Early Single Institutional Experience of Berlin Heart EXCOR® Pediatric Ventricular Assist Device in Japan

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**Background:** Since August 2015, the pediatric ventricular assist device (VAD), Berlin Heart EXCOR®, has been accepted for use in Japan.

**Methods and Results:** Between August 2015 and July 2016, 4 pediatric patients with endstage heart failure underwent LVAD implantation with the EXCOR® device. The median age and body weight at operation were 8 months and 4.8 kg. During a median follow-up of 7.3 months (range, 5.0–10.3), all patients survived. Two patients went on to heart transplantation and the remaining 2 are on a waiting list with stable hemodynamics.

**Conclusions:** The early outcomes of the Berlin Heart EXCOR® pediatric VAD were satisfactory. 

**Key Words:** EXCOR® device; Pediatrics; Ventricular assist device

The Organ Transplant Law in Japan was revised and enforced in 2010, which legally and ethically allowed for pediatric heart transplantation; in addition, donations from brain-dead cadavers under 15 years of age were accepted without written declaration of the donors themselves. Therefore, with the expectation of an increase in pediatric donor hearts, a pediatric ventricular assist device, the EXCOR® (Berlin Heart, Inc, Berlin, Germany), has been in use in Japan as a bridge-to-transplantation use since August 2015.

This study reviewed our initial 1-year experience of EXCOR® implantation for pediatric patients with body weight <10 kg.

**Methods**

**Patients**

The National Cerebral and Cardiovascular Center Institutional Review Board approved this retrospective study, and waived the need to obtain patient consent. Between August 2015 and July 2016, 4 pediatric patients with endstage heart failure related to dilated cardiomyopathy (DCM) underwent EXCOR® implantation (Table). The median age at LVAD implantation was 8 months old (range, 5–39), and the median weight was 4.8 kg (3.0–6.0).

**Results**

**Case 1**

An 11-month-old infant with idiopathic DCM, who had been unsuccessfully treated elsewhere for more than 2 weeks with inotropic agents and mechanical respiratory support, was transferred to the National Cerebral and Cardiovascular Center (NCCC) 1 week before official approval of EXCOR® usage. While waiting for LVAD implantation, her hemodynamic condition collapsed and she required urgent central extracorporeal membrane oxygenation (ECMO) using the Endumo® 2000 system (Heiwa Bussan, Tokyo, Japan), which was followed by EXCOR® implantation 6 days later. However, intracranial bleeding occurred 5 days after LVAD implantation, so removal of the hematoma was emergently performed. Intravenous heparin administration was discontinued 3 h before the surgery and protamine (1 mg/kg) was administered for complete reversal just before the surgery. Intravenous heparin administration was reinstituted 48 h after the intracranial operation and activated partial thromboplastin time was kept to 50–55 s. After 310 days of LVAD support, she underwent heart transplantation overseas without any complications. Incomplete paralysis of the left side of the upper and lower extremities remains with no persistent central neurological sequelae.
Case 4

A 1-month-old infant (weight 3.0 kg) with idiopathic DCM and cardiogenic shock who developed critical respiratory failure caused by a cardiogenic lung edema combined with pneumonia, was transferred to the NCCC. Soon after admission, veno-arterial peripheral ECMO was established using the Endumo® 2000 system, and her left atrium was vented with a percutaneous transfemoral catheter via a patent foramen ovale (PFO). Her hemodynamic status improved but respiratory recovery was somehow limited by thoracic compartment syndrome. Therefore, 12 days after ECMO establishment, conversion to central ECMO with left ventricular apex drainage and ascending aorta perfusion using a combination of the Endumo® 2000 system and EXCOR® pediatric inflow and outflow cannulae, removal of the atrial venting catheter and closure of the PFO was performed. After 4 days of central ECMO support, her respiratory function improved sufficiently to allow conversion to the EXCOR® pump under local anesthesia without mechanical right heart support. She is awaiting heart transplantation in a stable condition without any neurological complications.

Discussion

This study demonstrated acceptable early clinical outcomes of using the EXCOR® pediatric VAD as bridge-to-heart transplantation for pediatric patients with body weight <10 kg and endstage heart failure caused by DCM. Two patients went on to successful heart transplantation, and the remaining patients are on the waiting list under stable hemodynamic conditions.

Both small body weight and preoperative ECMO support have been reported as risk factors of LVAD implantation.4,8,9 However, our cohort included 3 patients with body weight <5 kg, and 2 patients required preoperative ECMO support as a bridge-to-LVAD; all of them survived and 2 went on to heart transplantation.
transplantation. The presented favorable outcomes are thought to be derived from the patients having a degenerative cardiomyopathy, not a congenital heart anomaly, and that their right ventricular function and respiratory function were preserved or improved with ECMO support before LVAD implantation. As previously reported, the Endumo is a durable and antithrombogenic ECMO system for small children, so its application as a bridge-to-LVAD implantation also contributed to the good outcomes.

In conclusion, the EXCOR® provides good hemodynamic conditions for pediatric patients with endstage heart failure, and thus is thought to be an ideal device as a bridge-to-heart transplantation. Contrary to our expectations, however, serious donor shortages continue. Therefore, it is essential to prevent and manage late complications after EXCOR implantation, such as thromboembolism and infection.

References