Outcomes of a multicenter trial of the Levitronix CentriMag ventricular assist system for short-term circulatory support

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Objective: The Levitronix CentriMag (Levitronix LLC, Waltham, Mass) ventricular assist system is designed for temporary left, right, or biventricular support. Advantages include ease of use, excellent reliability, and low thrombosis risk, which may allow wider application of short-term support and improved outcomes in patients with cardiogenic shock. This multi-institutional study evaluated safety, effectiveness, and outcomes of the CentriMag in patients with cardiogenic shock.

Methods: Thirty-eight patients were supported at 7 centers. Patients included 12 after cardiotomy, 14 after myocardial infarction, and 12 with right ventricular failure after implantable left ventricular assist device placement. Devices were implanted in left (n = 8), right (n = 12), or biventricular (n = 18) configuration. Support was continued until recovery, transplantation, or implantation of long-term ventricular assist device.

Results: Mean support duration for the entire cohort (n = 38) was 13 days (1–60 days), with 47% of patients (18/38) surviving 30 days after device removal. Mean CentriMag biventricular support (n = 18) duration was 15 days (1–60 days), with 44% (8/18) surviving at 30 days. Mean CentriMag right ventricular support with a commercially available left ventricular assist device (n = 12) duration was 14 days (1–29 days), with 58% (7/12) surviving at 30 days. Complications included bleeding (21%), infection (5%), respiratory failure (3%), hemolysis (5%), and neurologic dysfunction (11%). There were no CentriMag or pump failures.

Conclusions: In this preliminary study, the CentriMag provided short-term support for patients with cardiogenic shock with a low incidence of device-related complications and no device failures. (J Thorac Cardiovasc Surg 2011;141:932-9)

Despite many advances in the management of patients with acute heart failure, the outcomes for patients with refractory acute cardiogenic shock remain disproportionately poor.1,2 Further, the vast majority of these patients are often in hospitals that do not have access to advanced circulatory support technologies or resources to optimally manage these patients. Delay in referral to tertiary centers further exacerbates the poor outcomes of this group of patients. Clearly, there is a need for wider application of temporary circulatory support for such patients. Questions remain as to the ideal support system, the optimal duration of temporary support, and the ideal timing to bridge these patients to a long-term device.
Conducted in the United States to evaluate safety and effectiveness of the cannulas (Figure 1). The Levitronix CentriMag VAS is different from other blood pump, motor, drive console, backup motor, backup drive console, and components, with the exception of the single-use blood pump, are intended for reuse on multiple patients.

**MATERIALS AND METHODS**

**Device Description**

The Levitronix CentriMag VAS is composed of a single-use centrifugal blood pump, motor, drive console, backup motor, backup drive console, and cannulas (Figure 1). The Levitronix CentriMag VAS is different from other devices in that it is designed to operate without mechanical bearings or seals. This is possible because the motor levitates the rotor (the spinning component of the device) magnetically, so that rotation may be achieved without friction, regions of stasis, or component wear during operation. Eliminating bearings, regions of stasis, component wear, friction, and the sources of thermal damage reduces hemolysis and the risk of thrombus formation within the pump. The design is based on bearingless motor technology, which combines drive, magnetic bearing, and pump rotor functions into a single unit that has no valves, seals, mechanical bearings, or moving parts aside from the magnetically levitated rotor. The system is capable of operating across a range of speeds from 500 to 5500 rpm, generating flows as great as 10 L/min under normal physiologic conditions. All system components, with the exception of the single-use blood pump, are intended for reuse on multiple patients.

For support, 22F Medtronic (Medtronic, Inc, Minneapolis, Minn) arterial and 32F Edwards Lifesciences (Edwards Lifesciences, Irvine, Calif) venous canulas were used. For right ventricular (RVAD) support, the VAD inflow cannula was positioned in the right atrial appendage and the outflow cannula in the pulmonary artery. For left ventricular (LVAD) support, the left atrial inflow cannula was inserted into the interatrial septal groove, adjacent to the right superior pulmonary vein, with the outflow cannula in the ascending aorta. Intraoperative transesophageal echocardiography was used to confirm cannula positioning, absence of a patent foramen ovale, and adequate volume for support. Cannulas were secured with dual, pledged purse-string sutures. During weaning and assessment of ventricular function, anticoagulation was monitored and adjusted to reduce the risk of thrombosis formation during periods of reduced VAD flow. Anticoagulation varied according to the needs and condition of each patient. In general, activated clotting time (ACT) was checked before reduction of VAD flow for weaning, and additional heparin was administered if the ACT was less than 200 seconds. ACT was rechecked during weaning; if necessary, additional heparin was administered to maintain an ACT longer than 200 seconds.

**Study Description and Clinical Implementation**

Two parallel Food and Drug Administration–approved pilot trials were conducted in the United States to evaluate safety and effectiveness of the CentriMag VAS for short-term circulatory support. A total of 38 patients were enrolled in these trials as of March 2009. All participating institutions obtained institutional review board approval before study initiation. Informed consent was obtained from all subjects. A summary of each trial is provided here.

**Cardiogenic shock pilot trial.** This was a nonrandomized, multicenter pilot study to evaluate the use of the CentriMag system for as long as 14 days when used as either an LVAD or a biventricular assist device (BVAD) to treat patients in cardiogenic shock. Two groups of patients were evaluated: (1) patients with PCCS, and 2) patients with post–acute myocardial infarction cardiogenic shock (PMICS). No control population was used in this study. The intent was to maintain each patient on mechanical circulatory support until the patient recovered, underwent transplantation or was weaned onto a long-term VAD. All surviving patients were monitored as long as 6 months after support. For the treatment to be considered a success, patients needed to survive 30 days after support, to transplant, or to implantation of a long-term VAD.

Twenty-six patients were enrolled into the cardiogenic shock pilot trial; of these, 18 patients were implanted with both a CentriMag LVAD and a CentriMag RVAD for as a BVAD. The remaining 8 patients were implanted with a CentriMag LVAD only. Twelve subjects were enrolled in the PCCS arm, and 14 subjects were enrolled in the PMICS arm.

**Use of CentriMag RVAD after implantation of a commercial LVAD.** This trial was a nonrandomized, multicenter pilot study to evaluate the use of the CentriMag System for as long as 14 days as an RVAD after implantation of a commercially available LVAD. Patients were enrolled into this study either intraoperatively after unsuccessful weaning from cardiopulmonary bypass or postoperatively for hemodynamic decompensation. For those patients enrolled postoperatively, enrollment had to occur within 24 hours of the original surgery. No control group was used. Similar to the cardiogenic shock trial, the intent was to maintain the patient on mechanical circulatory support until the patient recovered, received a transplant, or was transitioned to a long-term RVAD. For the treatment to be considered a success, patients needed to survive 30 days after weaning, to heart transplant, or to long-term RVAD transition.

**Assessment of safety and efficacy.** Baseline hemodynamic and laboratory measurements were obtained before initiation of left, right or biventricular support with the CentriMag VAD, depending on patient requirements. Daily assessments were made of end-organ function, hemodynamics, and neurologic status. Patients were followed up until discharge and evaluated at 30 days and 6 months after device removal. Photography and gross examination of the pump, canulas, and connectors were performed at pump removal.

The following parameters were studied: (1) hemodynamics before, during, and after device support; (2) changes in hemodynamics during support; (3) end-organ function before, during, and after device support; (4) changes in end-organ function during support (5) CentriMag device–related adverse effects; and (6) 30-day survival after device removal.

**Adverse Events**

The following adverse events, regardless of their relationship to the device, were documented.

**Infection.** Any infection diagnosed during the period of VAS support was classified as device related unless the infection had been diagnosed and any organisms cultured before initiation of VAS support.

**Bleeding.** Bleeding was defined as blood loss resulting in either surgical exploration or blood transfusion requiring more than 3 units of packed red blood cells within a 24-hour period. Bleeding was classified as device related if it occurred from a VAS cannula attachment site.

**Respiratory failure.** Respiratory failure was defined as continued ventilator support for more than 3 days after implantation or subsequent reintubation or tracheostomy for respiratory distress. Respiratory failure was classified as device related if (1) respiratory dysfunction continued beyond the first 5 days after device insertion, (2) reintubation or tracheostomy was...
required for device malfunction, or (3) respiratory dysfunction was due to a device-related thrombotic vascular complication.

**Cardiac tamponade.** Cardiac tamponade was determined according to clinical examination and cardiac echocardiography.

**Hepatic dysfunction.** Hepatic dysfunction was defined as an increase to 3 times baseline values in any 2 of the following parameters: total bilirubin, serum alanine transaminase, serum aspartate transaminase, or lactate dehydrogenase after the third postoperative day.

**Renal failure.** Renal failure was defined as a greater than 3-fold increase in creatinine from baseline or a creatinine value greater than 6 mg/dL after the first postoperative day, not present before implantation and occurring less than 24 hours in which plasma free hemoglobin was more than 40 mg/dL.

**RESULTS**

Results are presented for (1) the combined cohort of patients enrolled in both the cardiogenic shock and RVAD after implantation of a commercial LVAD studies (n = 38), (2) patients enrolled in the cardiogenic shock trial for the indications of PCCS (n = 12) and PMICS (n = 14), (3) patients enrolled in the cardiogenic shock trial supported with CentriMag BVAD (n = 18) or PMICS (n = 8), and (4) patients enrolled in the RVAD after implantation of a commercial LVAD study (n = 12).

**Demographic Characteristics**

Overall patient demographic characteristics are presented in Table 1. Patient demographic characteristics in the cardiogenic shock trial subdivided by type of support (LVAD vs BVAD) are presented in Table 2. Mean age of patients in the entire cohort was 58 years (30–75 years). Mean age of patients with in the PCCS group was 58 years (33–73 years), and that in the PMICS group was 60 years (30–74 years). Of the 12 patients in the PCCS group, 5 received BVADs and 7 received only LVADs. Of the 14 patients in the PMICS group, 13 received BVADs and 1 received LVAD alone. Most patients in the PCCS group had undergone coronary artery bypass grafting; other procedures included ventricular septal defect repair, valve replacement, and failed cardiac transplant. In the PCCS group, left-sided inflow cannulation sites included the left atrium (n = 8) and left ventricular apex.

### TABLE 1. Demographic characteristics of study populations

<table>
<thead>
<tr>
<th>Age (y)</th>
<th>Cardiogenic shock protocol</th>
<th>LVAD after commercial LVAD protocol</th>
<th>Combined cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>After cardiectomy</td>
<td>After acute MI</td>
<td>After LVAD protocol</td>
<td>Combined cohort</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>58 ± 12.3</td>
<td>55 ± 14.3</td>
<td>58 ± 12.4</td>
</tr>
<tr>
<td>Range</td>
<td>33–73</td>
<td>32–75</td>
<td>30–75</td>
</tr>
<tr>
<td>Sex (no.)</td>
<td>Male</td>
<td>Female</td>
<td>Male</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>167 ± 11.0</td>
<td>152–185</td>
<td>173 ± 10.5</td>
</tr>
<tr>
<td>Range</td>
<td>155–192</td>
<td>173 ± 11.3</td>
<td>147–192</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>77 ± 14.1</td>
<td>55–99</td>
<td>88 ± 19.3</td>
</tr>
<tr>
<td>Body surface area (m²)</td>
<td>1.87 ± 0.2</td>
<td>1.59–2.12</td>
<td>2.00 ± 0.3</td>
</tr>
</tbody>
</table>

### TABLE 2. Demographic characteristics of cardiogenic shock groups

<table>
<thead>
<tr>
<th>Age (y)</th>
<th>BVAD (n = 18)</th>
<th>LVAD (n = 8)</th>
<th>Total (n = 26)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>58 ± 12.6</td>
<td>62 ± 8.9</td>
<td>59 ± 11.6</td>
</tr>
<tr>
<td>Range</td>
<td>30–74</td>
<td>49–73</td>
<td>30–74</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>Female</td>
<td>Male</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>12 (67%)</td>
<td>3 (37%)</td>
<td>15 (58%)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>172 ± 11.2</td>
<td>147–185</td>
<td>165 ± 9.1</td>
</tr>
<tr>
<td>Range</td>
<td>147–185</td>
<td>170 ± 10.9</td>
<td>147–185</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>84 ± 19.1</td>
<td>48–117</td>
<td>81 ± 14.5</td>
</tr>
<tr>
<td>Body surface area (m²)</td>
<td>1.96 ± 0.3</td>
<td>1.40–2.33</td>
<td>1.90 ± 0.2</td>
</tr>
<tr>
<td>Range</td>
<td>1.70–2.55</td>
<td>1.40–2.55</td>
<td>1.94 ± 0.2</td>
</tr>
</tbody>
</table>

**MI**, Myocardial infarction; RVAD, right ventricular support device; LVAD, left ventricular assist device.
FIGURE 2. Thirty-day survival. RVAD, Right ventricular assist device; PCCS, postcardiotomy cardiogenic shock; MI, myocardial infarction.

(n = 4). In the PMICS group, left-sided inflow cannulation sites included the left ventricular apex (n = 10) and the left atrium (N=3). The ascending aorta was used as the outflow cannulation site in all patients receiving left-sided CentriMag LVAD support.

Clinical and Hemodynamic Outcomes

Overall and subgroup 30-day postexplant survival, survivals to discharge, and 6-month survivals are shown in Figure 2 and Table 3. The mean duration of support for the overall group (n = 38) was 13 days (1–60 days), with 47% (18/38) 30-day survival after device removal, 42% (16/38) survival to discharge, and 32% (12/38) 6-month survival after device removal.

The mean duration of support for the patients supported with a CentriMag RVAD after implantation of a commercially available LVAD (n = 12) was 14 days (1–29 days), with 58% (7/12) 30-day survival after device removal, 42% (5/12) survival to discharge, and 33% (4/12) 6-month survival after device removal. Eleven of the 12 patients in the RVAD group underwent placement of the RVAD immediately after LVAD placement, and the remaining patient underwent placement approximately 96 hours after LVAD placement. Of the 7 survivors in the RVAD group, 6 patients were successfully weaned, and the remaining patient received a long-term Thoratec RVAD (Thoratec Corporation, Pleasanton, Calif).

The mean duration of support for the patients in the PMICS group (n = 14) was 17 days (1–60 days), with 50% (7/14) 30-day survival after device removal, 50% (7/14) survival to discharge, and 43% (6/14) 6-month survival after device removal. The mean duration of support for the patients with PCCS (n = 12) was 8 days (1–29 days), with 33% (4/12) 30-day survival after device removal, 33% (4/12) survival to discharge, and 17% (2/12) 6-month survival after device removal. The 20-day postexplant survival in the PCCS group was 33%, with a mean duration of support of 8 days, as opposed to the 50% 30-day postexplant survival of patients in the PMICS group, with a mean duration of support of 17 days. Of the 7 survivors in the PMICS group, 4 patients were successfully weaned, and the remaining 3 patients were bridged to a long-term VAD. Of the 4 survivors in the PCCS group, 3 patients were successfully weaned, and the remaining patient was bridged to a long-term VAD.

The mean duration of support for those patients with biventricular CentriMag support for cardiogenic shock (n = 18) was 15 days (1–60 days), with 44% (8/18) 30-day survival after device removal. Mean duration of support for those patients with LVAD CentriMag support for cardiogenic shock (n = 8) was 8 days (1–29 days), with 38% (3/8) 30-day survival after device removal.

Hemodynamics and End-Organ Function

Hemodynamic data are reviewed in Table 4. The central venous pressure and mean arterial pressure, plotted as a function of days of pump implementation (1–14 days) for survivors supported longer than 7 days improved during support and remained stable throughout support. Laboratory studies of blood urea nitrogen, creatinine, and bilirubin are shown in Table 5. Although serum creatinine and total bilirubin remained stable, there was a trend toward increased blood urea nitrogen with time among survivors supported for longer than 7 days.

Adverse Events

Table 6 lists all adverse events reported. As expected for this patient population, the rates of bleeding, infection, and respiratory failure were elevated. The number of events directly attributable to the device, however, was relatively low.

Device function and performance. Pump flow was stable in both groups through the course of the 14-day trial, with average flows ranging from approximately 3.5 to 6.0 L/min. There were no instances of CentriMag system or pump failure.

Infections. In the entire cohort (n = 38), 8 patients (21%) had 19 device-related infections. In the BVAD cohort (n = 18), 2 patients (11%) had 3 device-related infections.
In the RVAD cohort (n = 12), 3 patients (25%) had 9 device-related infections.

**Hemolysis.** Hemolysis was considered to be device related if it was observed beyond the first 3 days of mechanical circulatory support. In the entire cohort (n = 38), 2 patients (5%) had device-related hemolysis. One patient was implanted with BVAD CentriMag devices for PMICS, was successfully supported for a total of 60 days (pumps were electively changed at day 30), and was then subsequently successfully bridged to support with a total artificial heart. Hemolysis was believed to have been due to cannula malpositioning. The other patient, who was also implanted with BVAD CentriMag devices for PMICS, was effectively supported for a total of 7 days. Support was electively terminated after development of heparin-induced thrombocytopenia and refractory liver failure.

**Thromboembolic events.** Three neurologic events were classified as “questionably related to device” and 1 event was classified as device related. All events occurred in the PCCS group. The causes of all “questionable” events were indeterminate. Investigators reported risk of thromboembolism for these patients as a result of inadequate anticoagulation during weaning, intra-aortic balloon pump malfunction, or antithrombin III deficiency. The fourth case of neurologic dysfunction occurred in a patient implanted with BVAD support who exhibited signs of right-sided weakness 14 days after the implant. The investigator considered that a possible cause of the event was embolus from the device during a period of low flow.

**DISCUSSION**

Currently available circulatory support options for patients in cardiogenic shock are known for low survivals and the occurrence of significant complications, including
infection, bleeding, and adverse neurologic events.\textsuperscript{4,5} Intravascular balloon pumps and inotropic therapy have historically been the standard of care for patients in acute cardiogenic shock. Extracorporeal membrane oxygenation (ECMO), although suitable for cardiopulmonary support in some instances, does not unload the ventricles to the degree possible with a VAD, has a high rate of device-related complications, and requires that the patient be immobilized.\textsuperscript{6-8} Other commercially available extracorporeal devices have drawbacks, such as large priming requirements, lack of portability, limited duration of use, thromboembolic risk, and device size.

We have demonstrated in these preliminary studies that the CentriMag VAS is capable of providing total right and left ventricular unloading and circulatory support for patients with cardiogenic shock. The overall survival in this cohort of 38 patients was 47\% survival. In the post–myocardial infarction and RVAD after implantable LVAD groups were 50\% and 58\%, respectively. Pump performance data for the CentriMag indicated satisfactory hemodynamic support sufficient to meet the patients’ circulatory needs. The benefits associated with the CentriMag VAS include ease of implantation, adequate ventricular unloading, reliable device function, low incidence of device-related complications, and support conditions conducive to recovery and weaning. The 6-month survival of these patients is still relatively low, however, which strongly suggests that improvements still can be made in the overall management of these patients. The survival with this device is similar to those achieved with other, previous devices, and thus these outcomes are more related to this patient population and patient selection than directly to the type of device.

This study highlights the need for additional data to permit the selection of the best short-term circulatory assist system for a patient’s condition and expected course. Comparing survival outcomes (either survival to discharge or 30-day postimplant survival) between single-center studies does not allow a proper or accurate comparison between different support devices, because there are many variations in patient selection and management among centers. Until randomized studies are performed, comparison among different therapeutic modalities for acute cardiogenic shock will always have an inherent bias when based on a single center’s experience and outcomes. Nevertheless, we attempt to highlight some studies evaluating outcomes with the different modalities that provide short-term mechanical circulatory support.

The short-term VADs currently available include the widely used ABIOMED BVS (ABIOMED, Inc, Danvers, Mass) and Bio-Medicus systems (Medtronic) and the more recently introduced CentriMag system. In addition, ECMO is also a useful therapeutic modality for selected patients in this group. More recently, percutaneous options for short-term mechanical support have become available.

Samuels and colleagues\textsuperscript{9} reported a 31\% hospital discharge rate for patients with acute cardiac failure supported by the ABIOMED BVS system. Other single centers have also reported on their experiences with ABIOMED BVS devices, with acceptable results.\textsuperscript{10,11} The advantages and limited commercial availability of other systems have led to an extensive experience with this system; however, disadvantages include the need for performing anastomoses for aortic and pulmonary artery cannulation, with resulting bleeding complications, and the need for pump exchanges at approximately 1-week intervals.

Even though ECMO is the best option for patients requiring full cardiopulmonary support, major disadvantages include a limited duration of support, a high incidence of complications with increasing duration of support, and the need for fairly stringent anticoagulation. In addition, ECMO requires a dedicated team of personnel to allow its safe use. Pagani and associates\textsuperscript{6} of the University of Michigan reported a 43\% 1-year survival among patients with cardiogenic shock either from previous cardiac arrest or severe hemodynamic instability who were initially treated with ECMO as a bridge to LVAD implantation. In a study from Innsbruck, Hofer and colleagues\textsuperscript{12} reported excellent results with ECMO support in patients with cardiogenic shock. They reported a 50\% mortality in a similar group of patients supported by ECMO who were bridged to LVAD implantation, with most deaths due to multisystem organ failure with sepsis. The limited durability of ECMO (the risk of complications increases with increased duration of ECMO) led to bridging to long-term VAD support while patients still had unresolved end-organ dysfunction during ECMO support.

More recently, there have been several encouraging publications on the use of the CentriMag for support of patients in acute cardiogenic shock.\textsuperscript{13-15} John and coworkers\textsuperscript{14} reported in a single-center study use of CentriMag support in 12 patients with refractory acute cardiogenic shock and multiorgan failure. All patients were transferred from an outside hospital, with a 30-day survival of 75\%. The ease of

<table>
<thead>
<tr>
<th>TABLE 6. Adverse events</th>
<th>Patients with DREs</th>
<th>No. of DREs</th>
<th>DREs/100 d support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>8 (21%)</td>
<td>19</td>
<td>3.8</td>
</tr>
<tr>
<td>Bleeding</td>
<td>2 (5%)</td>
<td>2</td>
<td>0.4</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>1 (3%)</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Cardiac tamponade</td>
<td>1 (3%)</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Reoperation</td>
<td>7 (18%)</td>
<td>9</td>
<td>1.8</td>
</tr>
<tr>
<td>Hepatic dysfunction</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Renal failure</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Neurologic dysfunction\textsuperscript{a}</td>
<td>4 (11%)</td>
<td>4</td>
<td>0.8</td>
</tr>
<tr>
<td>Thrombotic, vascular</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Thrombotic, pulmonary</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>2 (5%)</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Device failure</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

DRE, Device-related event. *Includes 3 events categorized as “questionably related” to device.

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use of the CentriMag system allowed rapid assessment of ventricular recovery, weaning, and explantation. Its user-friendly nature is borne out by the fact that many suitably sized cannulas with good flow characteristics (including those used for routine cardiopulmonary bypass) can be successfully used. In addition, patients transferred with Biomedicus centrifugal pumps had easy conversion to extracorporeal CentriMag support. The CentriMag’s durability is also much greater than that of any other temporary circulatory assist device currently available. More recently, the Harefield group reported greater than 80% 1-month survival when using the Levitronix device as a bridge to decision in critically ill patients. Remarkably, the mean duration of support was almost 50 days. Prolonged use of this device occurred in more than 50% of cases, with the pump head prophylactically replaced at the bedside every 28 days. Recently, use of this device as a direct bridge to transplant has been reported in selected cases, with duration of support as long as 3 months. One option to consider for patients requiring temporary support with the CentriMag device who may need longer support is to design cannulas suitable for use with long-term support devices that can be used later, if necessary, when bridging to the long-term device.

The Thoratec implantable and paracorporeal VADs are also used for univentricular or biventricular support of patients with acute cardiogenic shock. Although these devices are different from other short-term devices in their durability, pulsatile flow, and potential for patient discharge, it should be noted that they are regarded as permanent devices. In the multicenter implantable VAD trial, support rates to successful outcomes were 70% for bridge to transplant and 67% for postcardiotomy recovery, versus historic results for the paracorporeal VAD trial of 69% for bridge to transplantation and 48% for postcardiotomy recovery.

Although many centers have reported survival with the CentriMag device greater than that reported in this study, it should be noted that there could be differences in populations or a selection bias in these individual series. In this study, despite the potential advantages of the CentriMag VAS, the survival with this device was similar to that achieved with other, previous devices. These outcomes may be reflective of the patient population and selection, as opposed to the type of device used.

The recent introduction of percutaneous VADs into the clinical arena has provided yet another option for patients with cardiogenic shock in select situations. In addition to gaining popularity as temporary support during high-risk coronary interventions, the TandemHeart (CardiacAssist Inc, Pittsburgh, Pa) and Impella (ABIOMED) percutaneous VADs have been successfully used for support of patients in cardiogenic shock. Whereas their primary advantage is the relative expediency of institution of hemodynamic support, potential disadvantages include the limitation of flow, thereby potentially restricting its use in larger patients. Other disadvantages include the limited duration of support, lack of percutaneous support for the right ventricle, possibility of cannula dislodgment and lower extremity ischemia, the need for strict anticoagulation, and the inability to transfer supported patients to tertiary care centers. Relative to the percutaneous devices, the CentriMag VAS is more versatile, because it can support patients as a bridge to decision, bridge to transplant, or, more commonly, bridge to permanent VAD support. The relative disadvantage of the CentriMag VAS and other surgically implanted temporary devices with respect to the percutaneous devices is that the former require a sternotomy and the need to be in a surgical operating room (as opposed to a catheterization room) for implantation.

Although this nonrandomized, controlled clinical trial had strict enrollment criteria and standardized definitions, there remains a potential for variation among centers with respect to patient management, surgical techniques, antibiotic protocols, and management of postoperative complications. The major limitations of this study were the lack of a control group and the small number of patients studied. The overall number of patients was relatively small and divided among 3 distinct patient populations, limiting the ability to perform intragroup and intergroup comparisons.

CONCLUSIONS

Although major progress has been made in the selection, mechanical support, and management of patients with chronic end-stage heart failure with the successful introduction of many new and innovative implantable devices, the options and outcomes of patients supported for acute refractory heart failure remain poor. This is mainly because of the critical condition of patients with acute cardiogenic shock but also because of the limited availability and often delayed institution of mechanical circulatory support for this group of patients. We have demonstrated in these preliminary studies that the CentriMag VAS is capable of providing biventricular support for patients with medically refractory acute cardiogenic shock with an acceptable survival. We do not know how the relative roles and interplay will be between surgical and percutaneous VADs in even the near future. Until these protocols are refined and standards of care are defined, it remains imperative that we continue to be innovative, open-minded, and aggressive in continually striving to improve outcomes for this critically ill group of patients.

References


