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## **Ventricular assist devices in pediatrics**

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## **Abstract**

The implantation of a mechanical circulatory device for end-stage ventricular failure is a possible therapeutic approach in adult and pediatric cardiac surgery and cardiology. The aim of this article is to present mechanical circulatory assist devices used in infants and children with special emphasis on extracorporeal membrane oxygenation, Berlin Heart assist device, centrifugal pump and Medos assist device. The success of long-term support with implantable ventricular assist devices in adults and children has led to their increasing use as a bridge to transplantation in patients with otherwise non-treatable left ventricular failure, by transforming a terminal phase heart condition into a treatable cardiopathy. Such therapy allows rehabilitation of patients before elective cardiac transplantation (by removing contraindications to transplantation mainly represented by organ impairment) or acting as a bridge to recovery of the native left ventricular function (depending on underlying cardiac disease). Treatment may also involve permanent device implantation when cardiac transplantation is contraindicated. Indications for the implantation of assisted circulation include all states of cardiac failure that are reversible within a variable period of time or that require heart transplantation. This article will address the current status of ventricular assist devices by examining historical aspects of its development, current technical issues and clinical features of pediatric ventricular assist devices, including indications and contraindications for support.

**MeSH:** Ventricular assist device, ECMO, Centrifugal pump, Heart failure, Medos, HeartMate, Berlin Heart, Thoratec, Jarvik 2000

## Definition

A ventricular assist device is a pump that is attached between the heart and the aorta or pulmonary artery which helps to circulate a person's blood when the heart can no longer adequately support circulation. The aim of such a device is to unload the heart and to provide an adequate peripheral circulation with sufficient organ function. In reducing cardiac work and oxygen consumption the required energy for repair processes and synchronized heart performance can be spared and leads to a quicker recovery of “stunned” myocardial segments.<sup>1</sup>

There is great interest in implanting ventricular assist devices for circulatory support in children. Ventricular assist devices of various design and function principles have been used for temporary support of failing hearts aiming at myocardial recovery or keeping the patient alive until later transplantation. Despite improvements in operative techniques, management of cardiopulmonary bypass and myocardial protection, myocardial dysfunction can occur after operation for complex congenital heart disease with involvement of the left and right ventricle.<sup>2</sup> Approximately 5 % of children undergoing open heart surgery need mechanical circulatory assistance.<sup>3</sup> Reports of ventricular assist device support in smaller children (< 20 kg) remain limited.<sup>2</sup> This is partly due to technical considerations, for example, low flow rates may be a risk for thromboembolic complications when adult-sized systems are applied in children.<sup>4</sup> Moreover, left ventricular assist devices can only be inserted when intracardiac shunts are closed, and right ventricular assist devices require some kind of pulmonary valve.<sup>5</sup>

Owing to the lack of sufficiently small, commercially available valves, and the tendency for thrombus formation in small pumps, the attempt to scale down adult blood pumps for pediatric use remains difficult. However, the need for pediatric ventricular assist devices is increasing: first owing to the possibility of corrective operations for many previously inoperable forms of complex congenital heart disease in younger and smaller patients than before, and second, to the success of pediatric heart transplantations which leads to an increase of the number of transplant candidates and of the waiting time for the rare donor organs.

A surgical infrastructure consisting of a well equipped neonatal and pediatric intensive care unit and a permanently accessible laboratory for monitoring coagulation status is needed to obtain satisfactory results.

## History of ventricular assist devices in adults

To repair and replace a heart a medical dream. The first concept of circulatory support as a prosthesis that could replace the heart and sustain sufficient flow for peripheral circulation was probably postulated by the French physician Legallois in 1812.<sup>6,7</sup> In 1849 Loebell began his work on an isolated kidney model and in 1854 Claude Bernard conducted the famous *foie lavé* experiment.<sup>8</sup> Between 1848 and 1858 Brown-Séguard demonstrated the need to oxygenate the blood that was used as perfusion solution. In 1868 Ludwig and Schmidt achieved extracorporeal oxygenation, using venous blood-gurgle in a flask. Von Schroeder built the first steady-flow bubble oxygenator in 1882; Frey and Gruber developed the first film oxygenator in 1885. In 1916 McLean discovered heparin, which allowed the blood to circulate through artificial

tubes for a longer time. Dale and Schuster in 1928 were the first to construct a diaphragm pump. The transatlantic flyer Lindbergh, spurred on by his sister-in-law's heart disease, together with Carrel, developed an oxygenating pump, and demonstrated the possibility of extracorporeal perfusion. In 1934 DeBakey introduced the concept of a continuous flow blood transfusion instrument that was a simple roller pump.<sup>9</sup> In 1937 Gibbon described a heart-lung machine and reported on first animal experiments. In 1954 Gibbon carried out the first successful human open heart operation (atrium septal defect closure on a 18 year old girl) with the use of the heart-lung machine.<sup>10,11</sup> In 1957 Akutsu and Kolff implanted two compact pumps into a dog's chest following cardiectomy. In 1961 Dennis performed a left heart bypass by inserting cannulae in the left atrium and returning blood through the femoral artery.<sup>12</sup>

In 1962 Kolff and Mouloupoulos developed the intraaortic balloon pump and demonstrated their value in an animal model.<sup>13</sup> In 1966 Kantrowitz performed its first clinical application in a 45-year-old woman in cardiogenic shock.<sup>14</sup> In 1963 Spencer supported a 6-year old girl after an operation to repair a ventricular septal defect.<sup>15</sup> In 1964 Liotta published results from the first clinical implantation of a pulsatile left ventricular assist device.<sup>9</sup> In 1968 Raffert reported on a centrifugal pump for blood pumping. In 1969 Cooley implanted the first artificial heart, keeping the patient alive for over sixty hours. The Jarvik-7 artificial heart, named after its designer Robert K. Jarvik, an American physician, was first used during the early 1980s<sup>16</sup> and in 1982 a team led by DeVries of the University of Utah implanted the Jarvik-7 for the first time. The patient survived with a Jarvik-7 for 112 days. At that time patients were anchored to large consoles with poor quality of life. The Jarvik-7 was further developed by Cardiowest and is nowadays known as CardioWest Artificial Heart.

The Novacor LVAD (Baxter Corp., Oakland, CA), initially designed for permanent use, has been used as a bridge to transplantation since 1984. Unlike Jarvik this ventricle is placed heterotopically below the diaphragm allowing the natural heart to remain in place.<sup>17</sup> Early systems required a large console but eventually, a wearable version, supported by a small electronic controller and batteries worn on a belt, was introduced in 1993.<sup>18–20</sup>

Since 1987 centrifugal Biomedicus pump started in clinical use. In 1988 "Berlin Heart" (Berlin Heart Institut, Mediport Kardioelektronik Berlin, Germany) pumps became available.<sup>21</sup> The first HeartMate ventricular assist devices were implanted in 1992. The Medos ventricular assist device has been in clinical use since 1994 with the first implantation in an adult patient performed by Sievers. In 1994 Abiomed BVS 5000 ventricular assist device became available at Hahnemann University Hospital, Philadelphia, PA.<sup>22</sup>

## History of ventricular assist devices in children

Despite the success of ventricular assist devices in adults, little has been done to develop similar devices for pediatric patients. Scientific and engineering efforts have all been focused on heart-lung machines and circulatory support systems for adults. Indeed, the first neonatal oxygenator was released in the 1990s.<sup>23</sup> In 1973 Soeter described the use of extracorporeal life support in a 4-year-old girl with severe hypoxemia after repair of Tetralogy of Fallot.<sup>24</sup> The system employed used a rotary pump with a membrane oxygenator and a heat exchanger. The patient was weaned from the support within 48 hours and was discharged on the 13th postoperative day. In 1974 Bartlett reported the use of extracorporeal membrane oxygenation in pediatric patients with respiratory failure or after repair of congenital heart disease.<sup>25,26</sup> Hill and Pyle described two patients who had severe postcardiotomy dysfunction, and who both died despite the implantation of extracorporeal membrane oxygenation.<sup>27,28</sup> In 1989 the Extracorporeal Life support Organization was founded as an organization to study the clinical use of extracorporeal membrane oxygenation and maintained the Extracorporeal Life support Organization registry which compiles data on the use of extracorporeal membrane oxygenation. These data show that pediatric cardiac support has accounted for approximately 13 % of total extracorporeal membrane oxygenation utilization.<sup>29</sup>

In 1980 Pollock reported the first use of an intraaortic balloon pump in children,<sup>30</sup> when a 6 year old child was pumped following a cardiac operation. In 1983 Veasy reported the use of small balloon catheters in 15 children.<sup>31</sup> Despite the commercial availability of pediatric-sized balloon catheters in the early 1980s, intraaortic balloon pump for children and infants has not become widespread.

The Thoratec ventricular assist devices (Thoratec Laboratories Corporation, Pleasanton, CA) have been available since the early 1980s, and can be implanted in children and adolescents.<sup>32</sup> Ventricular assist devices using centrifugal pumps have been used for infants and children since the development of a pediatric centrifugal pump head by Medtronic Bio-Medicus (Eden Prairie, MN) in the late 1980s.<sup>33–35</sup>

In 1992, the “Berlin Heart” offered the first commercially available system with miniaturized paracorporeal pumps and cannulae.<sup>21</sup> In the same year an 8-year-old child was supported with a Berlin Heart for 8 days in intractable circulatory failure, followed by a successful transplantation and an uneventful postoperative course.<sup>21</sup> The first implantation of a Medos ventricular assist device as a bridge to transplant took place in 1994.<sup>36</sup>

## **Types of ventricular assist devices**

The use of temporary ventricular assist devices in adults and children is now routine, and the development of permanent ventricular assist devices and total artificial hearts is the subject of ongoing research in the United States, Europe, Australia, Japan, China, Korea, Russia and other countries. A detailed description of all these devices is beyond the scope of this document and only those with significant design features or devices sufficiently developed to be nearing clinical trials will be discussed.

Blood pumps are divided into two main groups according to the nature of their flow: nonpulsatile and pulsatile pumps. Nonpulsatile pumps produce flat continuous flow in which there is no pulse pressure. These pumps include centrifugal pumps and axial flow pumps. As a bridge to cardiac transplantation in adults the most widely used devices are those with pulsatile flow (Abiomed, Thoratec, Novacor, Berlin Heart, Heart Mate, Medos). In these devices blood is forced by positive pressure produced by the pump, squeezing the artificial ventricle which is contained within a rigid shell. Overall survival rates range in non-pulsatile centrifugal pumps is between 25 - 40 %<sup>2,37,38,39</sup> and in the pulsatile pneumatic or electromechanical pumps between 25 - 80 %.<sup>40,39,38</sup>

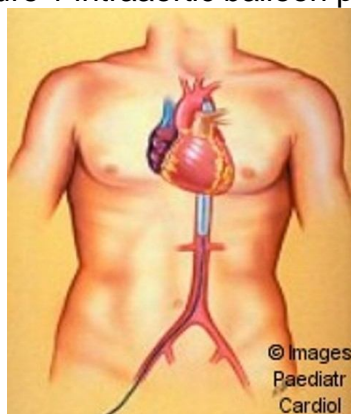
Different devices function similarly. Blood is generally drawn at left/right atrial/ventricular level, run into an artificial ventricle and is reintroduced at aortic and/or pulmonary level. With these systems it is possible to maintain a paraphysiological circulation for long periods of time.

Energy sources are pneumatic for devices like Thoratec, Abiomed, Medos, Berlin Heart, Heart Mate and electric for extracorporeal membrane oxygenation, Novacor and Heart Mate. The patient's hemodynamic characteristics determine the use of mono- or biventricular assist devices. Implantation of left ventricular assist devices is contraindicated in the presence of high pulmonary vascular resistance, shunting or if, shortly after implantation of left ventricular assist device, fall in cardiac index, reduced diuresis and central venous pressures > 25 mmHg are recorded: in these cases a biventricular device is needed. In children such problems as low cardiac output syndrome and right heart failure including pulmonary vasoreactive crises after cardiac operations are common.<sup>4</sup>

### Intraaortic balloon pump

Set-up	Sausage shaped flexible balloon pumping chamber which works by counterpulsation, inflating and then decompressing out of phase with the cardiac cycle. <sup>14</sup>
Position	Percutaneous placement by femoral artery approach, ideally positioned with its tip overlying the aortic knob in the frontal view radiograph of the chest <sup>42</sup> or directly placed in the aortic arch. In children implantation of intraaortic balloon pump often is an invasive procedure requiring femoral artery cutdown or insertion through the aortic arch. <sup>41</sup>
Sizes	Pediatric balloon sizes are available from Datascope Corporation (Paramus, NJ). Standard volumes of balloons used in children are 2.5 - 20 ml in volume and are mounted on 4,5 - 7,0 French catheters.
Anticoagulation	There is no need for anticoagulation.
Function	Managing acute left ventricular dysfunction after myocardial infarction or cardiac surgery predominantly in adult persons. <sup>41</sup> Increasing of diastole blood flow to coronary arteries and other core organs by increasing blood pressure during diastole. Significant decrease in oxygen consumption by deflating, as myocardial work and strain diminish with decrease in afterload. Partial cardiovascular assistance, supplementing cardiac output by 20 - 30 %.
Survival/support times	12 % of adults undergoing cardiac surgery receive intraaortic balloon pump as ventricular assist device support, the survival of patients supported with balloon pumps after cardiac surgery range from 20 - 50 %. <sup>43</sup> It is often in place for days, occasionally for weeks. The largest experiences with intraaortic balloon pump in children have been published by Pollock <sup>30</sup> and Del Nido <sup>46</sup> . Pollock reported 14 children that underwent intraaortic balloon pump following cardiac operation. 43 % were long-term survivors, all children < 5 years died. Del Nido reported successful intraaortic balloon pump in a 2 kg infant, there was no correlation between patient age and survival. In another study <sup>47</sup> patient ages ranged from 5 days - 18 years; weight ranged from 4.2 - 40 kg; the survival in children under 3 years of age was 75 %. Park reported a survival of 44 % (4 of 9 children) in children with left ventricular dysfunction after cardiac surgery. <sup>45</sup>
Use in pediatrics	Limited number of implantations in children and infants owing to <ul style="list-style-type: none"> <li>* to the difficult insertion into small vessels with the risk of local arterial injury despite the utilisation of pediatric material,<sup>30,31</sup></li> <li>* to an increased aortic compliance which limits the effects of the inflation of the balloon for the diastolic pressure<sup>30</sup> and</li> <li>* a difficult synchronization to a rapid heart rate or arrhythmias.<sup>44</sup></li> </ul>
	Pollock reported intraaortic balloon pump to be ineffective in children less than 5 years of age because of the greater compliance of the small aorta. <sup>30</sup> Despite these facts clinical diastolic augmentation even in infants is reported. <sup>31</sup> Because measurement of cardiac output, coronary blood flow and afterload reduction are difficult in children, physiological benefits in using intraaortic balloon pump in children are indirectly measured such as by an increase in urine output. <sup>45</sup>

Figure 1 intraaortic balloon pump



## Extracorporeal membrane oxygenation (ECMO)

Set-up	The extracorporeal membrane oxygenation device consists of an arteriovenous or venovenous circuit, <sup>48</sup> a membrane or hollow fiber oxygenator, roller pump and heat exchanger.
Position	Transthoracic cannulation is performed in patients requiring extracorporeal membrane oxygenation support in the operating room or in cases of cardiac arrest in the immediate postoperative course. The venous cannula is implanted directly transthoracic in the right atrial appendage, the arterial cannula in the ascending aorta. Peripheral cannulation is performed in patients without cardiac surgery or in patients who require extracorporeal membrane oxygenation later in their postoperative course. Neck cannulation with cannulation of the right internal jugular vein and the common carotid artery is performed in neonates and children below 15 kg in weight whereas children and young adults are often cannulated via the femoral vessels. <sup>23</sup> Cannulae must be as short as possible to keep the volume of circulating blood as low as possible and to avoid loss of temperature.
Anticoagulation	Status of each patient's anticoagulation is monitored by whole blood activated clotting time. Continuous intravenous administration of heparin is monitored by activated clotting time levels of 180 - 200 seconds and measurement of anti Xa every six hours. <sup>48</sup> Activated clotting time can be maintained at lower levels if significant bleeding occurs. Platelets are maintained above 100.000/dl or above 150.000/dl in patients where bleeding is a critical problem and fibrinogen has to be maintained in levels above 100 mg/dl. <sup>23</sup>
Function	There is no direct cardiac pump support in using a venovenous circuit, but by eliminating hypoxia and decreasing pulmonary vascular resistance the right ventricular function can be improved. <sup>48</sup> Instead of roller pumps centres centrifugal pumps can be used, which maintain venous inflow dependent of gravity drainage and enable an adequate venous return at higher flow rates. <sup>49</sup> A disadvantage of using centrifugal pumps is the high negative pressure on the venous side possibly leading to hemolysis. <sup>49</sup>
Weaning	Decision of removal is based upon echocardiographic evaluations of the contractility of the left ventricle. An excellent indicator is the maintenance of an average pulsatile arterial pressure of more than 60 mmHg with low central venous pressures (< 8 - 10 mmHg), <sup>48</sup> ventilatory support and inotropic medication should be increased in appropriate levels. <sup>49,50</sup> At the time of weaning, flows are gradually turned down over several hours or days. Surgical removal of supporting systems depends on hemodynamic stability during minimal performance of the pump (< 0.08 l/min.) for more than 2 hours. Return of ventricular function in terms of a pulsatile waveform should be visible within 48 - 72 hours. <sup>23</sup> Those patients without return of ventricular function after 72 hours of support are considered for transplantation or termination of support if there are contraindications to transplantation. <sup>23</sup>
Survival/support times	Survival rate for neonatal and pediatric cardiac patients supported by extracorporeal membrane oxygenation reported by the Extracorporeal Life support Organization registry has been 42 %. <sup>29</sup> In a study by Duncan two thirds of all cardiac and non-cardiac extracorporeal membrane oxygenation patients could be weaned from support and 40 % survived to hospital discharge. <sup>48</sup> In other studies weaning rates varied from 45 - 80 %. <sup>3,44,49,51-54</sup>
Complications	Hemorrhagic events, severe hemolysis, infections, neurological and renal complications are reported in different studies as possible complications. <sup>3,48,51,52,55-56</sup>
Causes of death	Main causes of mortality include ventricular failure, multiple system organ failure, respiratory failure, anoxic brain injury, intracranial hemorrhage and arrhythmias. <sup>23,57-58</sup>
Use in pediatrics	Exclusive use in pediatric patients.

Figure 2 extracorporeal membrane oxygenation in a 7 days old child after Damus-Kaye-Stansel operation



### Centrifugal pump ventricular assist device

Set-up	The circuit consists of a centrifugal pump head and a flow probe, PVC tubing, aortic and venous cannulae and pump inlet and outlet pressure monitoring lines. Centrifugal pumps run at constant speed, there are no valves or diaphragms and the output is non-pulsatile. To install pulsatile flow it is possible to combine Biomedicus left ventricular assist device with an intraaortic balloon pump to augment diastolic filling and unload the left ventricle. <sup>59</sup>
Position	Placement on conventional extracorporeal circuit, when the cannulae have been brought across the skin via tight-fitting skin incisions, the pump is connected, deaired and assist circulation begins.
Sizes	For infants and children < 10 kg the 50 ml Bio-Pump, and for children > 10 kg the 80 ml Bio-Pump.
Anticoagulation	Systemic heparin anticoagulation is installed when postoperative bleeding subsides, activated clotting time levels are kept around 140 - 150 seconds, <sup>2</sup> while other authors report activated clotting time levels of 180 - 200 seconds, <sup>35,62</sup> platelets should be maintained at levels >100,000/dl, fibrinogen > 195 mg/dl. When using Carmeda heparin bonded tubes (Medtronic, Minneapolis, MN) activated clotting time levels can be maintained at 160 - 180 seconds. <sup>35</sup>
Function	Blood enters at the apex of the cone shaped pump and is ejected tangentially at the base of the cone. The constrained vortex pump design results in subatmospheric pressure at the tip of the cone and establishing suction in the venous cannula. <sup>2</sup> Blood derives from left or common atrium and is delivered to the ascending aorta. When inserted, good contraction of the right ventricle and right atrial pressure less than 12 mmHg indicate that right ventricular function is adequate to use this ventricular assist device. The centrifugal pump ventricular assist device is also capable of biventricular cardiac support using a right atrial/pulmonary arterial plus left atrial/aortic cannulation by using two pump heads, <sup>2</sup> but normally, if either the right ventricular or pulmonary function is inadequate, extracorporeal membrane oxygenation is required. <sup>60</sup> Reduction in preload and wall stress leads to a reduction of inotropic support. Centrifugal ventricular assist device can therefore improve myocardial function in dilated, poorly contracting hearts by reducing endsystolic and enddiastolic pressures and ventricular wall stress. <sup>61</sup> Decreased left atrial pressure reduces pulmonary capillary hydrostatic pressure which can avoid the need for increasing ventilatory support and reduces the risk of right ventricular failure.
Weaning	Improvement of ventricular function shows in the appearance of pulsatile systemic pressure traces at full flow. Transesophageal echocardiographic assessment of ventricular contractility and a positive Starling response on a reduced degree of ventricular assist device support are considered to be indications of myocardial recovery and therefore possible weaning. <sup>50</sup> Flow will be gradually reduced to a minimum of 150 ml/min.
Survival/support times	Survival was 24 % in a subset of 34 patients with a median age of 60 days and a median weight of 3.7 kg (1.9 - 5.9 kg). <sup>2,60</sup> Median support times are 70 - 75 hours. <sup>2,35</sup> Left ventricular centrifugal assistance allows survival of 24 % <sup>2</sup> - 45 % <sup>2,37-39</sup> until hospital discharge depending on patient's age and weight.
Complications	Bleeding, hemolysis, sepsis, neurological and renal defects. <sup>2,37,63</sup>
Causes of death	Ventricular failure, coagulopathy and arrhythmias. <sup>2,37</sup>
Use in pediatrics	Centrifugal assistance pump can be implanted in infants and children (in a study an infant aged 2 days and weighed 1.9 kg). <sup>2</sup> The centrifugal pump ventricular assist device (Bio-Pump, Bio-Medicus, Eden Prairie, MN) is a widely used ventricular assist device in pediatrics.

Figure 3 Bio-Pump blood pump





### Berlin Heart

Set-up	Berlin Heart ventricular assist device (Mediport Kardioteknik, Berlin, Germany) consists of a paracorporeal air-driven blood pump constructed of a polyurethane housing with an integrated diaphragm that forms a continuous interior blood contact, cannulae for connection of the pumps to heart chambers and great vessels and electro-pneumatic driving systems able to cope with high resistance of small-bore cannulae for pediatric patients (IKUS-2000-Driver by Mediport Kardioteknik, Berlin, Germany). <sup>21</sup> Blood and air chamber are separated by a multilayer, very thin and flexible membrane. <sup>64</sup> The electropneumatic console unit is capable of operating two blood pumps in an alternate left-right fixed rate mode. The semi-portable unit (weighing less than 10 kg) has a complete redundant backup system and an internal energy source enabling independent operation for more than 6 hours.
Position	Placement on conventional extracorporeal circuit, when the cannulae have been brought across the skin via tight-fitting skin incisions, the pump is connected, deaired and assist circulation begins.
Sizes	Blood pumps are available in sizes 12, 15, 25, 30, 50, 60 and 80 ml. <sup>21</sup> In the 50, 60 and 80 ml pumps mechanical mono-disc valves or polyurethane trileaflet valves are available. For small blood pumps (12 and 15 ml) an elastic polyurethane reservoir between atrial cannula and inflow chamber port is interposed improving chamber filling. <sup>21</sup> A Dacron cover in the middle part of the cannulae allows rapid ingrowth of patient's tissue as a biological barrier against infections. <sup>63</sup>
Anticoagulation	Continuous heparin infusion is maintained to keep an activated clotting time of 160 - 180 seconds. <sup>21</sup>
Function	Maintenance of circulation in infants and children threatened by imminent heart failure despite aggressive medical treatment and artificial respiration. A gain in time to restore organ function, decrease of capillary leakage and edemas (reduced capillary leakage in biventricular assist device due to pulsatile flow and less contact with synthetic surfaces), extubation, mobilization and the possibility to assess neurological status after regaining consciousness. If there is no improvement in myocardial function on biventricular assist device, there is an opportunity for transplantation.
Weaning	In a study weaning was performed in 3 of 34 pediatric cardiac patients after changing to extracorporeal membrane oxygenation for easier gradual weaning. <sup>21</sup>
Survival/support times	In a study using Berlin Heart assist device in 34 children (mean age 11.9 years, ranging from 6 days to 16 years) with severe cardiac failure as bridge to transplant, as rescue therapy after operation for congenital heart disease or in myocarditis, average support time was 17.9 days (9 hours - 111 days), survival time was 56%. <sup>21</sup>
Complications	Neurological events, bleeding after assist implantation and infections. <sup>21</sup>
Causes of death	Sepsis, multiorgan failure, pulmonary failure and hemorrhage. <sup>21</sup>
Use in pediatrics	The problem of limited pericardial space is the major surgical concern for ventricular assist device implantation in children especially in cases requiring biventricular support needing four cannulae. Children with dilated cardiomyopathy can therefore profit from biventricular assist device systems like the Berlin Heart. It is essential to mobilize children as soon as possible to improve their physical condition for later transplantation.

Figure 4 Berlin Heart ventricular assist device

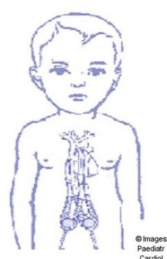


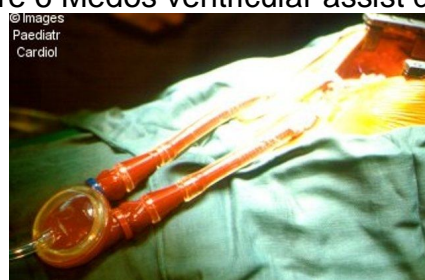
Figure 5 Berlin Heart pediatric pump



### Medos

Set-up	Medos consists of a pneumatically driven extracorporeal pump completely made of polyurethane including inflow and outflow valves that house in a conduit simulating aortic sinuses. The blood pump incorporates a multilayered diaphragm, which separates the blood flow chamber from the pneumatic drive chamber of the device. By using polyurethane trileaflet valves which are incorporated into the ventricular assist device high pump rates with low transvalvular gradients, rapid closure and minimal regurgitation can be achieved. <sup>68</sup>
Position	Inflow and outflow conduits are placed into left atrium and ascending aorta. <sup>67</sup> For left ventricular support outflow cannula is placed into the aorta and inflow cannula is placed into the pulmonary vein. Right ventricular support is established by placing the arterial cannula into the pulmonary artery and cannulation of the right atrial appendage.
Sizes	Different ventricular sizes (9-80 ml) can be matched to the patient's needs and guarantee an optimal washout of the pumps regardless of sizes and minimize the risk of thromboembolic complications. <sup>36</sup> The Medos ventricular assist device is available with stroke volumes of 10, 25, 60 and 80 ml for left-ventricular and with 10 % reduced stroke volumes for right-ventricular support in order to prevent pulmonary overflow.
Anticoagulation	Continuous heparin infusion is maintained to keep activated clotting time levels of 180 - 220 seconds. After removal of chest tubes, acetylsalicylate, 5 mg/kg/day, is added.
Function	Medos ventricular assist device system (Medos Medizintechnik GmbH, Stollberg, Germany) is a pulsatile, pneumatic driven paracorporeal assist device. It is developed for left-, right- and biventricular application by Reul <sup>65</sup> at the Helmholtz Institute in Aachen, Germany and the Medos Medizintechnik GmbH, Germany.
Survival/support times	Support times in a study at the Charité, Berlin, including 12 pediatric patients, were 8 hours to 25 days. Survival in using the left ventricular assist device mode was 80 %, in the RVAD mode 33 % and none in the biventricular assist device mode (1 patient). <sup>36</sup>
Complications	Neurological events, bleeding and infections.
Causes of death	Multiorgan failure, arrhythmias and bleeding.
Use in pediatrics	Circulatory support of newborns, children and adults by offering a variety of different-sized pumps.

Figure 6 Medos ventricular assist device



### Thoratec

Set-up	Prosthetic ventricles with 65 ml stroke volume pumping 5-6 l/min., cannulae for atrial or ventricular inflow and arterial outflow connections and a pneumatic drive console. <sup>70,71</sup>
Position	Implanted components are simplified by keeping complicated electromechanical components external to the body. <sup>69</sup> Thoratec ventricular assist device is placed on the anterior abdominal wall and is connected to heart and great vessels with cannulae crossing the chest wall. <sup>70</sup>
Sizes	One standard adult-size.
Anticoagulation	Patients are kept on standard anticoagulation (either heparin or coumadin). <sup>32</sup>
Function	Thoratec ventricular assist device (Thoratec Laboratories Corporation, Pleasanton, CA) is a paracorporeal pulsatile pneumatic ventricular assist device with the options of leftventricular or biventricular assistance.
Survival/support times	In a multicenter study including 58 pediatric patients (mean age 13.8 years, ranging from 7 to 17 years) 71 % survived to transplantation or recovery of the native heart, 65 % survived to discharge. <sup>32</sup> Survival between biventricular assist device and left ventricular assist device patients was 82 % for left ventricular assist device and 70 % for biventricular assist device patients. Longest support time on Thoratec left ventricular assist device was 515 days. <sup>69</sup> In a study including 22 adult patients (1990 - 1998) mortality on Thoratec left ventricular assist device support was 13 %, on Thoratec biventricular assist device support 36 %, mean duration of Thoratec left ventricular assist device support was 80 days, ranging from 1 - 226 days, mean duration of Thoratec biventricular assist device support was 57 days, ranging from 1 - 236 days (preliminary results of the Artificial Heart Program 2001).
Complications	Infections, prolonged ventilation, bleeding, neurologic complications and severe hypertension during support. <sup>32,71</sup>
Causes of death	Multiorgan failure, intracerebral hemorrhage, ischemic stroke, mesenterial infarction, arrhythmias, right heart failure and inability to achieve sufficient left ventricular assist device flow. <sup>32</sup>
Use in pediatrics	Body surface area 0,7 m <sup>2</sup> and an age of 7 years are the lower limits for applicable implantation of standard adult-sized Thoratec left ventricular assist device. <sup>32,71-72</sup> By implanting Thoratec pulsatile device in children the risk of thromboembolism is increased owing to reduction in flow velocities and blood stasis in the device. <sup>71</sup>

Figure 7 Thoratec pump



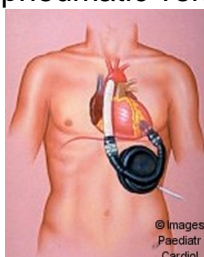
### Novacor

Set-up	Novacor left ventricular assist device consists of implanted components: a pump unit, valved conduits, an inflow conduit cannulating the left ventricle and an outflow conduit anastomosed to ascending aorta, plus external components: controller, percutaneous lead and power packs. The filling is drawn from the apex of the left ventricle and forwards the outflow into the aorta permitting an exclusively left ventricular support. The pump follows the output of the heart by a parallel connection to the natural circulation, providing automatic control, a degree of redundancy and the possibility of removal in case of ventricular recovery. <sup>73</sup>
Position	The artificial ventricle is positioned below the diaphragm in a subfascial preperitoneal abdominal fold and is connected by means of a percutaneous electric wire to the control system: just one wire emerges from the abdomen, lowering the danger of contamination from outside. <sup>74</sup>
Sizes	One standard adult-size.
Anticoagulation	Anticoagulation regime consists of coumadin to an international normalized ratio of 3.0 and acetylsalicylacide. <sup>74</sup>
Function	Novacor left ventricular assist device is an electrically powered, pulsatile, totally implantable system to provide therapy for end-stage congestive heart failure. <sup>18</sup>
Survival	Support times have steadily increased to a mean duration of left ventricular assist device support with the Novacor system of 1.5 years. <sup>40</sup> Data obtained from the Novacor European Registry showed a median support time of 100 days with a maximum of 4,1 years. There is a wide variation in survival between centres from 13 - 100 % with main survival rates between 40 - 60 %. <sup>74</sup> In the Novacor European Registry 49 % of the patients could be discharged from the hospital on left ventricular assist device. <sup>75</sup> Right heart failure, age > 65 years, acute postcardiotomy, acute infarction and respiratory failure associated with septicemia are preimplant risk factors for survival after Novacor implantation. <sup>75</sup> For patients without these risk factors, 1-year-survival after Novacor implantation is 60 %, for the combined group it is 24 %. <sup>75</sup>
Complications	Right heart failure, renal failure, bleeding, neurological events, local (predominant cultures: staphylococcus species) and systemic infections and endocarditis of the valved conduit. <sup>74</sup>
Causes of death	Sepsis, multiple organ failure, bleeding and stroke. <sup>75</sup>
Use in pediatrics	The Novacor system requires body surface areas > 1,5 m <sup>2</sup> and is feasible in children and adults.

### HeartMate

Set-up	The HeartMate ventricular assist device consists of a titanium housing containing a flexible diaphragm attached to a pusher plate. <sup>76</sup> The device incorporates two porcine valves and Dacron in- and outflow grafts. Movement of the pusher plate generates a pulsatile flow with a maximum stroke volume of 85 ml and a maximum pump flow of 10 l/min.
Position	It is implanted pre- or intraperitoneally with cannulation of left ventricular apex to access blood and with cannulation of the ascending aorta to return blood to circulation. <sup>77</sup>
Sizes	Standard adult-size.
Anticoagulation	HeartMate ventricular assist devices do not require systemic anticoagulation owing to specially textured blood contact surfaces to prevent formation of thrombogenic pseudo-intima. <sup>76</sup>
Function	The HeartMate ventricular assist device (Thermo Cardiosystems HeartMate, Woburn, MA) is a continuously rotating axial-flow impeller pump producing a steady pressure. The blood chamber is pressurized by a pusher plate, which forces a flexible plastic diaphragm upward. The motion propels the blood out through an outflow conduit and graft attached to the aorta. HeartMate ventricular assist devices are attached parallel to the cardiovascular system, leaving the heart's connections to the circulation undisturbed. Currently there are three HeartMate generations (I, II and III). In HeartMate III pumps utilize a magnetically levitated centrifugal-flow impeller configuration. Pulsatile pressures are generated by cycling between two impeller speeds. <sup>78</sup>
Survival	In a study including 12 pediatric and adolescent patients (mean age 16 years, ranging from 11 - 20 years) average support time was 123 days (0 - 397 days) and survival of 75 %. <sup>76</sup>
Complications	Bleeding, infection, neurologic events.
Causes of death	Air embolism, sepsis and pulmonary and cerebral infarcts associated with sepsis.
Use in pediatrics	The long-term implantable device requires body surface areas > 1,4 m <sup>2</sup> , thus limiting its utility for pediatric patients.

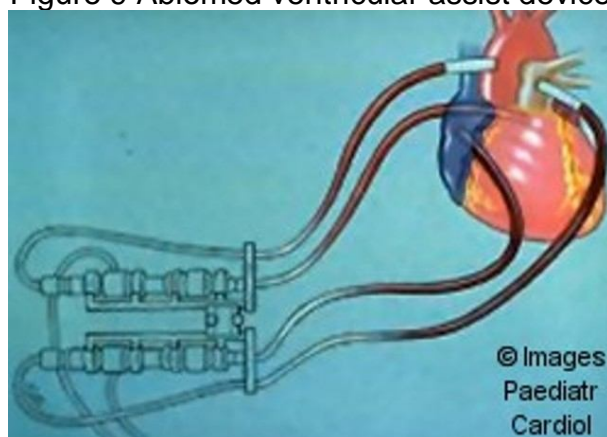
Figure 8 HeartMate pneumatic ventricular assist device



### Abiomed

Set-up	The pump contains a gravity filled chamber and an air actuated ventricular chamber, which provides a pulsatile blood flow and is capable of providing univentricular or biventricular support. <sup>72</sup> The atrial bladder, which is vented to the atmosphere, fills passively. The ventricular bladder is connected to the drive console by a 0.25-inch pneumatic line.
Position	External.
Sizes	Standard adult-size.
Anticoagulation	Activated clotting time levels have to be maintained 170-200 seconds. <sup>72</sup> In cases of flow between 2-3 l/min, activated clotting time levels should be maintained >300 seconds. <sup>72</sup>
Function	Abiomed BVS 5000 (Abiomed Cardiovascular, Inc., Danvers, MA) is a pneumatically driven pump. The BVS 5000 is used to provide circulatory support for patients with postcardiotomy failure or it can be used as a bridge to heart transplantation.
Survival/support times	In a study including 4 pediatric patients (age 12 days to 15 years) mean support time of Abiomed as left ventricular assist device was 7,5 days, survival was 100 %. <sup>72</sup> In another study including 2
	pediatric (8 and 14 years old, diagnosis: cardiac failure after Fontan procedure and dilated cardiomyopathy) and 17 adult patients (median age 34 years, ranging from 8 - 67 years) (left ventricular assist device in 14 patients, biventricular assist device in 5 patients) mean support time was 7 days (ranging from 2 - 24 days), survival was 63 %. <sup>79</sup> The 14 survivors were transplanted or weaned.
Complications	Bleeding, cerebral infarction, infections and renal failure. <sup>72,79</sup>
Causes of death	Multiorgan failure, sepsis and bleeding.
Use in pediatrics	This system requires at least 2 l/min flow <sup>72</sup> to prevent clotting, <sup>16</sup> thus imposing a minimum limit on patient body surface areas of approximately 1.0 m <sup>2</sup> . Their flow requirements limit the use of this device in the pediatric patient group.

Figure 9 Abiomed ventricular assist device



### Jarvik 2000

Set-up	Jarvik 200 is a valveless, electrically powered miniature axial flow pump that fits directly into the left ventricle and pushes oxygenated blood throughout the body.
Position	Owing to its intraventricular placement and small size the Jarvik 2000 minimizes risks for infection, thromboembolism and severe bleedings. <sup>81</sup> The fully implantable Jarvik 2000 model is powered by a redundant dual-coil motor. The device is implanted directly into the apex of the left ventricle with outflow via a 12-16 mm Dacron graft transmitting blood to the descending thoracic aorta.
Sizes	Standard adult-size.
Anticoagulation	Anticoagulation therapy is maintained in the first weeks after implantation and is not necessary afterwards. <sup>82</sup>
Function	The Jarvik 2000 is an electrically powered, miniature intraventricular axial flow left ventricular pump weighing 90 g, 2.5 cm in diameter and with displacement volume of 25 ml. <sup>43,80</sup> Extensive animal experiments showed that Jarvik 2000 is entirely free from embolic complications, easy to manage in the long term and able to deliver up to 5 –7 l/min of flow. <sup>80</sup> Hemolysis seems to be clinically not significant. Arterial pressure tracings demonstrate that flow from the device was pulsatile.
Use in pediatrics	Jarvik 2000 can be implanted in patients with body surface areas less than 1,5 m <sup>2</sup> , but as yet there was no implantation in pediatric patients. <sup>82</sup> It's use in pediatric cardiology is limited because Jarvik 2000 only supports the left heart, but for a number of pediatric indications assistance to both ventricles is needed.

Figure 10 Jarvik 2000

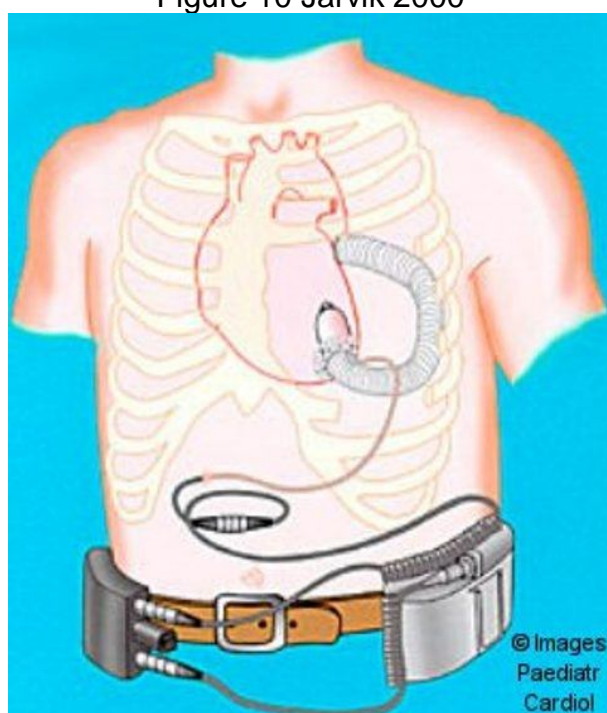


Table 1 Technical details of ventricular assist devices (summarised)

Type of device	Intraaortic balloon pump	ECMO	Centrifugal pump	Berlin Heart	Medos	Thoratec	Novacor	HeartMate	Abiomed	Jarvik 2000
position	intraaortic	external	external	external	external	external	external	external	external	internal
ventricular support	left	both	left, right or both	left, right or both	left, right or both	left, right or both	left only	left only	left, right or both	left
pediatric application	yes	yes	yes	yes	yes	yes	no	yes	yes	no
average duration	short	short	short	short	short	Intermediate long	long	long	intermediate	long
flow	pulsatile	non-pulsatile	non-pulsatile	pulsatile	pulsatile	pulsatile	pulsatile	pulsatile	pulsatile	non-pulsatile
power source	pneumatic	electric	electric	pneumatic	pneumatic	pneumatic	electric	electric or pneumatic	pneumatic	electric
Cannul. site	peripheral	peripheral arterial and venous	central or peripheral	central	central	peripheral or central	central	central	central	central
native ventricle	remains	remains	remains	remains	remains	remains	remains	remains	remains	remains
Anticoag.	not necessary	yes	not necessary	yes	yes	yes	yes	no	yes	no
patient ambulation	no	no	no	no	no	yes w/assistance	yes	yes	no	yes
patient discharge	no	no	no	no	no	no	yes	yes (electric)	no	yes

This system has the potential for use as a permanent ventricular assist device or as a bridge to transplantation or recovery in adults and pediatric patients needing left ventricular support exclusively.

### Indications and contraindications for the implantation of ventricular assist devices

No precise guidelines for the implantation of ventricular assist devices in pediatrics exist. The decision for implantation of a ventricular assist device can only be made by assessing the individual clinical situation of each patient with the help of a careful diagnostic approach. The indications for the use of ventricular assist device in pediatric cardiology depend on individual units' experiences.

The indications for the implantation of ventricular assist devices can be divided in cases of patients without operation like myocarditis, endocarditis, neoplasm or Eisenmenger syndrome, and postoperative indications with deterioration in preoperative ventricular function exacerbated by surgery (for example Bland-White Garland syndrome, hypoplastic left heart syndrome, neoplasm, postoperative change of hemodynamics, arterial switch in transposition of the great arteries after the neonatal period, secondary arterial switch after atrial switch or congenitally corrected transposition of the great arteries, Fontan or Fontan-type procedures with postoperative left ventricular deterioration, pulmonary hypertensive crisis refractory to prostacyclin or nitric oxide treatment, right ventricular failure in tetralogy of Fallot, myocardial failure from prolonged cross-clamp and cardiopulmonary bypass time, Kawasaki disease or procedures with intraoperative complications).<sup>5</sup>



Surveillance before implantation of a ventricular assist device is directed at registering onset of premonitory manifestations of potentially untreatable low flow rates. Ventricular arrhythmias, hypoxemia and renal dysfunction constitute prodromes of reduced flow and can be taken as indication criteria for ventricular assist devices. Organ dysfunction is also one of the main problems in ventricular assistance owing to the impossibility of determining reversal of organ damage. Contraindications for the implantation of a ventricular assist device include severe renal and hepatic failure, irreversible septic shock, severe neurological damage and hemorrhage.<sup>83</sup>

Contraindications for implantation of circulatory assist systems are the same as for cardiac transplantation as cardiac recovery is uncertain. Multiorgan failure is a clear contraindication, but early states of multiorgan failure can be reversed by circulatory mechanical assistance. Coagulation disorders, intracranial bleeding and severe neurological complications preclude the implantation of assist devices. Acute or chronic infection impair the implantation of a mechanical assist system,<sup>84</sup> but the implantation of an assist system in viral myocarditis is possible.<sup>85</sup> Patients after a prolonged run of cardiopulmonary bypass seem to be less favourable for mechanical assist as hemostasis is crucial for eventual outcome. Selection of the most appropriate support system may be decisive for survival of critically ill infants with an otherwise untreatable cardiac condition.

### **Intraaortic balloon pump**

In predominantly right ventricular failure which is often observed in congenital heart disease, intraaortic balloon pump is ineffective. In addition, myocardial ischemia for which intraaortic balloon pumps are useful is an uncommon cause of congestive heart failure in pediatrics. Intraaortic balloon pump appears of therapeutical value for children with a more moderate form of left ventricular dysfunction, but severe cases require the implantation of a left ventricular assist device.

A general indication is low cardiac output despite adequate treatment evinced by poor peripheral perfusion (low mean aortic pressure), metabolic acidosis, mixed venous  $pO_2 < 25$  mmHg, urine output  $< 1$  ml/kg/h and left atrial pressure  $> 20$  mmHg.<sup>41</sup> Malignant ventricular arrhythmias due to low coronary blood flow and high catecholamine support can profit from intraaortic balloon pump. Contraindications are patent ductus arteriosus, recent coarctation or aortic arch repair and significant aortic valve insufficiency.

### **Extracorporeal membrane oxygenation**

Biventricular support with extracorporeal membrane oxygenation<sup>23</sup> is the predominantly used ventricular assist device in children with heart disease who have failed conventional medical treatment. The use of extracorporeal membrane oxygenation has been proven to be life-saving in children with myocardial failure, because of the advantages of rapid priming of both right and the left heart and support of pulmonary function. Hypoxia and pulmonary hypertension are indications for circulatory support with extracorporeal membrane oxygenation.<sup>86</sup>

Postoperative support is established for failure to wean from cardiopulmonary bypass, cardiogenic shock or cardiac arrest after cardiac surgery.<sup>52,55,87,88</sup> Treatment with high-frequency ventilation, nitric oxide and liquid ventilation can fail when severe hypoxia occurs in the setting of congenital heart disease. Extracorporeal membrane oxygenation is the method of choice in the persistence of intracardiac shunts or in cases of profound respiratory insufficiency accompanying heart failure. Examples of congenital heart diseases often requiring postoperative circulatory support like extracorporeal membrane oxygenation are congenital heart diseases with shunts, total anomalous pulmonary venous connection because of preoperative respiratory problems and postoperative pulmonary hypertensive crisis.<sup>64</sup>

When myocardial recovery can be expected and immediate weaning of the extracorporeal circuit is not possible, extracorporeal membrane oxygenation is the method of choice for a few days after open heart surgery, for example after switch operation, total anomalous pulmonary vein drainage, Bland White Garland syndrome or after heart transplantation.<sup>89</sup>

Ishino recommends extracorporeal membrane oxygenation as a first choice for biventricular support after arterial switch operation, particularly in unusual and complex coronary patterns.<sup>64,90</sup> When right or biventricular failure develops in infants with imbalanced ventricles, extracorporeal membrane oxygenation is the optimal method of circulatory support. In cases of lung failure and pulmonary hypertension beside underlying cardiac diseases, implantation of extracorporeal membrane oxygenation should be favoured.<sup>91</sup> Pulmonary hypertension is a contraindication for the implantation of a left ventricular assist device because of the high risk for right ventricular failure after left ventricular assist device insertion.<sup>83</sup>

In a study involving cardiac and non-cardiac patients, indications for extracorporeal membrane oxygenation were hypoxia (36 %), cardiac arrest (24 %) and failure to wean from cardiopulmonary bypass (14 %).<sup>23</sup> Several studies emphasize failure to wean from cardiopulmonary bypass as a negative prognostic indicator,<sup>23,52,62,88</sup> whereas other studies could not find a negative impact.<sup>55,57,92</sup>

Several studies stress the importance of early institution of extracorporeal membrane oxygenation, before prolonged periods of low cardiac output result in severe organ damage. Low cardiac output in congenital heart disease with shunted single ventricle physiology, including patients with hypoplastic left heart syndrome after neonatal palliation, is an indication for implantation of extracorporeal membrane oxygenation.<sup>48,57,88</sup> Blood flow through shunts should be limited to ensure systemic perfusion and to avoid excessive pulmonary “flooding”. Contraindications include malignancy, multisystem organ failure, prematurity and severe central nervous system damage.<sup>48,51,56,88</sup>

### **Centrifugal pump ventricular assist device**

The clinical application of centrifugal ventricular assist devices has generally been limited to adults and large pediatric patients, but neonates and small pediatric patients requiring ventricular support post-cardiopulmonary bypass are also well supported by a centrifugal ventricular assist device.

In a major study,<sup>2,37</sup> the majority of patients receiving Biomedicus supporting systems had undergone palliative or reparative open heart operations (for

cyanotic heart vitia with increased or decreased pulmonary flow, right or left sided obstructive lesions, Bland White Garland syndrome) or transplantation, and could not be weaned from cardiopulmonary bypass, a subset therefore presenting with low cardiac output following satisfactory weaning. Only rarely was low cardiac output due to myocarditis or cardiomyopathy a primary indication.<sup>93</sup> According to Konertz, indications for implantation of centrifugal pumps are acute (nonsurgical) cardiogenic shock, rescue postcardiotomy support, low cardiac output after long pump runs in complex cardiac reconstructions and bridge to transplantation.<sup>84</sup> Centrifugal ventricular assist device can be applied in univentricular circulation, for example after Norwood operation for hypoplastic left heart syndrome or after bidirectional cavopulmonary shunts.<sup>2</sup> Contraindications are the same as mentioned for extracorporeal membrane oxygenation.

### **Novacor**

The main indications for implantation of Novacor systems are ischemic or idiopathic cardiomyopathy, acute myocardial infarction and myocarditis in adults.<sup>19,74,75</sup>

### **Berlin Heart**

Indications for implantation of a Berlin Heart assist device include bridge to transplant in chronic myocardial diseases or end stages of congenital heart disease, rescue therapy after operation for congenital heart disease, acute viral myocarditis,<sup>21</sup> cardiomyopathies, myocardial infarction, repeated cardiopulmonary resuscitation and postcardiotomy cardiogenic shock.<sup>63,90</sup> The best candidates for its application are patients with biventricular hearts without intracardiac shunting.<sup>91</sup> There is the possibility of switching from biventricular assist device to extracorporeal membrane oxygenation for easier weaning once normal functional patterns of the initially akinetic ventricles are observed.<sup>63</sup> Contraindications are the same as mentioned for extracorporeal membrane oxygenation.

### **Thoratec**

Patients receiving a Thoratec assist device suffer from various forms of end-stage cardiomyopathies, myocarditis, underlying congenital defects (transposition of the great arteries, Ebstein's anomaly, tetralogy of Fallot) and post-cardiotomy cardiac failure.<sup>32</sup>

### **Medos**

Indications for implantation of Medos ventricular assist device include heart failure after surgery for congenital heart diseases, cardiomyopathy or acute myocarditis, low cardiac output or cardiac arrest at the intensive care unit following successful weaning from cardiopulmonary bypass.<sup>36</sup> In a study at the Charité, Germany, indications were cardiogenic shock and postoperative failure (57 % recovery). Patients in cardiogenic shock had high mortality, only a minority could be successfully weaned or transplanted. In contrast patients

with postcardiotomy heart failure had a success rate of 50 % either by weaning or by transplantation.<sup>36,68</sup> Contraindications are multiorgan failure, severe coagulopathy, intracranial hemorrhage, neurological impairment and sepsis.<sup>36</sup>

### **HeartMate**

Severe cardiac failure in chronic dilated cardiomyopathy, resuscitation, acute myocarditis, and Ebstein's anomaly are reasons for implantation of HeartMate ventricular assist device in adolescent and pediatric patients.<sup>76</sup>

### **Abiomed BVS 5000**

The typical indications are failure to wean from cardiopulmonary bypass, precardiotomy shock, viral myocarditis, myocardial infarction and intractable arrhythmia.<sup>22,94</sup> Abiomed BVS 5000 is predominantly used for short-term mechanical support in postcardiotomy patients in cardiogenic shock expecting myocardial.<sup>79,56</sup>

### **Predictive factors**

The timing of the installation of a ventricular assist device is crucial for outcome of patients needing circulatory support. Several studies have shown that survival is better when extracorporeal life support is instituted after successful weaning from cardiopulmonary bypass.<sup>52,53,56,57,88</sup> Therefore the distinction between postcardiotomy patients on ventricular assist device because of failure to wean from cardiopulmonary bypass or because of myocardial dysfunction after successful weaning is important. Several studies group all sorts of postcardiotomy patients together and make comparison with other series difficult.<sup>87,96,97</sup> Best survival in patients (47 %) who could not be weaned from cardiopulmonary bypass is reported by Ziomek.<sup>57</sup> Overall necessity of ventricular assist device in this report is 6.8 %, a higher usage is reported by Raithel<sup>3,98</sup> who found that 8.4 % of pediatric patients required ventricular assist device after cardiac surgery. The key to survival lies in the institution of ventricular assist device before severe organ damage can manifest.<sup>58</sup>

Patients with incomplete repair of congenital heart disease do badly. Black reports 100 % mortality in this group.<sup>49</sup> Therefore complete surgical repair should be a prerequisite for the implantation of a ventricular assist device. Patients who suffer otherwise untreatable cardiac arrest after cardiac surgery may benefit of the installation of a ventricular assist device more than other groups. Del Nido reported survival rates of 64 %.<sup>96,99</sup>

The risk of embolic events remains a continuing concern. Formation of pseudo-intimas in the inflow conduit of ventricular assist devices was identified as a main source of embolism.<sup>100</sup> The development of this friable, easily detachable neo-intima could be reduced by changes in physical characteristics of new inflow conduits: reduced compliance, elimination of graft crimp and shorter length. The dosage of anticoagulant medication must be adjusted to specific requirements of prolonged activation of biological coagulation cascades by using more biocompatible blood contacting surfaces.

Left ventricular venting to ensure complete decompression of the left heart is an important factor contributing to the patient's outcome. Ventricular overdistension can be minimized by maintenance of low central venous pressures and high flow rates.<sup>57</sup> Otherwise left ventricular overdistension may result in elevation of left ventricular end-diastolic pressures when ventricular function is decreased and forward pulsatile flow is low. This may result in decreased coronary perfusion particularly of left ventricular subendocardial layers. In biventricular failure venting of the left ventricle is therefore advisable.<sup>62</sup>

A possible key to success in circulatory support (with the exception of the bridge to transplant concept) with ventricular assist devices lies in the reversibility of heart dysfunction. Once myocardial architecture is destroyed, no support can regenerate myocardial tissue. Emplacement of a ventricular assist device reduces pre- and afterload, this reduction in left ventricular volume decreases wall stress during ventricular assist device support period and helps avoid cell damage and cell loss in cardiomyopathies.<sup>101</sup> Unloading of the heart by using mechanical circulatory support appears to reverse pathological ventricular remodeling occurring in cardiomyopathies.<sup>102</sup> It is crucial to install circulatory support via ventricular assist device in time before myocardial architecture deteriorates.

Different assist devices can be combined, for example Biomedicus pump with intraaortic balloon pump to ensure pulsatile flow.<sup>59</sup> Loss of pulsatility has been blamed for development of capillary leakage during prolonged pump runs.<sup>103</sup>

In order to support children with severe cardiac dysfunction following open heart surgery, it is possible to use extracorporeal membrane oxygenation without oxygenator as so-called “no membrane oxygenator-ventricular assist device”.<sup>104</sup> In this configuration, the circuit becomes a roller pump ventricular assist device. This system, as opposed to the centrifugal pump system, retains the desirable effects of extracorporeal membrane oxygenation including pump servo-regulation, pressure monitoring, access ports for fluid/drug administration, air bubble detection, in-line blood gas monitoring and heat exchanger. In patients with a single ventricle, for example after Norwood stage I procedure, oxygenation is provided by the children's own lungs by leaving aortopulmonary shunts open.<sup>105</sup>

In a minority of patients, unloading of the left ventricle during left ventricular assist device allows a recovery of left ventricular function such that these patients can be weaned from circulatory assistance. In these selected patients ventricular assist device should not be a bridge to cardiac transplantation but rather to recovery.

### **Future development**

The duration of circulatory support is extending continuously with the ultimate goal of total replacement of the heart. There is a growth in the number of patients with decompensated heart insufficiency in the adult and pediatric population, which cannot be sufficiently dealt with by heart transplants owing to the shortage of donor hearts. An alternative surgical solution could be extended use of ventricular assist devices as temporary or permanent implantation.

Children in advanced cardiac failure and in profound cardiogenic shock who would otherwise die immediately may be kept alive using ventricular assist devices and may either completely recover or qualify for successful heart transplantation. Widely used devices such as extracorporeal membrane oxygenation or other ventricular assist devices may sustain the circulation for several days or weeks. These systems require continuous intensive care, and chances for extubation and mobilization are very small. Pediatric ventricular assist devices should allow ambulation and rehabilitation of the patient. Rehabilitation is of vital importance in the adult and pediatric population. An implantable device of appropriate size would meet the needs of rehabilitation and ambulation. The aim is to design a device that could be used for long periods of time as a bridge to heart transplantation and with the possibility of its use as a permanent heart replacement device.

The Jarvik 2000 is a potential device that could fulfill these criteria.<sup>72</sup> The number of heart transplantations is limited due to shortage of donor hearts. In order to salvage patients suffering from severe end-stage cardiac diseases, artificial hearts as permanent implants may alleviate this problem. At the same time an increased number of transplant-contraindicated patients are fitted with circulation assist devices of a permanent kind.

The possibility of having a new generation of systems so constructed to reduce the rate of complications, to minimize overall dimensions and to be easily managed (home care) should radically improve the risk-benefit ratio and economic concerns. However there are various problems to be solved: in addition to smaller, cheaper, simpler and more easily controllable pulsatile ventricular assist devices, there is a need for compact, durable and reliable nonpulsatile pumps, which can be completely implanted as a bridge to transplantation and/or for permanent use.

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