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Long-Term Paracorporeal Ventricular Support Systems: A Single-Center Experience

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ABSTRACT

Background. The Berlin Heart EXCOR is a first-generation paracorporeal, pneumatic ventricular assist device that creates pulsatile flow. It can be used for long-term support of the left and/or right ventricule during end-stage heart failure. The aim of this study was to share our clinical experience in 54 patients.

Methods. Between April 2007 and August 2012, 54 patients with end-stage heart failure underwent Berlin Heart EXCOR ventricular assist device implantation, including 5 females and 9 children. Twenty-four patients (44%) were in Intermacs level 1, 11 (21%) in level 2, and 19 (35%) in level 3. Biventricular support was applied to 13 patients. Device implantation was performed with an "on pump" beating heart technique while 6 other patients underwent intervention operations while the aortic valve has under cross-clamp. Tricuspid annuloplasty was performed in 6 patients.

Results. There was no peroperative death. Nine patients (17%) underwent re-exploration because of hemorrhage in the early postoperative period. Heart transplantation was performed in 32 patients (59%), while 10 (19%) are still under pump support with a mean follow-up of 13 months. Although 1 was successfully weaned from the system, 11 patients (20%) died during the support. Pump-head exchange was required 19 times in 17 patients because of visible thrombus or fibrin deposit in the pump head or due to membrane rupture.

Discussion. The use of long-term paracorporeal assist devices has decreased in recent years because of the increased popularity of implantable devices that permit longer survival and a better quality of life. We believe that the Berlin Heart EXCOR has a special role because it can be used in pediatric patients and especially in critical conditions like Intermacs levels 1 and 2.

END-STAGE heart failure is one of the important causes for morbidity and mortality. A number of illnesses cause this desperate situation including coronary artery disease and its complications, idiopathic dilated cardiomyopathy, and congenital heart defects. Heart transplantation is still the gold standard treatment for patients with end-stage heart failure.[1] As a result of donor scarcity, mechanical circulatory support (MCS) using ventricular assist devices (VAD) has developed as an innovative rescuer for patients with end-stage heart failure.[2] Mechanical circulatory support substantially improves vital functions. Compared with conventional therapy MCS seeks to keep the patient alive until transplantation, and to provide greater exercise tolerance, superior quality of life and recovery of organ malfunction.[3] Today, more than 35% of patients a waiting transplantation are undergoing.[1] VAD can be also used for recovery, or destination therapy in carefully chosen patients who require left ventricular, right ventricular, or biventriculars support.[2]

The Berlin Heart EXCOR (Berlin Heart AG, Berlin, Germany) is a first-generation device that contains a paracorporeal, pneumatic compressor-drived diaphragm pump with a tilting disk or polyurethane flexible trileaflet valves, silicone cannulas, and a stationary driving unit. The pump

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0041-1345/–see front matter
http://dx.doi.org/10.1016/j.transproceed.2013.02.073

head holds a polyurethane blood pump with a multilayer flexible membrane that separates the blood and air chambers. The system has adult pumps available in 50, 60, and 80 mL sizes; pediatric pump sizes are 10, 25, and 30 mL. This device provides left, right, or biventricular support for adult and pediatric patients.[4] The worldwide popularity of EXCOR in pediatric patients has increased dramatically in the last decade.[5]

Herein we have presented implantations in 54 patients of the Berlin Heart EXCOR VAD in our department.

METHODS

Between April 2007 and October 2012, 54 patients (48 males and 6 females) with acute or chronic end-stage heart failure underwent Berlin Heart EXCOR VAD implantation, including 9 children younger than 16 years of age. The patients' ages spanned 1.5 to 63 years (mean, 38 ± 18), mean height 165 ± 22 cm (range, 77–189), weight 69 ± 22 kg (range, 8–107 kg), and body surface area 1.74 ± 0.41 m^2 (range, 0.45–2.2 m^2).

The etiologies of heart failure among patients undergoing EXCOR implantation were dilated cardiomyopathy (n = 45; 83%) and ischemic cardiomyopathy (n = 9; 17%). Before VAD implantation, 24 patients (44%) were Intermacs level 1, 11 (21%) were level 2, and 19 (35%) were level 3.

Operative Technique

After performing a midline sternotomy incision and delivering systemic heparinization, arterial cannulation was achieved via the ascending aorta or femoral artery. Venous cannulation was performed using a bicaval right atrial technique. After initiation of cardiopulmonary bypass, the patient was placed in the head down position. A circular hole was created at the left ventricular apex with suitable numbers of polypropylene 3/0 or 4/0 sutures supported with Teflon pledgets placed around the hole. An apical cannula was introduced with close-fitting polypropylene sutures already placed around the hole. An additional circular continuous purse-string suture was placed around the apical cannula to prevent bleeding. The apical cannula was passed through the abdominal wall. The heart was defibrillated if necessary. During this period deairing was performed carefully. A side clamp was inserted into the ascending aorta. After making a longitudinal aortotomy incision, the aortic outflow cannula was placed in the ascending aorta with 4/0 or 5/0 continuous or mattress polypropylene sutures supported with Teflon pledgets. The outflow cannula was tunneled to exit the abdominal skin.

When the biventricular support mode was needed, a right atrial inflow cannula was placed into the right atrial wall with 4/0 or 5/0 continuous or mattress polypropylene sutures reinforced with Teflon pledgets. The right-sided outflow cannula was anastomosed to the main pulmonary artery using the same technique as the aortic anastomosis. After deairing, the left-sided pump was connected to the left ventricular apical and aortic outflow cannulae. The same procedure was accomplished for the right-sided pump and right-sided cannulas. Visible air bubbles were aspirated with a deairing needle. The pump was connected to the driving unit and the assisted circulation initiated; cardiopulmonary bypass flow was decreased gradually to be finally stopped.

An additional valvular procedure was performed under x-clamp in 12 patients (22%). In 3 subjects with significant aortic regurgitation, primary coaptation stitches at the 3 leaflet centers were applied to approximate the fibrous nodules of Arantius. The mechanical aortic valve was replaced with a stentless bioprosthesis in 3 patients; in 6, a tricuspid valve repair was performed using an annuloplasty ring.

During postoperative follow-up, judicious right ventricular support and anticoagulation regimen were established, particularly for patients with poor right ventricular systolic functions employing inhaled nitric oxide (NO), milrinon, and catecholamines in the early postoperative period. We started fluid restriction and inhaled iloprost treatment in these patients after extubation.

After 12–24 hours postoperative anticoagulation with unfractioned heparin infusions kept the activated partial thromboplastin time (aPTT) between 60 and 80 seconds as tested every 4–6 hours. Target aPTT levels were determined by the platelet count, fibrinogen level, and thromboelastography results. In addition to heparin, diyridamol was begun on postoperative day 3. Subsequently warfarin Na was given as an anticoagulant to keep the international normalized ratio (INR) at 2.7–3.5. Acetylsalicylic acid was started around day 5 to 6 after the operation after removal of the mediastinal drains. In some patients clopidogrel added as an antiaggregant according to the results of platelet aggregation tests. The transparent polyurethane pump chamber was regularly checked using light to detect possible thrombus and fibrin depositions.

RESULTS

Among 54 patients supported with the VAD, 13 received biventricular support. In all patients the Berlin Heart EXCOR was used for MCS. There was no peroperative death. The mean length of intensive care unit stay was 12 ± 9 days (range, 5–42). The mean support was 256 ± 200 days (range, 3–704). The mean support time in pediatric cases was 384 ± 207 days (range, 30–670). Ten (19%) patients are still on circulatory support. Thirty-two (59%) patients underwent heart transplantation. One subject who was managed with left VAD implantation and coronary artery bypass grafting was weaned from the system. The overall survival rate until transplantation or after weaning was 80% (n = 43).

Nine patients (17%) underwent re-exploration because of postoperative hemorrhage or cardiac tamponade in the early postoperative period. Ten cerebrovascular complications occurred in 9 patients (17%), including 2 pediatric cases. Thromboembolic cerebral complications, including transient ischemic events and prolonged reversible ischemic neurological deficits, were observed in 4 patients, 1 of whom experienced a severe stroke and concomitant intracranial bleeding on postoperative day 420. Another subject displayed intracerebral hemorrhage, whereas 2 patients had nonfatal cerebral hemorrhages without neurological sequelal. Two pediatric patient died due to thromboembolic cerebrovascular complications after more than 400 days of support. Thrombus formations that caused pump dysfunction were encountered 17 times in 15 cases (28%), requiring pump head exchange. The mean support time to pump head exchange was 223.6 days (range, 30–414). Pump exchange was easily performed as soon as possible without anesthesia or adverse event. Cannula infection observed in 5 patients was controlled with local antiseptic dressings.