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Original Articles

Pulsatile Mechanical Cardiac Assistance in Pediatric Patients with the Berlin Heart Ventricular Assist Device

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Abstract: Mechanical cardiac assistance for neonates, infants, children and adolescents may be accomplished with pulsatile ventricular assist devices (VAD) instead of extracorporeal membrane oxygenation or centrifugal pumps. The Berlin Heart VAD consists of extracorporeal, pneumatically driven blood pumps for pulsatile univentricular or biventricular assistance for patients of all age groups. The blood pumps are heparin-coated. The stationary driving unit (IKUS) has the required enhanced compressor performance for pediatric pump sizes. The Berlin Heart VAD was used in a total number of 424 patients from 1987 to November 2001 at our institution. In 45 pediatric patients aged 2 days–17 years the Berlin Heart VAD was applied for long-term support (1–111 days, mean 20 days). There were three patient groups: Group I: "Bridge to transplantation" with various forms of cardiomyopathy ($N = 21$) or chronic stages of congenital heart disease ($N = 9$); Group II: "Rescue" in intractable heart failure after corrective surgery for congenital disease ($N = 7$) or in early graft failure after heart transplantation ($N = 1$); and Group III: "Acute myocarditis" ($N = 7$) as either bridge to transplantation or bridge to recovery. Seventeen patients were transplanted after support periods of between 4 and 111 days with 12 long-term survivors, having now survived for up to 10 years. Five patients (Groups I and III) were weaned from the system with four long-term survivors. In Group II only one patient survived after successful transplantation. Prolonged circulatory support with the Berlin Heart VAD is an effective method for bridging until cardiac recovery or transplantation in the pediatric age group. Extubation, mobilization, and enteral nutrition are possible. For long-term use, the Berlin Heart VAD offers advantages over centrifugal pumps and ECMO in respect to patient mobility and safety. **Keywords:** ventricular assist device, pediatric heart surgery, mechanical cardiac assistance, pulsatile cardiac assist. *JECT. 2003;35:115–120.*

INTRODUCTION

The development of the Berlin Heart Ventricular Assist Device (VAD) goes back to the 1960s, when a group of engineers at the Free University of Berlin under Dr. E. Bucherl started working on total artificial hearts (1,2). The same group of engineers also developed a paracorporeal VAD, called the Berlin Heart. The device came into use at the Deutsches Herzzentrum Berlin for bridging to transplantation of adult patients and adolescents in 1987 (3). The first use of a 50 mL pump for left ventricular support in an 8-year-old child took place in 1991 (4). In 1992, smaller pump sizes for pediatric patients became available (5). Since 1994 the Berlin Heart paracorporeal blood pumps have been heparin-coated (Carmeda, Stockholm, Sweden).

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MATERIAL AND METHODS

The Berlin Heart VAD (Berlin Heart AG, Berlin, Germany) consists of paracorporeal, pneumatic compressor-operated diaphragm pumps with valves, silicone cannulae, and the stationary driving unit, originally designed by the "Institut fuer Kunstherz und Sensorik" (IKUS).

Figure 1. Neonatal 10-mL polyurethane valve Berlin Heart blood pump.

Figure 2. Berlin Heart cannulae. Neonatal, pediatric, and adult arterial cannulae on the left; neonatal, pediatric, and adult atrial cannulae in the middle; neonatal, pediatric, and adult apex cannulae on the right.

Blood Pumps

The blood pumps are available in various sizes allowing for a wide range of desired pump minute volumes (PMV). Currently, pumps with 10, 25, 30, 50, 60, and 80 mL blood volume are manufactured. The blood pumps consist of a translucent, semirigid housing of polyurethane. The pump chamber is divided into a blood and an air chamber by a flexible diaphragm in three layers. The two diaphragm layers facing the air chamber serve as driving membranes; the layer facing the blood chamber is moved by the two driving membranes (6). A de-airing nipple, into which a cannula can be introduced to eliminate residual air when preparing the pump for implantation, is integrated into the blood chamber. To direct the blood flow, trileaflet polyurethane valves are mounted in the pediatric pumps (10, 25, 30 mL); whereas, either metal tilting disc (Sorin Biomedical, Turin, Italy) or trileaflet polyurethane valves are available for the adult pump sizes (50, 60, 80 mL). Because of the higher flow resistance of the pediatric cannulae and higher pump rates in this population, higher pump afterload than in adult pumps is produced. The potential for valve leakage leading to retrograde filling of the blood chambers and, therefore, limiting the efficiency of the system is minimized using the polyurethane trileaflet valves (7).

All blood-contacting surfaces inside the pump, including the polyurethane valves, consist of the same material and are heparin coated. The coating has proved to be effective for up to 6 months after implantation. These heparin-coated blood pumps have been in use for over 250 days in adult patients without visible fibrin deposits (6). The inflow and outflow connectors are made of highly polished titanium. The edge of the connector is designed to make a smooth connection to the silicone cannula.

Cannulae

The Berlin Heart cannulae are made of silicone rubber with an extremely smooth internal surface. Standard cannulation of the right heart is accomplished by drainage of the right atrium and ejection of the right pump blood volume into the pulmonary artery. On the left side, cannulation of either the left atrium or the left ventricular apex is possible. Pump outflow is directed into the ascending aorta. For special applications in adult patients, where optimal unloading of the left ventricle is wanted, but apical cannulation is not feasible, a transmitral cannula is available. A large bore cannula for direct insertion into the apex of the left ventricle with connection to the descending aorta may be used for adult patients in selected cases.

Various cannula designs and diameters exist to match patient sizes and anatomies. For the pediatric patients, internal diameters of 3.2, 6.4, and 9.5 mm are available. Another option may be a so-called dual stage cannula for some pediatric sizes; it combines a smaller diameter cannula tip with a larger diameter connection to the blood pump. All adult cannulae have internal diameters of 12.7 mm, the large bore left ventricular apex cannula with connection to the descending aorta has an internal diameter of 16 mm. The outside of the cannulae is covered with a Dacron velours surface at the contact site with the abdominal wall and skin to encourage rapid ingrowth into surrounding tissue; thereby preventing ascending infections.

Atrial cannulae for adult patients have different sized cages for insertion into the atrium, available from 22–26 mm in length to match the variations in wall thickness. The pediatric sizes are manufactured with standard cage lengths. For improved left ventricular drainage, various apex cannulae for direct cannulation of the left ventricle are available for all patient sizes and age groups. In recent years, we have preferably used apical cannulation for optimal unloading of the left ventricle, which is a prerequisite for myocardial recovery.

The arterial cannulae for adult patients are available with three different angles (45, 60, and 85°) at the connection sites to the blood vessels. These cannulae and the cannulae for children are sewn onto the wall of the arterial vessels at the Dacron sewing ring. The infant and neonate arterial cannulae have a short metal tip for insertion into the blood vessel wall with a Dacron sewing ring around it. These cannulae produce a considerably reduced afterload to the native heart than conventional heart–lung machine cannulae (8).

All Berlin Heart cannulae exit the body through the upper abdominal wall.

Driving Unit

The Berlin Heart VAD for pediatric patients is powered by the IKUS stationary driving unit. Transparent PVC driving lines of 2-m length connect the paracorporeal blood pumps to the driving unit. Compressed air is pumped into the driving lines and moves the pump diaphragm into its endsystolic position, thereby ejecting the blood volume. In pump diastole, a vacuum is created to enable diaphragm movement into the filling position.

The driving unit consists of three separate compressor units: one for the left pump, one for the right pump, and one reserve compressor. In the case of malfunction of one compressor unit, the reserve unit will take over. Should two compressor units simultaneously stop working, an acceptable pump minute volume for both pumps is produced by the third compressor unit with a pump rate of 90 beats per minute.

Figure 3. Stationary IKUS driving unit for univentricular and biventricular mode.

Two redundant internal computers control the compressor and pressure/vacuum regulator actions. User control is enabled through an industrial notebook computer at the top of the device. An internal rechargeable battery provides electrical power for up to 1 hour.

The maximum positive driving pressure is 350 mmHg, maximum negative driving pressure minus 100 mmHg, pump rate 30–150 beats per minute with a relative systolic duration of 20–70%.

The system may be operated in univentricular or biventricular (BVAD) mode. A special feature is the option of independent control for each side concerning pump rate, systolic pump pressure, diastolic pump pressure, and length of systole.

Pump action in biventricular mode may be set to left/right synchronous for simultaneous, left/right asynchronous for alternating, and left/right separate for independent pump action. Electrocardiogram triggering may be used optionally. The possibility of separate rates for left and right pumps is especially important in the case of recovering right ventricular function in BVAD mode, where the pump minute volume of the right pump may have to be reduced to prevent pulmonary edema.

Special Equipment Considerations in Pediatric Patients

The selection of appropriate pump chamber sizes is of utmost importance, especially in pediatric patients. To ensure complete washout of the pump chamber with every stroke of the pump, a full-empty mode is advisable. Minimum pump rate during routine operation should not be set below 50 beats per minute. Because too large a pump chamber will result in a low pump rate with high stroke volume, high systolic blood pressures may occur (9). Maximum pump rate should not exceed 90 to 100 beats per minute because higher pump rates do not necessarily lead to higher PMV (7). Filling of the blood chamber may be compromised, and excessive driving pressures are needed for the desired full-empty mode.

Pediatric VAD pumps require higher compressor performances than adult pumps because a higher resistance to flow is created in the small diameter cannulae. Also, a higher pump rate than in adult patients may be necessary. Therefore, a driving unit with adequate power reserve must be used.

For pediatric patients we aim at a cardiac index of 3.0–3.5 L/min/m^2 of pulsatile flow. Under clinical conditions, the limiting factor for pump minute volume for a given pump size is pump preload in the majority of cases. A certain amount of flow loss because of high peak flows and

valve regurgitation should be taken into account. The range of pump minute volume for each pump size may be estimated as: (pump stroke volume × pump rate) –10% (Table 1).

For biventricular support, a pair of pumps with the right pump one size smaller than the left pump is usually used. If two pumps of the same size are in operation, the pump rate for the right pump may be set lower if desirable. Because in children with congenital heart disease, unclosed atrial septum defects may be prevalent, the option for independent regulation of PMV for the right and left side of the heart is a helpful tool for further optimizing cardiac support.

Device Management by Perfusionists

For implantation of the device, cardiopulmonary bypass (CPB) is instituted to facilitate the surgical procedure. Aortic cross clamping and cardioplegia are not necessarily needed. A second perfusionist will scrub at implantation and prepare the blood pump(s) at the operating table. The blood chamber is pressurized for a final leakage test. The de-airing cannula is inserted into the de-airing nipple over a small guiding needle and secured with two ligatures. The blood chamber is filled over the de-airing cannula with saline. Additional heparin administration into the saline is not necessary. After connection of the pump to the inflow and outflow cannula, any residual air in the system may be aspirated through the de-airing cannula. The pump is connected with the driving line and started at the driving unit in manual mode with single beats to check proper functioning of the system. The de-airing cannula is removed. When sufficient preload permits the start of the VAD, the driving unit is switched to a slow fixed rate. Pump rate, systolic pressure, diastolic pressure, and length of systole are then adjusted to achieve a full-empty mode of the pump(s) and the desired PMV while CPB is being discontinued. Protamine administration should be done carefully to avoid untimely dysfunction of the heparin coating.

For postoperative care, perfusionists and medical engineers will perform daily rounds to inspect the blood pumps and connection sites with the help of a strong flashlight. Any visible fibrin deposit or thrombus will be documented using a score system, and either cleaning of the pump to cannula connection or exchange of the blood pump will be performed when decided upon by the surgical team. At our institution, perfusionists and medical engineers are also involved in patient mobilization and transportation. Either a perfusionist or a medical engineer is available 24 hours a day in house for troubleshooting.

Table 1. Estimation for range of pump minute volume (PMV).

Pump Size	PMV 50 Min^{-1}	PMV 100 Min^{-1}
10 cc	0.45 L/min	0.9 L/min
25 cc	1.1 L/min	2.2 L/min
30 cc	1.3 L/min	2.7 L/min
50 cc	2.2 L/min	4.5 L/min
60 cc	2.7 L/min	5.4 L/min
80 cc	3.6 L/min	7.2 L/min

PATIENTS

The Berlin Heart VAD was used in a total number of 424 patients from 1987 to November 2001 at our institution. In 45 pediatric patients, aged 2 days–17 years (mean age, 7.8 years), the Berlin Heart VAD was applied for long-term support (1–111 days, mean 20 days). Left ventricular support was sufficient in 16 patients; biventricular support was needed in 29 patients.

The pediatric patients can be divided into three groups. Group I: "Bridge to transplantation": these patients had advanced chronic myocardial diseases with various forms of cardiomyopathy ($N = 21$) or were in end stages of congenital heart disease ($N = 9$). Life-threatening heart failure occurred before transplantion became possible. Implantation of the assist device was aimed at recovery of severe organ impairment to make subsequent heart transplantation feasible. Group II: "Rescue": in patients in whom heart failure early after corrective surgery for congenital heart defects occurred and who could not be treated with medication alone, cardiac support was initiated with the goal of keeping these patients alive to gain time for consideration of either weaning from the device or subsequent heart transplantation. In this group, patients were in intractable heart failure after corrective surgery for congenital disease ($N = 7$) or in early graft failure after heart transplantation ($N = 1$). All patients had at least one episode of cardiopulmonary resuscitation before implantation of the device. Group III: "Acute myocarditis": patients with acute viral myocarditis unresponsive to conservative therapy ($N = 7$) were also included in the assist device program. Weaning from the device was the goal for patients in this group.

Patient Outcomes

Seventeen patients were transplanted after support periods of between 4 and 111 days. Twelve long-term survivors have now been alive for up to 10 years after heart transplantation.

Five patients could be weaned from the assist device. These patients were in Group I ($N = 1$) and Group III ($N = 4$). Four patients are now long-term survivors, having lived for up to 6 years after weaning.

In Group II, only one patient survived after successful transplantation. All patients were in a serious state with multiorgan failure before implantation of the device. Patient deaths occurred for reasons related to pre-existing severe circulatory failure. Since 1992, the condition of these patients has been considered an indication for ECMO or centrifugal pump assist device at our institution (10).

All patients were anticoagulated with intravenous heparin infusion. Target activated clotting time (ACT) was 140–160 seconds, with PTT levels of 60–80 seconds. Coumadin was not used in the pediatric subgroup. Recently, additional antiplatelet therapy with acetylsalicylic acid and dipyridamole has been instituted more frequently in children to support the effects of heparin monotherapy.

DISCUSSION

Pediatric patients requiring mechanical cardiac assistance may have their circulation supported by either intraaortic balloon pumps (IABP), extracorporeal membrane oxygenation (ECMO), or VADs in form of either centrifugal pump VAD or pneumatic pulsatile VAD. With VADs, both univentricular or biventricular support is possible.

IABP may be an option for pediatric circulatory support and has successfully been used in infants (11,12). However, it has been used less frequently in pediatric patients, compared to adults, because of difficulties with inserting the catheters into small blood vessels, synchronization to rapid heart rates, and because of increased aortic compliance (13).

ECMO support is predominantly used for cardiac assistance in the majority of pediatric heart surgery departments (14). An advantage of this technology is the availability of the material and components. Also, ECMO support seems to be the only alternative where intracardiac shunts or associated lung failure make VAD support ineffective. ECMO may be more readily initiated on the intensive care unit when needed for patient resuscitation (15).

However, significant disadvantages of ECMO are the requirements for immobilization, intensive care monitoring, and higher doses of anticoagulation. Patients cannot be extubated and mobilized (14). This may play an important role when neurocognitive function has to be assessed (16), especially if a decision about possible heart transplantation must be made.

Furthermore, extended periods of ECMO increased the incidence of renal failure and sepsis. Renal failure, extended periods of circulatory support, and prolonged periods of cardiopulmonary resuscitation before initiation of ECMO were associated with high mortality (17). Capillary leak syndrome after CPB in children is associated with significantly increased morbidity (18) and has also been reported during ECMO use (19).

For children suffering from myocarditis, where prolonged support seems necessary for the recovery of native heart function, ECMO support may have its limitations (13).

Centrifugal pump VAD has been used successfully in the pediatric age group (20). It is a readily available, easy to use, and relatively cheap device. It is possible to use centrifugal pumps in univentricular or biventricular support mode. However, some of the limitations of ECMO technique apply here as well because patients must be kept immobilized and sedated for the time of support. In addition, the components of the system do not allow long-term assistance. Centrifugal pump VAD and ECMO may, therefore, not be the best options for patients requiring long-term cardiac assistance (21).

For bridging to transplantation, donor organ shortage has created the need for longer periods of circulatory assistance (10). Children on prolonged pulsatile VAD support may take part in everyday activities and have closer contact with their families when awake and extubated.

For patients requiring postcardiotomy support after resuscitation, pulsatile VAD support may not be suitable in every case, as compared to other methods of cardiac assistance. ECMO or support with centrifugal pumps may have its place for that patient group (8).

Myocardial recovery with VADs for patients with severe heart failure has been attributed to recovery of the circulatory system, reversal of left ventricular remodeling, and molecular remodeling attributable to prolonged unloading of the myocardium (22). Bridging to recovery with VADs can be accomplished not only in adults but also in children (23).

CONCLUSION

For a select group of pediatric patients, pulsatile mechanical cardiac assistance in the form of paracorporeal, pneumatic diaphragm pumps may be superior to other methods of circulatory support. In our institution, pulsatile VADs are preferred for patients where bridging to transplantation or bridging to recovery is intended. In the near future, implantable left VADs for children, based on the axial flow principle, may be a new option for prolonged cardiac assistance.

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