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The First Pediatric Heart Transplantation in Saudi Arabia Bridged by Berlin Heart (EXCOR) Ventricular Assist Device

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Abstract

Pediatric patients on the waiting list for heart transplantation incur the highest risk of death for any organ transplantation. Berlin Heart EXCOR provides a reliable support as a bridge to heart transplantation or recovery for all pediatric age groups. We report the first successful experience of Berlin Heart EXCOR mechanical circulatory support and heart transplantation in pediatric patients in Saudi Arabia. The purpose of this report is to highlight the clinical events and share lessons learned from this endeavor.

Keywords: Heart failure, Pediatric cardiomyopathy, Heart transplant, Mechanical circulatory support, Bridge Berlin Heart EXCOR

1. Introduction

Heart failure in pediatric population is a major cause of morbidity and mortality with a variable prevalence that could reach up to 7/10,000 [1]. The waiting list mortality for pediatric heart transplant remains extremely high reaching up to 17% and 25% for children and infants respectively [2].

In the current era, the evolution of mechanical circulatory support as a bridge to transplantation has significantly reduced the heart transplant wait-list mortality compared to previous eras with equivalent post-transplant survival [3,4].

The BH-EXCOR was implanted for the first time in 1990 in the German Heart Center in Berlin, hence the name Berlin Heart. Thereafter, the BH-EXCOR gained more wide-spread use around the world with longer-term application that reached up to 22 months in children [5–7].

Currently, the BH is the only VAD approved for pediatric patients. It is an extracorporeal, pulsatile,

pneumatic-driven assist device. It can provide left or right ventricular support or both and it can be used as a bridge to recovery or transplantation (Figs. 1 and 2).

This report is aimed to share our experience at King Abdulaziz Cardiac Center at the Ministry of National Guard Health Affairs, Riyadh, Saudi Arabia, in performing the first successful heart transplantation bridged with BH-EXCOR in pediatric patients in Saudi Arabia.

2. Case series

We present case series of two siblings (brother and sister) with familial dilated cardiomyopathy, presented with advanced heart failure requiring mechanical support.

2.1. Case 1

A Six-year-old boy (height 129 cm, weight 21 kg and blood group O positive), who was diagnosed at

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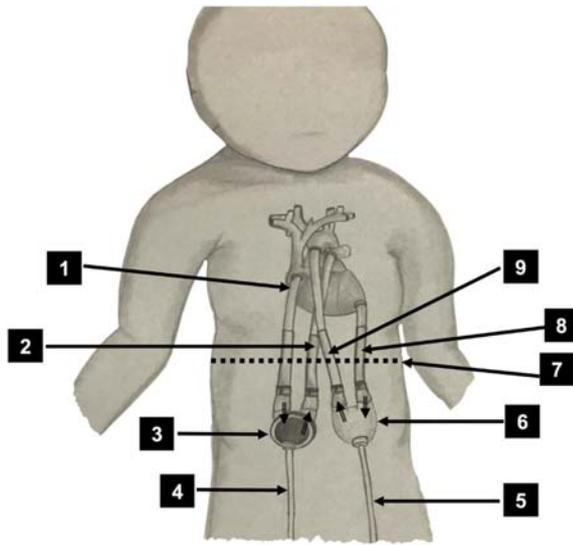


Fig. 1. Biventricular support EXCOR system. Illustration of the Biventricular support with BH-EXCOR. 1: Right atrial cannula (RVAD-inflow), 2: Pulmonary artery cannula (RVAD-outflow), 3: RVAD blood pump, 4: RVAD driveline, 5: LVAD driveline, 6: LVAD blood pump, 7: Line representing the exit sites of the cannula outside the body (Extra corporeal), 8: LV apex cannula (LVAD-inflow), 9: Aortic cannula (LVAD-outflow), Line arrows show the direction of blood flow. Artwork by: Ms. Sarah A. Alghamdi

the age of 4 years. Despite being on a maximum medical therapy, he continued to require frequent admissions for intravenous medication, then he became inotrope-dependent. His echocardiography



Fig. 2. IKUS driving unit. Image source: Berlin Heart.

revealed severely diminished left ventricular (LV) function (ejection fraction of 10%). He had mild mitral valve regurgitation and mild tricuspid regurgitation. His clinical condition deteriorated further with low cardiac output and cardiogenic shock state (INTERMACS-1). He was Initially placed on Levetronix PediMag device and was switched over BH-EXCOR LVAD (pump size 30 ml) in February 2020. He remained on BH-EXCOR for 16-months until he was successfully transplanted in June 2021. He was discharged home six weeks after the heart transplantation in excellent clinical condition.

2.2. Case 2

A Nine-year-old girl patient, and the older sister to Case 1, (height 138 cm, weight 32 kg, and blood group O positive) who was on maximum medical therapy. At the end of December 2020, she presented to the ER with progressive hypotension and renal impairment (INTERMACS-2). Despite being on maximal medical therapy, and inotropic support, her condition kept deteriorating. Her echocardiography showed severely diminished LV function (ejection fraction of 5%) and severe mitral valve regurgitation. The right ventricular function was moderately diminished with moderate tricuspid valve regurgitation. In December 2020, BH-EXCOR LVAD (pump size 30 ml) implantation was performed. Unlike her brother, the sternum was electively left open and was closed 48 hours after the implantation. She remained well and was transplanted in March 2021 (4-months on BH-EXCOR). She was discharged home four weeks after heart transplantation in excellent clinical condition.

3. Discussion

Heart transplantation is the gold standard therapy for end-stage heart failure. There is however, a shortage of donor organ which leads to waitlist mortality. The evolution of ventricular assist device has significantly ameliorated the waitlist mortality and has led to improved candidacy rate for heart transplantation.

Pediatric patients on BH-EXCOR waiting for heart transplantation require meticulous and diligent multidisciplinary care. This care includes adherence to the device surveillance and maintenance protocols with regular periodic cannula and pump checks for thrombin strands, clots, abnormal sounds or noises at the valve areas and periodic check of the pump filling and emptying with the prompt institution of the required adjustment measures.

Anticoagulation is an important aspect to be tightly controlled. In our patients we utilized the Edmonton protocol (Warfarin and INR monitoring with target level between 2.7 and 3.5) modified by using dual antiplatelet therapy with ASA and Clopidogril managed by dedicated clinical pharmacist in collaboration with treating physicians. This regimen has led to more flexibility in mobilizing the patients [8].

The infection prevention, early recognition and treatment are other pillars for success. The cannulas exit sites are sources of chronic colonization and potential systemic infections. Our protocol included strict periodic surveillance of cannulas exit sites every 48–72 hours and cleaning of the area with Normal Saline 0.9%, the disinfection with octenidine solution or gel and the application of an antimicrobial silver dressing around each exit site. Periodic swabs were collected in order to timely identify any colonizing microorganism. The dressing change was performed by critical care nurses specifically trained for this procedure. A dedicated team of Infectious Diseases experts closely monitored both patients since their admission up until their discharge post-transplant procedures.

Mobility, physiotherapy and optimal nutrition are cornerstones in the management of patients on BH-EXCOR. Dedicated experienced staff are essential to ensure the maintenance of physical activity, muscle mass, nutritional support and weight gain. Our patients received regular and systematic physical and nutritional support including active and passive exercises and tailored meals. Our patients were involved in the management of their physical activity and weight by owning a personal log-book for their activity and weight gain.

The psychological aspects and well-being of these patients was a major part of their management. It is obvious that children bound to VAD in the hospital are subjected to major psychological stress. Our patients were managed by dedicated pediatric psychologist, psychiatrist, social workers and trained nursing staff to alleviate their psychological burden. They were engaged in many programs and activities including drawing, painting, celebrating events, competitions and attending on-line schooling.

During the hospital stay on BH-EXCOR, case 1 (the boy) underwent a pump change 12-months after the implantation due to structural degeneration of the pump valves recognized from abnormal noise. This pump exchange was done expeditiously under strict sterile conditions using moderate sedation. No other major adverse events were encountered.

These two cases were not selected, rather, they came through emergency room. The cases were accepted and managed after building a strong infrastructure and trained staff. It should be noted though, the careful case section -whenever possible- is important to maximize chances of success in a newly developed program. The success of such a program, particularly with extended stay on BH-EXCOR for 22 months (both siblings) require a harmonious teamwork with diligent, passionate and meticulous care that focuses on details while looking at the patient holistically; physical, psychological and social aspects.

4. Conclusion

We reported the first successful experience in Saudi Arabia, of bridge to transplant in the pediatric population using BH-EXCOR, in siblings with familial dilated cardiomyopathy.

Conflict of interest statement

The authors have no conflict of interest to report.

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Author contributions

Conception and design of Study: Abdullah A. Alghamdi, Hatem Elmontaser, Ahmed A. Arifi, Joao Dantas, Muayed A. Al-Zaibag. Literature review: Abdullah A. Alghamdi, Hatem Elmontaser, Ahmed A. Arifi, Joao Dantas, Muayed A. Al-Zaibag. Acquisition of data: Abdullah A. Alghamdi, Hatem Elmontaser, Ahmed A. Arifi, Joao Dantas, Muayed A. Al-Zaibag. Research investigation and analysis: Abdullah A. Alghamdi, Hatem Elmontaser, Ahmed A. Arifi, Joao Dantas, Muayed A. Al-Zaibag. Data collection: Abdullah A. Alghamdi, Hatem Elmontaser, Ahmed A. Arifi, Joao Dantas, Muayed A. Al-Zaibag. Drafting of manuscript: Abdullah A. Alghamdi, Hatem Elmontaser, Ahmed A. Arifi, Joao Dantas, Muayed A. Al-Zaibag. Revising and editing the manuscript critically for important intellectual contents: Abdullah A. Alghamdi, Hatem Elmontaser, Ahmed A. Arifi, Joao Dantas, Muayed A. Al-

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