

Mechanical Ventricular Circulatory Support in Children; Bad Oeynhausen Experience

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Introduction: Recently various mechanical circulatory support systems are being used all over the world, nevertheless the size of the devices limits the implantation in pediatric cases. Accordingly we report our experiences with assist devices applied for pediatric patients.

Patients and Methods: Twenty-nine children underwent mechanical circulatory support implantation operation. The diagnoses of preoperation were dilated cardiomyopathy in 16, congenital heart disease in 12 and allograft dysfunction in 1.

Results: From November 1987 to January 2004 we implanted 7 LVAD, 11 BVAD and 11 ECMO in pediatric patients. The 29 patients were supported from 11 to 231 days (mean 32.3 days). Three children were supported by Thoratec LVAD. Biventricular Thoratec[®] VAD was used in 3 children. Three children were supported by Medos-HIA system LVAD, and 8 children by biventricular VAD using the Medos-HIA system. One child was supported by Novacor[®] LVAD. Fourteen children were supported by ECMO. We succeeded in heart transplantation in 10 cases, but lost 16 children during the support. Bleeding occurred in 7 cases, thrombosis occurred in 6 cases, infection occurred in 8 cases, pneumothorax occurred in 3 cases and neurological deficit occurred in 2 cases.

Conclusion: The development of assist device for children which has long durability and small in size as a future subject is desired. Further clinical and experimental research and application of those assist devices for children are in progress. (*Ann Thorac Cardiovasc Surg* 2005; 11: 307–12)

Key words: mechanical circulatory support, heart transplantation, pediatric patient

Introduction

The incidence of severe heart failure due to acute myocarditis, idiopathic cardiomyopathy and congenital heart disease (CHD) is estimated ca. 200 patients/1 million in

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Received February 15, 2005; accepted for publication March 16, 2005.

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Read at The 40th Annual Meeting of Japanese Society of Pediatric Cardiology and Cardiac Surgery, June 30-July 2, 2004, Tokyo, Japan.

Germany. Generally there are not enough donor hearts for children in any country, therefore we sometimes use the mechanical circulation support system for these children. In this respect the mechanical circulatory support system has been receiving increasing attention.

The aims for application of mechanical circulatory support are as follows:

- 1) To maintain systemic circulation
- 2) To avoid multiple organ failure
- 3) To bridge for heart transplantation

Recently, various mechanical circulatory support systems, centrifugal pumps or pneumatic assist devices, are being used worldwide, nevertheless the size of device limits implantation in pediatric cases. Accordingly we report our experiences with assist devices applied for pediatric patients.

Patients and Methods

790 cases underwent mechanical cardiac support operation at our hospital from November 1987 to January 2004. Twenty nine of them were pediatric cases (3.7%). In pediatric cases for mechanical circulatory support we have implanted extracorporeal membrane oxygenation (ECMO) by centrifugal pump, Thoratec ventricular assist device (Thoratec® VAD; Thoratec Corporation, Pleasanton, CA, USA), Novacor® ventricular assist device (Novacor LVAS; Baxter Healthcare Corp., Oakland, CA, USA) or Medos-HIA VAD system (Medos-Helmholtz Institute, Aachen, Germany). We used ECMO or left ventricular assist device (LVAD) or biventricular assist device (BVAD) for postcardiotomy heart failure. If the purpose was bridging for heart transplantation, we used a single ventricular assist device or BVAD.

Our indications for mechanical circulatory support are 1) low output syndrome under optimal inotropic support, 2) agitation, disturbed consciousness, 3) cardiac index <2 l/min/kg, 4) urine output <1 ml/min/kg, 5) central venous pressure >15 mmHg.

Patient population

Twenty nine children underwent mechanical circulatory support implantation operation. Table 1 shows clinical characteristics of patients. The preoperative diagnosis were dilated cardiomyopathy (DCM) in 16, CHD in 12 (transposition of great arteries (TGA):1, tetralogy of Fallot (TOF):1, double-inlet right ventricle (DILV) + TGA:1, ventricular septal defect (VSD):1, pulmonary artery atresia (PAA):1) and allograft failure in 1. Mean age was 5.2 years old (1.6-17.7 years old). Male and female ratio was 17/12. Patients weight ranged from 3.0 to 78.0 kg (mean 8.7 kg).

Type of devices

1) ECMO system

Our ECMO system has a Bio-Medicus centrifugal pump (Bio-Medicus Co, Eden Prairie, MN, USA) and oxygenation system. The outflow cannulation site was the ascending aorta and venous cannulation was the right atrium in all cases.

2) Thoratec

The pump is placed in the paracorporeal position and the system consists of prosthetic ventricles with a 65 ml stroke volume and appropriate cannulas for atrial or ventricular inflow and arterial outflow connections. Ventricular devices are controlled either with a hospital-based pneu-

Table 1. Clinical characteristics of patients

Age (year)	1.6-17.7 (m=5.2)
Male/female	17/12
Body weight (kg)	3.0-78.0 (m=8.7)
Diagnosis	Cases
DCM	16
CHD	12
(TGA;8, TOF;1, DILV+TGA;1, VSD;1, PAA;1)	
Allograft dysfunction	1

DCM, dilated cardiomyopathy; CHD, congenital heart disease; TGA, transposition of great arteries; TOF, tetralogy of Fallot; DILV, double inlet left ventricle; VSD, ventricular septal defect; PAA, pulmonary artery atresia

matic drive console or with a portable drive unit.¹⁾

3) Novacor LVAS

The system is partially implantable. The device is driven by electrical solenoid energy and has porcine valves in outflow and inflow. Ventricular device is controlled either with a hospital-based drive console or with a portable drive unit in the same way as the Thoratec controller.

4) Medos-HIA VAD system

The system is driven pneumatically, available in three different ventricular sizes of 10, 25, and 60 ml. For right ventricular, we are able to implant the 10% smaller sizes of 9, 22.5, and 54 ml. The system has been developed by Reul and coworkers at the Helmholtz Institute in Aachen, Germany. The system is not heparin coated and has polyurethane trileaflet valves.

Thoratec®, Novacor® or Medos-HIA systems were placed using a median sternotomy with a cardiopulmonary bypass in all cases. In the left ventricle assist case, the outflow cannulation site was the ascending aorta and inflow cannulation was the apex of the left ventricle in all cases. Otherwise in right ventricle assist cases the outflow cannulation site was the pulmonary artery and the inflow cannulation was the right atrium.

Results

Device support

From November 1987 to January 2004 we implanted VAD for 29 pediatric patients; LVADs in 7 cases, BVADs in 11 cases and ECMOs in 11 cases. The mean duration of the supporting time was 32.3 days (range from 11 days to 231 days). The mean duration of the patients in whom the ECMO system was implanted was 3.1 days. With the Medos-HIA system the mean duration of the patients was

Table 2. Mechanical ventricular circulatory support

Assist devices	Cases
LVAD	7
BVAD	11
ECMO	11 (+3)
Systems	Cases
Thoratec	
LVAD	3
BVAD	3
Medos-HIA	
LVAD	3
BVAD	8 (3 after ECMO)
Novacor LVAD	1
ECMO	14
Results	
Support time (days)	11-231 (m=32.3)
Heart transplantation	10 (34.5%)
Death during support	15 (51.7%)

LVAD, left ventricular assist device; BVAD, biventricular assist device; ECMO, extracorporeal membrane oxygenation

23.8 days. The patients with an implanted Thoratec system had a mean duration of 72.8 days.

Three children were supported by Thoratec LVAD. Three children were supported by biventricular Thoratec® VAD. In Thoratec® VAD cases the mean body weight of patients was 42.3 kg. Three children were supported by the Medos-HIA system LVAD. Eight children were supported by the Medos-HIA system BVAD. Three of them were exchanged to the Medos-HIA system from ECMO. On 3 children we used a 10 ml pump for left ventricle. The mean body weight was 4.1 kg. On another 8 children we used a 25 ml pump for left ventricle. The mean body weight was 16.4 kg. One child was supported by Novacor® LVAD (body weight was 78.0 kg). Fourteen children were supported by ECMO (Table 2). The mean age of those with ECMO supported was 4.2 years old, whereas the mean age of patients with VAD was 12.7 years old.

Complications

Table 3 presents the complications in those children. The major complications were bleeding, thrombosis and infection. Bleeding occurred in 7 cases (24.1%), thrombosis occurred in 6 cases (20.7%), infection (local or system) occurred in 8 cases (28.3%), pneumothorax occurred in 3 cases (10.3%) and neurological deficit occurred in 2 cases (6.9%). A bleeding complication was defined as blood loss of more than 1,500 ml/m² in 24 hours. A neurologic complication was defined as neurologic deficits

Table 3. Mechanical ventricular circulatory support

Complications during MCS	Cases (%)
Bleeding	7 (24.1)
Thrombembolism	6 (20.7)
Infection (local or system)	8 (28.3)
Pneumothorax	3 (10.3)
Neurological deficit	2 (6.9)

MCS, mechanical circulatory support

proven and differentiated by computed tomographic scan. Infection definition included several parts: a pocket infection was defined as being associated with local signs of infection with purulent secretions and with positive bacterial cultures. The presence of a septic complication was indicated by a body temperature above 38.5°C, white blood cell count more than 12,000/mm³, high output states, low systemic vascular resistance, and positive blood cultures.

Outcome

Figure 1 shows our latest results. In the LVAD implanted group, 5 children received heart transplantation, 1 child died and 1 case was weaned from LVAD and is still alive now. In the BVAD implanted group, 3 received heart transplantation and another 8 died. In the ECMO implanted group, 2 of them received heart transplantation, 7 died and 2 were weaned off from ECMO and are still alive now.

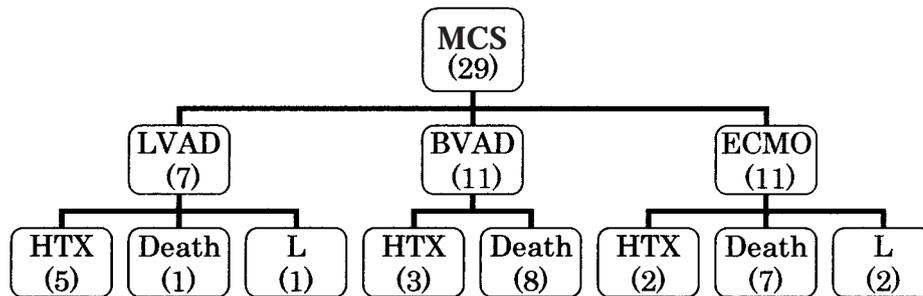
We succeeded in heart transplantation in 10 cases (34.5%), but lost 16 children during the support. Total survival rate was 44.8%.

Discussion

In recent years the number of pediatric patients who require heart transplantation has increased. About a quarter of pediatric patients die while awaiting heart transplantation. During this time, many patients need extensive circulatory support, for example high dosed inotropic support or circulatory assist device. In end-staged patients to avoid multiple organ failure; renal failure or liver dysfunction, some kind of mechanical circulatory support is necessary.^{2,3)}

There are a lot of reports that describe successful use of ECMO as a bridge to heart transplantation in pediatric patients.^{4,5)}

ECMO is the most familiar and readily available, but is not suitable for long term use in contrast to other assist devices. The ECMO sustains the circulation for several



LVAD, left ventricular assist device; BVAD, biventricular assist device; ECMO, extracorporeal membrane oxygenation; L, weaned off and alive; HTX, heart transplantation; MCS, mechanical circulatory support

Fig. 1. Outcome after mechanical circulatory support in 29 children.

days, maximal a few weeks.⁶⁻⁸ The ECMO system requires constant monitoring and adjustment by a perfusionist or a physician. Furthermore, we have to be concerned about the risk of bleeding or infectious complications. Patients usually cannot be extubated and mobilized.⁹ Furthermore, vascular access has been a problem in ECMO cannulation. Even the question of whether the use of the carotid artery for outflow induces neurological complications is now controversial. The ECMO system is very easy to implant, but we found two problems, one of them is that the durability is very short, the other is that the flow of device is not a pulsatile flow. Levi et al. described that patients with pulsatile VAD had stable hemodynamics and a high quality of life.⁵ The use of ECMO after cardiac surgery has shown to be successful especially in small children with myocardial failure. If there is no pulmonary dysfunction, ECMO is not always the optimal method for prolonged circulatory support. The advantages of ECMO systems are easier cannulation and oxygenated support in pulmonary dysfunction.¹⁰

Some authors reported the usefulness of an intraaortic balloon pump.^{11,12} Nevertheless, the effectiveness of intraaortic balloon pumps is still limited in small children and infants by increased aortic elasticity, rapid heart rate with small stroke volumes, and the difficulty of insertion into a small artery. Furthermore the intraaortic balloon pump has limited effectiveness in patients who suffer from right heart dysfunction.¹¹

The VAD by centrifugal pump is easy to use and available world widely. Several recent reports describe the ability of the VAD by centrifugal pump.¹³⁻¹⁵ If necessary, two centrifugal pumps are used for biventricular assistance.

Certainly the cost is relatively inexpensive. However, as with the ECMO system too, patients cannot be mobilized and must stay in the intensive care unit.¹⁶ Duncan and coworkers reported the availability of the ECMO and the VAD by the centrifugal pump. In that report they treated 106 children (67 cases ECMO, 29 cases VAD). In the ECMO group 45 cases were successfully weaned off and 27 cases survived. In the VAD group 19 cases were successfully weaned off and 12 cases survived.¹³ However, the median duration of support was relative short; 4.8 days in the ECMO group and 1.8 days in the VAD group.

Since 1990 new assist devices for pediatric patients are available in Germany. One of them is the Medos-HIA VAD system, another one is the Berlin Heart VAD. Both those new assist devices are pulsatile VAD, in the paracorporeal position. Children on prolonged pulsatile VAD support may take part in everyday activities and have closer contact with their families when awake and extubated.¹⁶

There were less hemorrhagic and thromboembolic complications than with the ECMO system.¹⁷⁻¹⁹ We had 11 pediatric cases with these devices. Three of them were implanted as LVAD, the other as BVAD.

Another Berlin Heart VAD (Berlin Heart AG, Berlin, Germany) is driven pneumatically, too, and the ventricular has a variation of seven sizes; 12, 15, 25, 30, 50, 60, and 80 ml. The device has mechanical monodisc valves (Sorin Biomedica Cardio S.p.A, Saluggia, Italy) or polyurethane trileaflet valves, and is coated by heparin.^{6,18,20} We have no experience with the Berlin Heart VAD. Merkle and coworkers¹⁶ reported their experiences with the Berlin Heart VAD. They reported 45 cases with the Berlin Heart VAD system. According to the report in 45 pedi-

ric patients, aged 2 days-17 years, the system was implanted for long-term support (mean 1-111 days). The weaning rate was 11.1% and they succeeded in heart transplantation in 17 cases.¹⁶⁾

Thoratec® VAD is available worldwide for cardiac failure in children or in adult patients. The availability is already shown by many reports.¹⁾ We have reported the availability for a bridge to heart transplantation. Thoratec® VAD has been used in more than 100 patients in our hospital with different indications and we have had no major technical problems. The size of the device console and the paracorporeal location of the blood pumps make the system unsuitable in some patients for long time support.^{1,21)}

HeartMate® VAD (Thermo Cardiosystems Inc., Woburn, Mass, USA) or Novacor® VAD is implantable in the body of the patient, the patients are able to have a good quality of life with a portable battery and controller, and patients are able to go home while awaiting transplantation. Nevertheless, those implantable assist devices are designed for adult patient and are not suitable for relatively small children.

For the patient awaiting heart transplantation, it is important, that the device has long durability. A lot of reports have shown that HeartMate® VAD and Novacor® VAD have good durability. But those devices are mainly used for adult patient with a relatively large body surface area (>1.8 m²).²²⁾ HeartMate® VAD or Novacor® VAD could be applied for adolescent patients with body surface area >1.5 m² in need of long-term circulatory support.

Duncan et al. reported a recovery rate of 60% in pediatric patients with fulminant myocarditis treated with mechanical support and total survival rate including transplantation was 80%.²³⁾ Survival rate of the postcardiotomy heart failure was reported from 30% to 70%.¹¹⁾ Our results showed that overall survival rate was 44.8%. We consider our result appropriate, as we had no patients with acute myocarditis.

Conclusion

Our experience has shown that 1) an extracorporeal circulatory support for example ECMO system is suitable for small children, 2) a paracorporeal circulatory support for example Thoratec® VAD or Medos-HIA system is for relatively larger children, or necessary biventricular support and 3) an implantable device, for example Novacor LVAS, is for large children and patients in need of long time support as bridging to heart transplantation.

The development of an assist device for children which has long durability as is desirable. Further clinical and experimental research and application of those assist devices for children are in progress.

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