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ORIGINAL ARTICLE

# Impact of Long-Term Support with Berlin Heart EXCOR® in Pediatric Patients with Severe Heart Failure

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**Abstract**
Berlin Heart EXCOR® (BHE) ventricular assist device (VAD) (Berlin Heart, Berlin Heart AG, Berlin, Germany) implantation is prevalent in patients with severe heart failure. However, clinical outcomes of pediatric patients on long-term BHE support remain mainly unknown. This study aimed to report our clinical experience with long-term support of pediatric patients with severe heart failure supported by BHE VAD. Clinical outcomes of 11 patients (median age 8.4 months; two male), who underwent LVAD implantation of the Berlin Heart EXCO® (BHE) VAD (Berlin Heart, Berlin Heart AG, Berlin, Germany) between 2013 and 2017 at our institution were reviewed. The median support period was 312 (range 45–661) days and five patients were supported for more than 1 year. The longest support duration was 661 days. No mortality occurred, and six patients were successfully bridged to heart transplantation, while three patients were successfully weaned off the device. Two patients are currently on BHE support while they await heart transplantation. Four patients had cerebral bleeding or infarction, but only one case of persistent neurological deficit occurred. No fatal device-related infection occurred during LVAD support. BHE VAD can provide long-term support for pediatric patients with severe heart failure with acceptable mortality and morbidity rates with long-term support.

**Keywords** Berlin Heart EXCOR® · Long-term support · Pediatric patients · Growth

## Introduction

The use of Berlin Heart EXCOR® (BHE) ventricular-assisted device (VAD) (Berlin Heart, Berlin Heart AG, Berlin, Germany) for patients with severe heart failure has become prevalent in the current decade, with more than 1500 BHE implantations were performed in 2014 [1]. The reported support duration with these devices was 26–63 days [1, 2]. However, in Japan, since the donor heart shortage is a serious issue, the waiting periods for heart transplantation are longer than the global average. Although some case reports of pediatric patients on long-term BHE support have been previously published [3, 4], the clinical results are unknown. The aim of this study was to report our clinical experience and evaluate the outcome of long-term support of 11 patients with implanted BHE VAD device.

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## Methods

### Patients

Between 2013 and 2017, all 11 pediatric patients with severe heart failure underwent implantation of the BHE VAD implantation at Osaka University. The median patient age was 8.4 months (range 4.4–56.3 months), and two of the 11 patients (18%) were male. The median body surface area (BSA) was 0.33 $m^2$ (range 0.25–0.61 $m^2$). The median body weight before BHE implantation of the BHE was 6.4 kg (range 3.8–13.6 kg), and the median standard deviation of weight was − 2.2 (range − 4.8 to − 1.3) (Table 1).

Of the 11 patients, 8 cases were diagnosed with dilated cardiomyopathy (DCM), 2 had restrictive cardiomyopathy (cases 9 and 10), and 1 had left ventricular non-compaction (case 3). No patient had complicated complicated

**Table 1** Patient characteristics before BHE implantation

| Case | Age (months) | Sex | Height (cm) (SD) | Body weight (kg) (SD) | BSA ($m^2$) | Diagnosis | Comorbidity | LVDd (mm) | LVDs (mm) | EF (%) |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 4 | M | 59 (− 2.7) | 4.9 (− 2.4) | 0.27 | DCM | – | 33 | 32 | 18 |
| 2 | 6 | F | 65 (− 0.1) | 5.7 (− 2.2) | 0.31 | DCM | – | 34 | 29 | 31 |
| 3 | 14 | M | 74 (− 1.9) | 8.2 (− 1.6) | 0.40 | NCLV | – | 29 | 21 | 55 |
| 4 | 5 | F | 62 (− 2.7) | 3.9 (− 4.5) | 0.25 | DCM | – | 53 | 51 | 7 |
| 5 | 8 | F | 66 (− 3.1) | 3.8 (− 4.8) | 0.26 | DCM | – | 45 | 43 | 10 |
| 6 | 5 | F | 67 (1) | 5.6 (− 1.8) | 0.32 | DCM | Myocarditis | 47 | 43 | 19 |
| 7 | 23 | F | 71 (− 3.6) | 6.4 (− 3.8) | 0.35 | DCM | – | 35 | 35 | 32 |
| 8 | 7 | F | 68 (− 0.7) | 6.8 (− 1.3) | 0.33 | DCM | WPW | 38 | 35 | 15 |
| 9 | 16 | F | 69 (− 4.4) | 7.1 (− 2.7) | 0.35 | RCM | Muscular VSD | 27 | 18 | 63 |
| 10 | 56 | F | 100 (− 1.0) | 13.6 (− 1.4) | 0.61 | RCM | – | 46 | 36 | 44 |
| 11 | 16 | F | 74 (1.0) | 7.7 (− 2.0) | 0.40 | DCM | – | 45 | 42 | 4 |

*M* male, *F* female, *DCM* dilated cardiomyopathy, *NCLV* non-compaction left ventricle, *RCM* restrictive cardiomyopathy, *WPW* Wolff-Parkinson-White syndrome, *VSD* ventricular septal defect

congenital heart disease. Case 6 was complicated with myocarditis, case 8 was complicated with Wolff-Parkinson-White (WPW) syndrome, and case 9 was complicated with muscular ventricular septal defect (VSD). Three patients were supported by extracorporeal membrane oxygenation (ECMO) before BHE implantation. The median pre-operative ejection fraction was 19% (range 4–63%) (Table 1).

## Surgical Procedures

Surgical procedures used for BHE implantation have been previously described by several reports [3, 4]. Median sternotomy was performed in all patients. All patients except case 9 underwent BHE implantation under usual cardiopulmonary bypass (CPB) with a beating heart. In case 9, VSD patch closure was performed after the cardiac arrest was induced. After reversing the cardiac arrest, the BHE was implanted on a beating heart.

## Berlin Heart EXCOR Settings

The BHE rate was set to endure an adequate perfusion, ranging from 120 to 200 mL/kg/min. The other parameters were set with the aim of a full-empty full-fill operating modality [5].

## Anticoagulant Management

For postoperative anticoagulation, a continuous unfractionated heparin infusion was started on the first post-operative day at an initial dose of 10 IU/kg/h, and was adjusted every 6 h to maintain an activated partial thromboplastin time of 50–60 s. On post-operative days 2, diprydamole was administered at a dosage of 4 mg/kg/day and aspirin was subsequently administered at 4 mg/kg/day after drain removal. Once the patient's hemodynamic status was stable and enteral feeding was optimized, warfarin was administered in addition to diprydamole and aspirin to maintain a prothrombin time international normalized ratio (PT-INR) of 2.7–3.5. After stabilizing the PT-INR, heparin was reduced and subsequently stopped and PT-INR measurement was performed every 2–3 days.

If any thromboembolic event occurred, warfarin oral administration was discontinued immediately. If necessary, vitamin K, fresh frozen plasma, and blood coagulation factor IX were administered. Brain infarction or hemorrhage area was checked for several days by computed tomography, and if it did not increase, warfarin administration was restarted. The target level of PT-INR was not changed.

### Regular Check-Ups of Cardiac Function After Implantation of BHE Implantation

After BHE implantation, cardiac function was calculated with cardiac echography every 3 months and with cardiac catheterization at 3 and 12 months. If possible, cardiac evaluation without BHE support (VAD off test) was attempted during these regular check-ups. In case of adequate recovery of the cardiac function, weaning the patients from the device was attempted.

### VAD Off Test

If possible, "VAD off test" was performed as previously described [6]. VAD was stopped during cardiac catheterization and the pressure study and echocardiography were performed. Further, pressure study was also performed after volume load (10 mL/kg over 10 min). If the conditions of the study were fulfilled, BHE would be explanted in a few weeks.

### Administration of Anti-heart Failure Drugs

After BHE implantation, anti-heart failure drugs, such as angiotensin-converting enzyme inhibitors (enalapril) and beta-blockers (carvedilol) were administrated. The target dosages of both drugs were 0.3 mg/kg/day. By 3 months after the implantation of the BHE, the drugs were gradually increased to these dosages. If necessary, diuretics were administered while watching for signs of right heart failure, such as generalized edema and hepatomegaly, and based on the results of cardiac catheterization.

### The Height and Weight Gain

Patients' nutritional condition was evaluated according to their daily calorie intake, which was calculated based on the calorie intake required for each age. The standard deviation (SD) calculated from the standard height and weight of Japanese children was defined as an indicator of growth [7]. The first steps taken by the pediatric patients during BHE support were considered indicative of development.

### Statistical Analysis

Continuous variables are presented as medians and ranges. Categorical variables are reported as frequencies. All statistical analyses were performed using JMP 10.0 software (SAS Inc., Cary, NC, USA).

## Results

### Operative Results

The surgical outcomes of included patients are detailed in Table 2. All the patients underwent BHE implantation for left ventricular support. The median operation time was 281 min (range 21–330 min) and median CPB time was 131 min (range 110–173 min). Radiofrequency catheter ablation (RFCA) was performed in case 8 one day before BHE implantation on extracorporeal membrane oxygenation. VSD patch closure was performed in case 9 concomitantly with BHE implantation. No major complications occurred during surgery, although case 6 underwent omental packing for mediastinitis. The median duration of postoperative ventilator support was 7.5 days (range 2–30 days).

**Table 2** Operative results

| Case | Age (months) | Additional procedure | Support type | Pump size (ml) | Ope time (min) | CPB time (min) | Respirator (days) | Tracheotomy | Major complication |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 4 | – | LVAD | 10 | 308 | 169 | 17 | – | – |
| 2 | 6 | – | LVAD | 10 | 281 | 171 | 6 | – | – |
| 3 | 14 | – | LVAD | 10 | 284 | 173 | 6 | – | – |
| 4 | 5 | – | LVAD | 10 | 217 | 110 | 30 | + | – |
| 5 | 8 | – | LVAD | 10 | 256 | 148 | 2 | – | – |
| 6 | 5 | – | LVAD | 10 | 218 | 116 | 8 | – | Mediastinitis |
| 7 | 23 | – | LVAD | 10 | 224 | 131 | 70 | + | – |
| 8 | 7 | RFCA | LVAD | 10 | 330 | 116 | 2 | – | – |
| 9 | 16 | VSD closure | LVAD | 10 | 291 | 141 | 7 | – | – |
| 10 | 56 | – | LVAD | 25 | 300 | 125 | 9 | – | – |
| 11 | 16 | – | LVAD | 15 | 256 | 112 | 12 | + | – |

*RFCA* radiofrequency catheter ablation, *VSD* ventricular septal defect, *LVAD* left ventricular-assisted device

Tracheostomy was necessary in three cases (cases 4, 7, 11), of which two cases (cases 4, 7) were weaned off the ventilator and case 11 had undergone tracheostomy before BHE implantation (Table 2).

Due to uncontrollable heart failure, three patients needed ECMO prior to VAD implantation. ECMO was not planned for these patients; however, all three patients had been prepared for heart transplant registration before ECMO implementation. ECMO support duration prior to VAD placement was 4, 5, and 7 days, respectively.

## Late Survival

The clinical outcomes of the study subjects are detailed in Table 3. All the patients survived. Five patients were supported by BHE for more than 1 year and the longest support periods on BHE was 661 days. BHE was explanted successfully in three patients (27%). Six of the 11 patients successfully underwent heart transplantation after a median duration of 312 days (range 45–661 days) of support.

The exit site of the drive line was clean in the majority of our patients, although three patients had minor issues (cases 7, 8, 10) and were under daily infection control treatment. None of the patients required surgical treatment for driveline infection.

The cerebrovascular accident (CVA)-free survival rate is shown in Fig. 1. Four patients had at least one cerebral complication. Case 11 developed a hemorrhage (50 mm) in her right frontal and parietal lobes with ventricular perforation on the 54th day of VAD support. Thirteen days later, she had a new hemorrhagic event involving the left posterior lobe and required the hematoma evacuation. Fortunately, her ejection fraction recovered to 68% at this point, and she was weaned from the device on the 110th day of support with incomplete left-sided hemiplegia. Currently, she cannot speak well, but she can play with her hands. Although her neurological symptoms have persisted, she has not experienced any new cerebral events and continues to be treated without inotropic support at an outpatient clinic (Table 3).

## The Height and Weight in Pediatric Patients

The median of the daily intake calorie for the calorie intake required for each age was 0.32 ($n=11$), 1.04 ($n=11$), 1.12 ($n=10$), 1.14 ($n=9$), 0.84 ($n=8$), and 1.03 ($n=3$), respectively, before BHE implantation, and at 1, 3, 6, 9, and 12 months after BHE implantation (Fig. 2). The median SD of height on BHE support was − 1.9 ($n=11$), − 1.3 ($n=11$), − 1.3 ($n=10$), − 1.4 ($n=9$), − 1.4 ($n=8$), and − 0.1 ($n=3$), respectively, before BHE implantation and, at 1, 3, 6, 9, and 12 months after BHE implantation (Fig. 3). The median SD of body weight on BHE support was − 2.2 ($n=11$), − 2.5 ($n=11$), − 2.2 ($n=10$), − 2.1 ($n=9$), − 0.9 ($n=8$), and − 0.2 ($n=3$), respectively, before BHE implantation, at 1, 3, 6, 9, and 12 months after BHE implantation (Fig. 4). Four infants (cases 1, 5, 6, and 9) took their first steps while on BHE support (case 10 who was a 4-year-old girl was excluded because she could already walk by herself before BHE implantation). All the children, except for two cases (cases 7 and 9), experienced relatively good weight gain.

Case 7 was diagnosed with DCM and underwent BHE implantation at the age of 1 year and 11 months (body weight: 6.4 kg (− 4.4 SD)). She, however, presented with third-degree atrioventricular block 30 days after BHE implantation. Pacemaker implantation was performed on post-BHE day 45, with subsequent improvement of her hemodynamic parameters. However, right ventricular enlargement, right atrial enlargement, and tricuspid valve

**Table 3** Clinical results

| Case | Support duration (days) | Outcome | Major complication | | | |
|---|---|---|---|---|---|---|
| | | | CVA | Neurological deficiency | Drive line infection | Right heart failure |
| 1 | 421 | Transplant | + | − | − | − |
| 2 | 273 | Transplant | + | − | − | − |
| 3 | 45 | Transplant | − | − | − | − |
| 4 | 312 | Transplant | − | − | − | − |
| 5 | 661 | Transplant | − | − | − | − |
| 6 | 412 | Wean off | − | − | − | − |
| 7 | 330 | Transplant | − | − | + | + |
| 8 | 283 | Wean off | − | − | + | − |
| 9 | On going | On going | − | − | − | + |
| 10 | On going | On going | + | − | + | − |
| 11 | 110 | Wean off | + | + | − | − |

*CVA* cerebral vascular accident

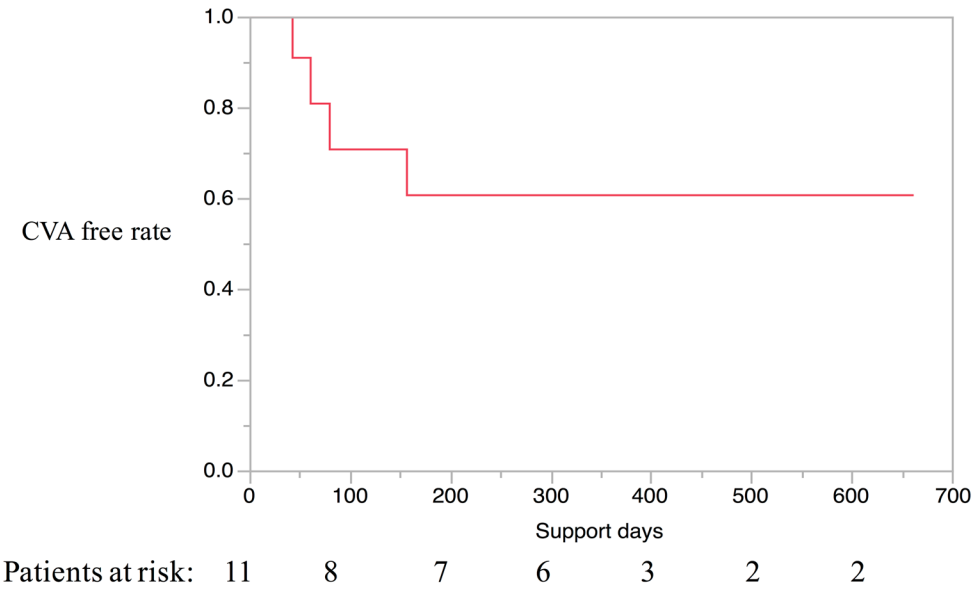


**Fig. 1** The CVA-free rate at 1, 3, 6, and 12 months were 0, 19.2, 39.4, 39.4%, respectively

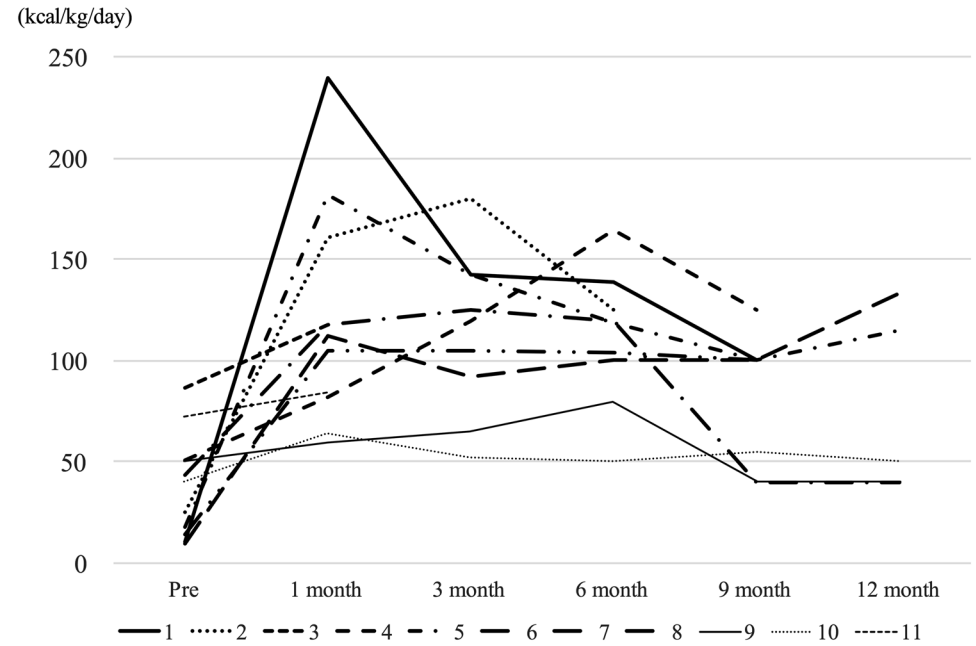


**Fig. 2** Pre- and postoperative median daily nutrition intake was 40.0 at preoperation and 120.3 kcal/kg/day at 1 month after BHE implantation

insufficiency also worsened and central venous pressure (CVP) was elevated to 20 mmHg, which was indicative of exacerbation of right heart failure exacerbation. Hence the BHE pump rate was increased from 85 to 100 beat per minutes which resulted in temporary decreased in CVP to 12 mmHg; however, it increased again to 18 mmHg at 4 months after BHE implantation. Hence, spironolactone (dosage 3.5 mg/kg/day), furosemide (dosage: 3.5 mg/kg/day), and tolvaptan (dosage 0.2 mg/kg/day) were administered to reduce the cardiac preload. However, the symptoms of right heart failure such as liver dysfunction with coagulopathy and absorption disorders were gradually progressed, and catecholamine administration was restarted at 9 months after BHE implantation. The patient finally underwent heart transplantation on the 330th day after BHE implantation, although her weight before heart transplantation was only 7.9 kg (− 3.3 SD) at the age of 3 years, and her malnutrition and severe weight loss were not improved.

Case 9 was a patient with restrictive cardiomyopathy who underwent BHE implantation at the age of 1 year and 4 months [body weight: 7.1 kg (− 2.7 SD)]. Dobutamine support was continued for 4 months after BHE implantation because of high CVP. Cardiac catheterization at 6 months after BHE implantation showed that her CVP was 16 mmHg.

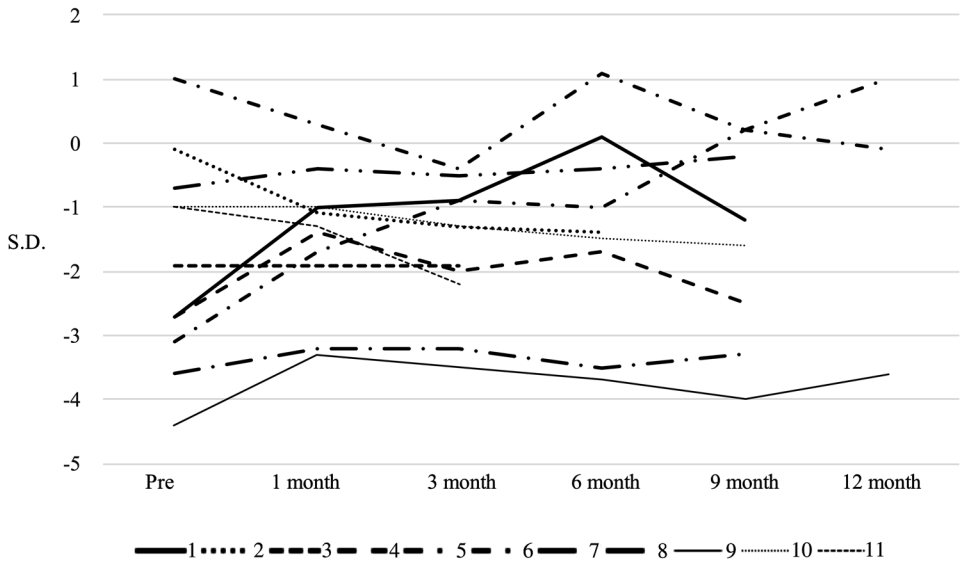


**Fig. 3** Pre and postoperative median SD of height was − 1.9 at preoperation and − 1.1 at 9 months after BHE implantation

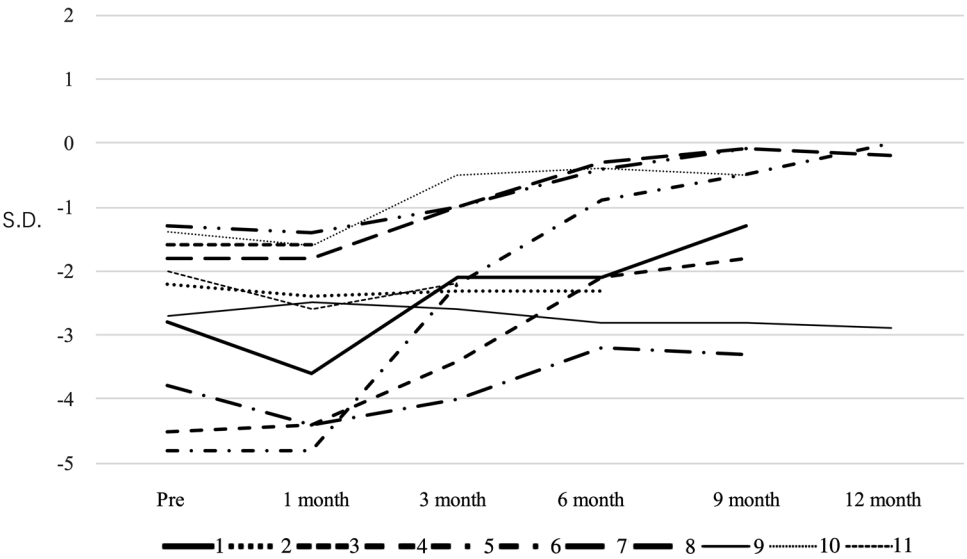


**Fig. 4** Pre and postoperative median SD of weight was − 2.2 at preoperation and − 0.9 at 9 months after BHE implantation

Spironolactone (dosage 2.5 mg/kg/day), furosemide (dosage 2.5 mg/kg/day), and tolvaptan (dosage 0.3 mg/kg/day) were administered to reduce the cardiac preload. However, due to worsening the renal function, it was difficult to add more diuretics. She took her first steps while on BHE support, but her body weight was only 8.1 kg (− 2.8 SD) at the age of 2 years and 4 months and she had chronically poor weight gain. She is currently on BHE support while she awaits heart transplantation.

## Discussion

BHE, a paracorporeal pneumatically driven VAD, is the only VAD for small pediatric patients that showed acceptable clinical results [2, 7, 8]. Due to the shortage of cardiac donors in Japan, pediatric patients must wait for long periods for heart transplantation and appropriate circulation management without any complications is essential during

this time. Some studies have reported complications on BHE support, such as mortality, CVAs, and driveline infections, even with short support durations (26–72 days) [1, 2, 9]. Here, we report the clinical results of long-term BHE support, and to the best of our knowledge, this is the first report describing of the growth and development of pediatric patients on long-term BHE support.

CVA is one of the major complications of BHE. Some studies on BHE implantation reported that the probability of CVA occurrence with BHE was approximately 20–40% [2, 10] and that the incidence of CVAs up to 1 month after BHE implantation [10–12]. In this study, no CVA event occurred up to 1 month after BHE implantation. Neurological complications with residual paralysis occurred in only one case on the 54$^{th}$ day (case 11). According to EXCOR® Pediatric IDE Study Protocol, all patients should receive anticoagulant treatment during BHE support. In our institute, all patients, even infants, were taking aspirin, dipyridamole and warfarin. Aspirin and dipyridamole were administered with the constant dose of 4 mg/kg/day. PT-INR was examined daily until its value stabilized, and subsequently was assessed every 2 to 3 days. Warfarin was adjusted finely in increments of 0.1 mg after each blood test. This fine adjustments could be one of the reasons for the relatively low incidence of CVA occurrence. Checking the pump filling and emptying is also essential for preventing from thrombosis. When the pump filling or emptying is insufficient, we evaluated the hemodynamic situation of the patients and adapted the driving parameter.

Three of 11 patients were successfully weaned from the support device. Two cases (cases 6, 8) had DCM with myocarditis and WPW syndrome, respectively, and the main causes of BHE implantation were these comorbidities. After the treatment of these comorbidities, the patients' cardiac functions recovered gradually, allowing explanation of the device after 9 and 14 months of LVAD support. This suggests that if the comorbidities that are the main cause of heart failure are treatable, they should be treated as possible. Long-term BHE support showed that the patients' cardiac functions might be gradually recovered after treating the comorbidities. The reason why long-term BHE implantation is useful is that severe heart failure makes the administration of diuretics and anti-cardiac failure drugs, such as beta-blockers and angiotensin-converting enzyme inhibitors, difficult. Helping cardiac function by VAD can prevent a cardiogenic shock related to anti-heart failure drug administration. The anti-heart failure drugs can be administered safely after the BHE implantation. This study reveals that administration of these drugs in patients on BHE support could contribute to recovery of cardiac function.

Our patients seemed to gain weight well while on BHE support. The reasons for this could have been increased cardiac output, absence of the need for fluid and nutrition restriction, and administration of diuretics while on BHE support. Di Molfetta. et al. [5] reported that the appropriate perfusion rate on BHE in children weighting less than 10 kg ranges from 100 to 200 mL/kg/min. We also set the BHE rate from 120 to 200 mL/kg/min. The patients became more active as their body weight increased, even on BHE support, and physical development occurred. Our experience suggests that the growth and development of the pediatric patients can be expected even on BHE support if appropriate circulatory management and nutrition are provided. The combination of stable circulatory support, adequate nutrition, and absence of the need for diuretics enables pediatric patients to gain weight and improves their physical development.

On the other hands, two patients with right heart failure demonstrated poor weight gain. Zafar et al. [13] showed that a 100-day survival is 60% for biventricular assist device (BiVAD) support of EXCOR. Clinical results of long-term support more than 300 days remain unclear; however, it is expected that the survival rate at 300 days or more would be worsened. In Japan, the waiting period for heart transplantation is usually longer. Additionally, no report of long-term support for BHE is currently available. Therefore, we opted to manage patients with right heart failure by inotrope administration instead of BiVAD implantation and fortunately, patients could receive heart transplantation. We found that intensive inotrope and diuretic management could cope with right heart failure cases that require support. However, BiVAD implantation should also be considered when heart failure is not controllable by inotrope and diuretics. In addition, in childhood-onset uncontrollable severe heart failure, there were some cases (27%) that could be explanted of EXCOR support with long-term support. There has been no report on the myocardial reversibility of children compared to adults, and it is thought that it is necessary to analyze predictors from the point of view of the pathological, genetic, and molecular levels. This study has shown that for pediatric patients, long-term support may increase the options for explantation of VAD, and long-term support may increase the possibility of VAD explantation.

In pediatric patients requiring long-term VAD support, the clinical outcomes were acceptable, although in patients with right heart failure, it was difficult to keep general condition and get good weight gain.

## Conclusion

This study reported the clinical outcomes in pediatric patients with severe heart failure on long-term BHE support at a single center. Long-term BHE VAD support might be satisfactory and acceptable in pediatric patients with right heart failure. No fatal outcomes, no significant device-related infections with good weight gain were obtained on BHE support. Our results highlight that BHE is suitable for

long-term support of pediatric patients with severe heart failure, except those with right heart, as a bridge to heart transplantation or recovery.

## Compliance with Ethical Standards

**Conflict of interest** None of the authors has any financial relationship related to this manuscript to disclose.

**Ethical Approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and its later amendments or comparable ethical standards.

**Informed Consent** Informed consent was obtained from all individual participants included in the study.

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