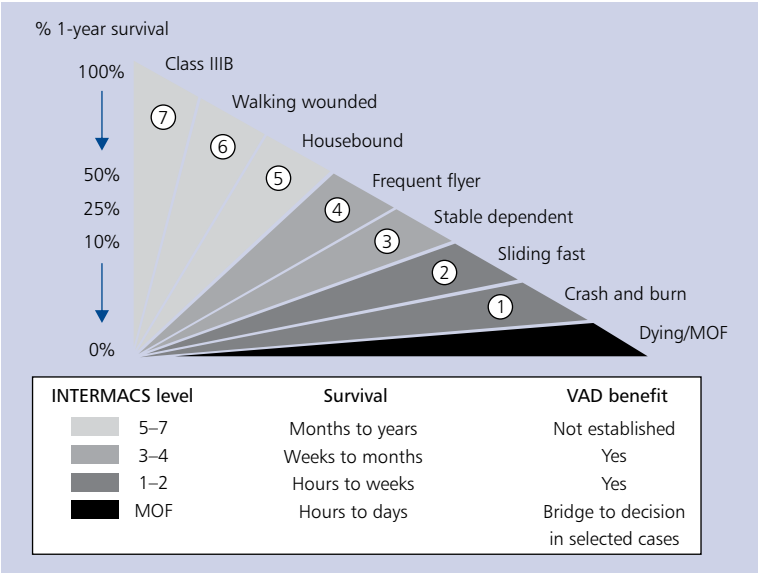


Figure 1. Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) scale; MOF — multi-organ failure; VAD — ventricular assist device

In certain situations, if the patient's prognosis is uncertain, extracorporeal membrane oxygenation (ECMO) or a centrifugal pump can be used initially until stabilisation is attained. Such a scheme of management enables the right decision and the use of a very cost-intensive technique for patients with better prognoses for survival. Among the patients of the Silesian Centre for Heart Diseases, the implantation of the BerlinHeart EXCOR® system was preceded by the use of other methods of extracorporeal life support in three cases: in two by ECMO and in one by LEVITRONIX rotary pump support.

The indication for implantation of right ventricle assist device was right ventricular function assessment by direct measurement of central venous pressure (> 15 mm Hg) and intraoperative transoesophageal echocardiography — assessment of tricuspid annular plane systolic excursion, or increased tricuspid regurgitation and a decline in right ventricular ejection fraction, causing a decrease in the cardiac output below 2 L/min and an increase in lactate levels > 3 mmol/L.

### *Patients*

In the period from 28.12.2009 until 01.08.2015, BerlinHeart EXCOR® cardiac support systems with pneumatic ventricular assist devices were implanted in 27 children. Girls predominated in the treated patients (n = 16; 59.3%). The age of patients ranged from 20 days to 15 years, with the mean of 5.43 ± 5.26 years. All the children presented overt signs of HF and were dependent on intravenous infusions of inotropic drugs. According to the INTERMACS scale, 55.5% (n = 15) of children were qualified as group 2, 11.2% (n = 3) as group 1, 25.9% (n = 7) group 3, and 7.4% (n = 2) as groups 4 and 5, respectively. In 77.7% (n = 21) of the patients, left ventricular assist devices (LVAD) with apical cannulation were implanted; in the remaining 22.3% (n = 6) biventricular assist devices (BIVAD) were used.

Congestive cardiomyopathy was the predominant diagnosis in the analysed group — 33.4% (n = 9) of patients, in 55.5% (n = 5) of whom myocardial non-compaction was diagnosed histologically. In one patient the indication for implantation was extreme HF with trophic skin changes, with several episodes of ventricular fibrillation in the course of restrictive cardiomyopathy. Congenital heart defect as a cause of cardiac failure was diagnosed in 25.9% (n = 7) of patients with predominant diagnosis of anomalous origin of the left coronary artery from the pulmonary artery (Bland-White-Garland syndrome [BWGS]) in 57% (n = 4) of patients, five (18.5%) children were diagnosed with cardiomyopathy developed in the course of myocarditis of various aetiologies, and five (18.5%) with idiopathic cardiomyopathy.

Venoarterial ECMO was used in two patients due to cardiorespiratory failure immediately prior to implantation. In one of them in the course of ECMO therapy (after previous cardiac arrest), the neurological status was assessed before making a final decision on how to proceed. In the case of one patient with suspected inflammatory cardiomyopathy and a potential chance of quick regeneration, a LEVITRONIX rotary pump was used. BerlinHeart EXCOR® system cannulas were used for connection of the assist device. After verification of the diagnosis by histopathology and after 30 days of support with no evidence of regeneration, a BerlinHeart EXCOR® ventricular assist device was connected without any problems to the previously implanted cannulas.

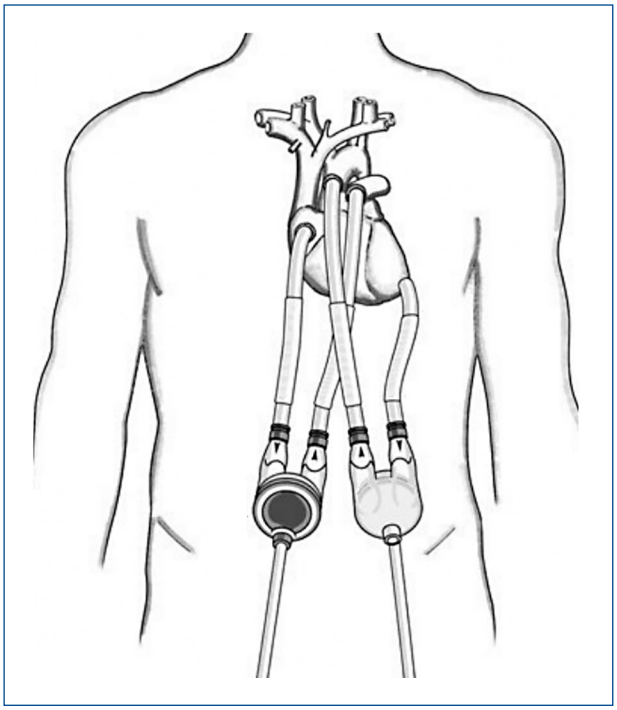

Figure 2. Mechanical circulatory support implantation scheme, the inflow cannula is implanted through the left ventricular apex, which ensures complete voiding of the ventricle, whereas the outflow cannula is implanted into the ascending aorta. The right ventricular inflow cannula is implanted into the right atrium, and the outflow cannula into the pulmonary artery trunk

The system consists of pneumatic pumps with polyurethane valves (with a stroke volume of 10, 15, 25, 30, and 50 mL), or mechanical single-disc valves (with stroke volume of 50, 60, and 80 mL) remaining outside the body, and silicone catheters implanted respectively into the right atrium, the main pulmonary artery, the aorta and the apex of the left ventricle. The size of the chamber used depends on the patient's body weight and is adjusted to ensure the indexed cardiac output of over 2.4 L/min/m$^2$ of body surface area. The system is subserved by an Ikus (Berlin Heart) control unit. For chambers of larger capacity (50, 60, and 80 mL), it is possible to use a lighter, mobile control unit.

The implantation procedure was carried out in a conventional manner as described earlier [1, 2] according to the diagram (Fig. 2), using extracorporeal circulation.

### *Anticoagulation regimen*

The standard anticoagulation regimen proposed by the manufacturer of the system was used throughout the postoperative period. The use of heparin coating in both the chamber and the cannulas (Carmeda AB, Upplands Väsby, Sweden) enabled the start of anticoagulant therapy in all patients 24 h after implantation. Initially, unfractionated heparin at a dose of 15 IU/kg/h was administered with activated partial thromboplastin time monitored every 6 h until a level 1.5–2.2 times the normal value was reached. On subsequent days when the patient received enteral feeding and was haemodynamically stable, and there was no significant bleeding, a vitamin K antagonist was administered at a dose of 0.2 mg/kg/day to achieve international normalised ratio (INR) values between 2.8 and 3.5, with gradual reduction of unfractionated heparin infusion. If the INR values were unstable, a low-molecular-weight heparin at a 1–1.5 mg/kg dose was additionally administered in two doses. On the following days, antiplatelet agents were included in the treatment schedule: dipyridamole at a dose of 4 mg/kg/day divided into four doses and acetylsalicylic acid at a dose of 1 mg/kg/day until the level ensuring the activity of adenosine diphosphate (ADP) test < 50% and arachidonic acid (ASPI) test < 30% was reached. In exceptional cases, the treatment was modified, e.g. in one patient with suspected pulmonary embolism, alteplase was used (at a dose of 1.5 mg/kg), and in other three with fibrin deposits, epoprostenol was administrated at the initial dose of 2 ng/kg/min. The observed minor bleeding, especially from the oral mucosa, was treated locally. In the period of infection, the observed problems with stabilisation of INR levels and ADP and ASPI test activity required periodic cessation of anticoagulation and antiplatelet treatment.

### *Explantation criteria*

Explantation of the system was considered in two situations: either an improvement of myocardial function, or the occurrence of complications making it impossible to continue the treatment. Myocardial function improvement was assessed by echocardiography, performed according to the scheme developed for the BerlinHeart EXCOR® system. Not only was the increase in left ventricular ejection fraction (LVEF) assessed, but also the increase of the left ventricle muscle thickness and cardiovascular function in gradually prolonged periods of limited mechanical support (gas analysis, lactate levels). Dobutamine stress echocardiography was not used to assess heart function improvement.

## RESULTS

During the observation period, a rupture of the membrane occurred in one patient, first in the left and after a month in the right ventricular assist chambers. In both cases there were no complications. The chambers were replaced immediately and sent to the manufacturer. In one case there was a crack in the pneumatic supply line and in another unsealing of the connector of ventricular assist chamber. The equipment was replaced without any complications. The results are presented in Table 1.

In the analysed group of paediatric patients, implantation of circulatory support allowed regeneration of the myocardium, enabling explantation of the system in five (18.5%) children; 10 (37%) children underwent heart transplantations with positive results, and nine (33%) children died, including eight deaths in the course of the therapy and one immediately after explantation of the system. Three (11.1%) children continue to be supported. In six (22.2%) cases, implantation of the system was an urgent procedure, 17 (63%) implantations were emergency ones, and four (14.8%) elective (Fig. 3). The average duration of support was 169 days (6–1215 days). All heart transplantations were performed in children with left ventricular assist systems. Among the patients with BIVAD, one child is now being supported in the Silesian Centre for Heart Diseases Paediatric Cardiac Surgery Unit and waiting for transplantation. In the group of children under one year of age, a high risk of serious neurological complications reaching 70% was observed. Practically no such complications were observed in the group of older children. The mortality in the youngest age group was also the highest — 50%, whereas in the group 1–6 years old, it was 33.3%, in 6–12 years old — 12.5%, and in the oldest group of children over 12 years of age — 33.3% (Fig. 4). There was only one patient after Fontan operation, in whom a BIVAD was used and failed. In that patient, ECMO coupled with the right ventricular assist system was additionally used. The need for extracorporeal oxygenation resulted from impaired lung function caused by a combination of thromboembolic complications generated by the right ventricle assist system, concurrent with bleeding caused by the necessity of aggressive anticoagulation. In another patient, haemofiltration due to renal failure was instituted successfully in the course of mechanical circulatory support. One patient with BIVAD developed the signs of severe aortic regurgitation, probably as a result of past infectious endocarditis. This resulted in a recirculation of blood between the cannulas, making it impossible to obtain the desired systemic cardiac output and, more importantly, to control it precisely. Since the patient did not present any signs of heart regeneration and was qualified for transplantation as a target treatment, we closed the aortic valve with an occluder from access through the apical cannula. This enabled setting the support parameters back to the nominal values, stabilisation of the patient, prompt extubation, and a return to everyday activities. Implantation was performed without any complications in the catheterisation laboratory and under transoesophageal ultrasound control.

We evaluated the survival curves for all patients, as well as according to gender and age groups (Fig. 5). The highest mortality was recorded during the first three months of circulatory support, particularly among girls. The youngest patients

Table 1. Preoperative data

| | Gender | Type | LVAD/BIVAD pumps [mL] | EF [%] | Diagnosis | Reop. | INTERMACS scale | Age [years] | Weight [kg] | Implantation mode | Support time [d] | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | M | LVAD | 30 | 15 | Non-compaction cardiomyopathy | n | 3 | 9 | 23.5 | Elective | 184 | OHT |
| 2 | F | LVAD | 30 | 20 | Congestive cardiomyopathy | n | 2 | 9 | 18 | Urgent | 88 | OHT |
| 3 | M | LVAD | 10 | 12 | Non-compaction Post-cardiotomy heart failure (VSD) | y | 2 | 1.5 | 8.2 | Urgent | 104 | OHT |
| 4 | F | LVAD | 50TD | 15 | Congestive cardiomyopathy | n | 2 | 10 | 30 | Emergency | 150 | OHT |
| 5 | F | BIVAD | 50TD/50TD | 40 | Single ventricle | y | 5 | 12 | 39 | Elective | 52 | Death |
| 6 | F | LVAD | 10 | 18 | Non-compaction cardiomyopathy | n | 1 | 0.4 | 7.7 | Emergency | 279 | Regeneration |
| 7 | F | LVAD | 10 | 10 | BWGS | y | 2 | 0.5 | 4.3 | Urgent | 175 | Regeneration |
| 8 | F | BIVAD | 10/10 | 18 | Idiopathic cardiomyopathy | n | 2 | 0.3 | 5.3 | Emergency | 39 | Death |
| 9 | F | LVAD | 50PU | 47 | Non-compaction cardiomyopathy | n | 2 | 12 | 39.5 | Urgent | 69 | OHT |
| 10 | F | LVAD | 10 | 10 | Myocarditis, cardiomyopathy | n | 2 | 0.2 | 4.9 | Emergency | 45 | Death |
| 11 | F | LVAD | 10 | 20 | BWGS | n | 2 | 0.5 | 5.9 | Urgent | 26 | Regeneration |
| 12 | F | LVAD | 10 | 28 | BWGS | n | 1 | 0.3 | 4.7 | Urgent | 41 | Regeneration |
| 13 | M | LVAD | 60 | 12 | Myocarditis, cardiomyopathy | n | 2 | 15 | 57 | Urgent | 273 | Regeneration |
| 14 | M | BIVAD | 15/15 | 10 | Restrictive cardiomyopathy | n | 2 | 3.5 | 11,2 | Urgent | 216 | Death |
| 15 | F | BIVAD | 30/30 | 17 | Non-compaction cardiomyopathy | n | 2 | 9 | 23 | Urgent | 200 | On system |
| 16 | F | LVAD | 10 | 12 | Post-cardiotomy heart failure (VSD) perioperative complication | y | 1 | 1 | | Urgent | 310 | OHT |
| 17 | M | LVAD | 25 | 27 | Idiopathic cardiomyopathy | n | 3 | 2 | 12 | Urgent | 73 | OHT |
| 18 | F | LVAD | 30 | 0 | Myocarditis, cardiomyopathy | n | 3 | 4 | 17.5 | Urgent | 89 | OHT |
| 19 | M | BIVAD | 25/25 | 23 | BWGS | y | 2 | 0.75 | 8.9 | Emergency | 25 | Death |
| 20 | F | LVAD | 10 | 26 | Congestive cardiomyopathy | n | 3 | 1.5 | 6.9 | Urgent | 33 | Death |
| 21 | M | LVAD | 10 | | Non-compaction cardiomyopathy | n | 3 | 0.7 | 6 | Urgent | 61 | Death |
| 22 | F | BIVAD | 10/10 | 17 | Congestive cardiomyopathy | n | 2 | 0.33 | 5,3 | Urgent | 6 | Death |
| 23 | M | LVAD | 30 | 12 | Idiopathic cardiomyopathy | n | 3 | 8 | 18 | Urgent | 1215 | On system |
| 24 | F | LVAD | 25 | 25 | Myocarditis, cardiomyopathy | n | 4 | 4 | 13 | Elective | 197 | On system |
| 25 | M | LVAD | 60TD | 15 | Myocarditis, cardiomyopathy | n | 3 | 12 | 64 | Elective | 433 | OHT |
| 26 | M | LVAD | 60TD | | Idiopathic cardiomyopathy | n | 2 | 15 | 46 | Emergency | 96 | OHT |
| 27 | F | LVAD | 60PU | 26 | Idiopathic cardiomyopathy | n | 2 | 14 | 61 | Urgent | 64 | Death |

BIVAD — biventricular assist devices; BWGS — Bland-White-Garland syndrome; EF — ejection fraction; F — female; INTERMACS — Interagency Registry for Mechanically Assisted Circulatory Support; LVAD — left ventricular assist devices; M — male; n — not; OHT — orthotopic heart transplant; y — yes; VSD — ventricular septal defect

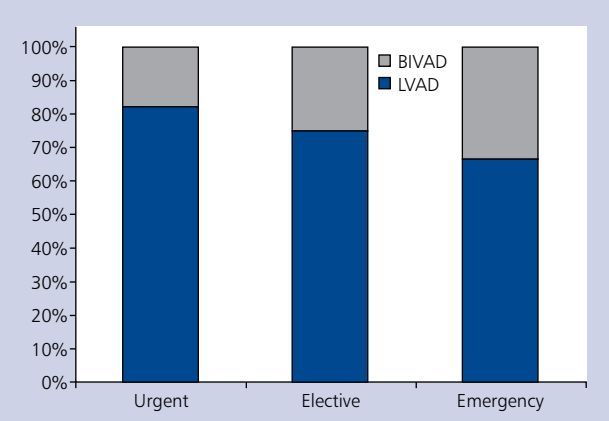


Figure 3. Support type (left ventricular assist devices [LVAD]/ /biventricular assist devices [BIVAD]) according to qualification

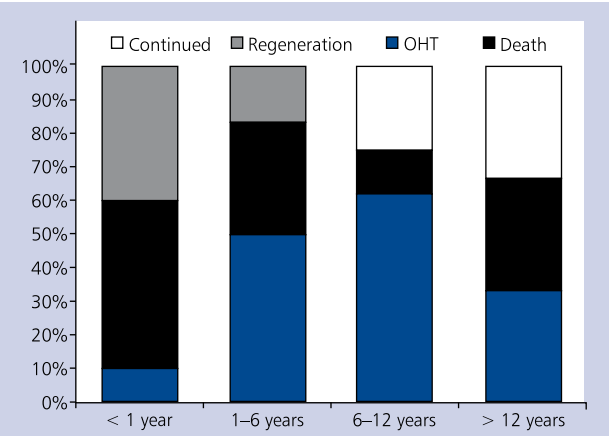


Figure 4. Outcomes of mechanical circulatory support stratified by age groups; OHT — orthotopic heart transplant

(below one year of age) are the most difficult group of patients, where the mortality within four months reaches 50%.

The patients in whom myocardial regeneration occurred formed a heterogeneous subgroup, wherein the average duration of circulatory support was 143.6 days (26–279 days), and the most common reason for implantation was cardiac failure in the course of BWGS (60% of patients). Anomalous origin of the left coronary artery from the pulmonary artery was also the most frequent diagnosis in patients with congenital heart defects (80% of patients). In the youngest patient, LVEF increase from 10% to 45% was achieved after 20 days of circulatory support, and the system was explanted successfully.

We observed one case of systemic infection in the course of therapy caused by *Stenotrophomonas maltophilia*. Nine patients presented thromboembolic events with signs of neurological dysfunction confirmed on computed tomography of the brain. Two patients on BIVAD died because of acute bleeding from the respiratory tract. There were no peripheral thromboembolic complications.

The key issue in the daily nursing care proved to be local infections around the implanted cannulas, observed in 19 patients. Such infections were not observed immediately after the surgery, but appeared after haemodynamic stability was achieved and the patients emerged from the catabolic state, with the associated rapid increase of subcutaneous tissue volume. This condition caused intussusception of the implantation site into the wound and the development of saprophytic flora infections, especially with *Staphylococcus epidermidis*. All wounds were treated typically with good outcomes.

## DISCUSSION

Implementation of the circulatory support programme for children in three Polish cardiac surgery centres has contributed to saving over a dozen children. In the analysed group, ten successful heart transplantations were performed, and heart regeneration allowing the patients to return to normal physical activity was achieved in five cases. The 20% mortality rate is consistent with the average world level in this group of patients. Multicentre analysis of the use of BerlinHeart EXCOR® including 97 patients treated in 17 centres in the United States showed a 23% mortality [8] and in the data presented by the Deutsches Herzzentrum Berlin [9, 10] the respective successfully completed treatment rates were 43% and 76%, depending of the follow-up period. Our records indicate that the BerlinHeart EXCOR® circulatory support system is an effective and promising method used as a bridge to transplantation or a treatment enabling regeneration of the myocardium. As follows from the analysed data, the method is associated with a high risk of neurological complications in children under one year of age. At the same time, it is safe and effective in older children. Mechanical circulatory support treatment must be carried out in a hospital, because the patients need frequent control of blood coagulation parameters and immediate adjustments of medications. Despite numerous constraints, the method allows moderate physical activity. The patients are very positively disposed towards mobile drivers enabling independent movement of a child with the circulatory support system. Unfortunately, such units are available only for ventricles with a capacity of 50 mL and above, and their function is also dependent on the diameter of the implanted cannulas. The mobile unit operates in a system controlled by pneumatic pistons in contrast to the pressure-controlled stationary unit, which results in lower tolerance to hydrodynamic drag of the assist system, additionally aggravated by the smaller cannula diameters. Such cannulas are typically used in paediatric patients. It should be kept in mind that for most patients, circulatory support is only a bridge to transplantation, and prolongation of the support period leads to an increased risk of serious complications. Based on epidemiological data, we can predict a significant increase in the number of children

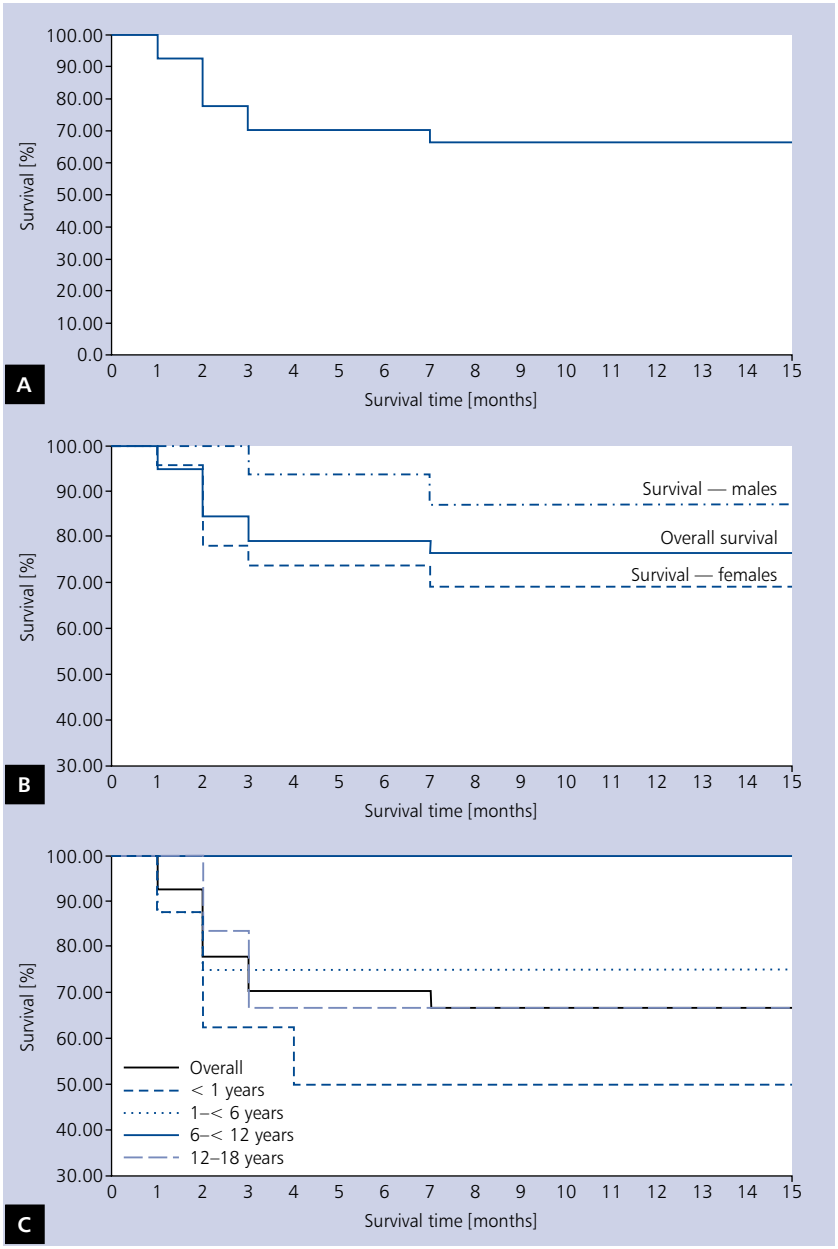


Figure 5. Kaplan-Meyer survival curves for all the patients (**A**), according to gender (**B**) and for the particular age groups (**C**)

treated, but it should be remembered that the factor imposing a limitation on the method is the availability of organs for transplantation because it is difficult to accept the ventricular assist device as a target treatment. The use of mechanical circulatory support for infants with ischaemic cardiomyopathy in the course of the treatment of BWGS seems to be promising.

Long-term hospitalisation of children generates also psycho-social problems, sometimes requiring psychiatric intervention. An important part of therapy is to implement a programme of school education and to provide psychological care for the patients.

## CONCLUSIONS

In conclusion, the results of the application of the BerlinHeart EXCOR® system in Poland do not differ from those presented by the best centres of Europe and America; the optimal treatment results were obtained in children over one year of age who were implanted with a single-ventricle assist device, whereas the patients below one year of age implanted with BIVAD are at a high risk of treatment failure.

***Conflict of interest:*** *none declared*

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