Bridge-to-Decision Therapy With a Continuous-Flow External Ventricular Assist Device in Refractory Cardiogenic Shock of Various Causes

Hiroo Takayama, MD, PhD; Lori Soni, MD; Bindu Kalesan, PhD; Lauren K. Truby, BS; Takeyoshi Ota, MD, PhD; Sophia Cedola, MS; Zain Khalpey, MD, PhD; Nir Uriel, MD; Paolo Colombo, MD; Donna M. Mancini, MD; Ulrich P. Jorde, MD; Yoshihumi Naka, MD, PhD

Background—Mortality for refractory cardiogenic shock remains high. In this patient cohort, there have been mixed results in mechanical circulatory support device use as a bridge-to-decision therapy. We evaluated a continuous-flow external ventricular assist device (VAD), CentriMag VAD (Thoratec Corp., Pleasanton, CA), in patients with various causes of refractory cardiogenic shock.

Methods and Results—This is a retrospective review of adult patients who underwent surgical CentriMag VAD insertion as bridge-to-decision therapy. From January 2007 through June 2012, 143 patients received CentriMag VAD. The cause of refractory cardiogenic shock was failure of medical management in 71 patients, postcardiotomy shock in 37, graft failure post–heart transplantation in 22, and right ventricular failure post–implantable left VAD in 13. Mean age was 52 ± 16 years, and 71% were in INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) profile 1. Among 138 device runs, device configuration was BiVAD in 67%, isolated right VAD in 26%, and isolated left VAD in 8%. Median duration of support was 14 days (interquartile range, 8–26). Survival was 69% at 30 days and 49% at 1 year. The next destination after the CentriMag VAD was myocardial recovery in 30%, device exchange to an implantable VAD in 15%, and heart transplantation in 18%. The failure of medical management and the graft failure post–heart transplantation groups had higher 30-day survival compared with the postcardiotomy shock group. Major bleeding events occurred in 33% and cerebrovascular accidents in 14%. There was no CentriMag pump failure or thrombosis.

Conclusions—Bridge-to-decision therapy with CentriMag VAD is feasible in a variety of refractory cardiogenic shock settings. Patients with postcardiotomy shock have inferior survival.

Key Words: heart-assist devices • shock, cardiogenic

Mechanical circulatory support device (MCSD) technology has made progress in the past decade, especially in implantable left ventricular assist devices (LVADs). MCSDs have also been used for patients in refractory cardiogenic shock (RCS) as rescue therapy, an indication referred to as bridge to decision. Survival in patients with RCS was found to be diminished compared with more stable patients when treated with the Heartmate II, an implantable intracorporeal long-term LVAD. Instead, short-term VADs have been accepted for this application, and among them the CentriMag VAD (Thoratec Corp., Pleasanton, CA) has been gaining popularity. This pump relies on magnetic levitation bearingless technology and can generate 10 L/min of continuous flow at a low rotational speed of 5500 rpm. Various types of cannulas can be connected to the CentriMag system. In addition, absence of mechanical or contact bearings, valves, or blood sacs as well as a magnetically suspended rotor exposes blood to less stagnation, turbulence, and hemolysis, and have nearly eliminated component failure. These features also facilitate an easy insertion procedure, flexible configuration, combined use with an oxygenator, longer-term use, and easy postoperative maintenance. These features make the CentriMag VAD appropriate for bridge-to-decision therapy. We evaluated the use of this VAD in patients with various causes of RCS.

Clinical Perspective on p 806

Methods

This study was approved by our institutional review board. Informed consent was waived because of the retrospective nature of the study. We reviewed charts of all consecutive patients who underwent surgical implantation of CentriMag VAD for RCS from January 2007 through June 2012. Hemodynamic and laboratory values were recorded immediately before VAD insertion and at 24 hours after initiation of VAD support. The outcomes of interest included 30-day and 1-year survival as well as destination after the CentriMag VAD support. Myocardial recovery was defined as device explantation without any other type of heart replacement therapy and subsequent hospital discharge or survival to 30 days after explantation. Complications including infection, cerebrovascular accident, and bleeding were defined according to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) criteria.

**Original Article**

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**Clinical Perspective on p 806**

**Methods**

This study was approved by our institutional review board. Informed consent was waived because of the retrospective nature of the study. We reviewed charts of all consecutive patients who underwent surgical implantation of CentriMag VAD for RCS from January 2007 through June 2012. Hemodynamic and laboratory values were recorded immediately before VAD insertion and at 24 hours after initiation of VAD support. The outcomes of interest included 30-day and 1-year survival as well as destination after the CentriMag VAD support. Myocardial recovery was defined as device explantation without any other type of heart replacement therapy and subsequent hospital discharge or survival to 30 days after explantation. Complications including infection, cerebrovascular accident, and bleeding were defined according to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) criteria.
Our algorithm of bridge-to-decision device therapy for RCS during the study period was previously described. Cardiomyopathy shock is characterized by (1) a systolic blood pressure of <90 mmHg, a cardiac index <2.0 L/min per m², pulmonary capillary wedge pressure >16 mmHg (or evidence of pulmonary edema in the absence of a pulmonary artery catheter), and evidence of end-organ failure, and (2) the inability to be weaned from cardiopulmonary bypass for postcardiomyopathy shock (PCS) despite the aforementioned measures. These patients are then rapidly evaluated by our multidisciplinary MCSD Heart Team for the absence of what we consider contraindications to MCS, including the patient’s or family’s will against MCS, clinical judgment against MCS by the primary team, >30 minutes of ongoing cardiopulmonary resuscitation (from the beginning of the cardiopulmonary resuscitation until our team arrives bedside), septic shock, and extremely short-term predicted life expectancy because of comorbidities. Advanced age is considered one of most important comorbidities in assessing predicted life expectancy, but is not an absolute contraindication. A bridge-to-decision device (CentriMag VAD or venoarterial extracorporeal membrane oxygenation [VA ECMO]) is promptly placed. VA ECMO is chosen: (1) when a patient has unclear neurological status because of prolonged cardiopulmonary resuscitation or other reasons; (2) when hemodynamics of a patient are too unstable to safely transfer the patient to the operating room; (3) when a patient has developed severe coagulopathy because of shock liver, received potent antiplatelet therapy because percutaneous coronary intervention, or other causes.

Our implantation technique allows ambulatory rehabilitation as reported elsewhere. In brief, the operation is usually performed through a median sternotomy. For the LVAD, the inflow cannula (31–40F) is inserted into the left atrium or the LV apex, and the outflow cannula (18–24F) is inserted in the ascending aorta. The LVAD inflow is chosen based on possibility of myocardial recovery and remaining LV contractile function. For the right VAD (RVAD), the inflow cannula (31F) is inserted in the right atrium, and the outflow cannula (18–24F) is inserted in the main pulmonary artery. The cannulas are secured with snares, which prevent cannula dislodgement and allow ambulatory rehabilitation. Anticoagulation with intravenous heparin is initiated once the drainage from the mediastinal tube has become serosanguinous and is continued throughout the support with a goal partial thrombin time of 60 to 80 seconds.

While supported with the device, the patients are managed by the multidisciplinary MCSD Heart Team and undergo evaluation for heart transplantation or implantable LVAD as destination therapy. Once their general condition improves, the myocardial function is evaluated by weaning the device (Figure 1), and the bridge-to-decision device is explanted to 1 of the following destinations: exchange to implantable VAD, explantation for myocardial recovery, or explantation for heart transplantation. For patients undergoing device exchange to implantable VAD, HeartMate II LVAD (Thoratec Corp) is used for patients who need only LV support, and Thoratec paracorporeal VAD, implantable VAD (Thoratec Corp), or total artificial heart (SynCardia System, Inc, Tuscon, AZ) is considered for biventricular support.

Statistical Analysis
Mean and SDs were determined for continuous variables. One-way ANOVA and paired t tests were used to compare continuous variables across the 4 groups and pre- and post-VAD laboratory values, respectively. Categorical variables were presented and compared as numbers and percentages and compared using χ² tests. Kruskal–Wallis test was used to compare number of pressors and inotropes across the 4 groups, whereas median and interquartile ranges (IQRs) were presented. Because we had complete follow-up for all subjects, the 30-day and 1-year survival was estimated as proportions. Logistic regression was used to derive odds ratios and 95% confidence intervals. Differences in baseline preoperative characteristics (significance of P<0.10) were adjusted in the multivariable logistic regression. STATA version 13.1 (Stat Corp., College Station, TX) was used to perform statistical analysis.

Results
Patient Characteristics and Surgical Technique
A total of 143 patients received CentriMag VAD support with a total of 158 device runs. Thirty-eight were transferred from other hospitals. During the same period, a total of 96 patients received device runs. Thirty-eight were transferred from other hospitals. During the same period, a total of 96 patients

![Figure 1](http://circheartfailure.ahajournals.org/Downloaded from http://circheartfailure.ahajournals.org)
received VA ECMO insertion for RCS, and 29 of them underwent device exchange from VA ECMO to CentriMag VAD. The CentriMag VAD patients were divided into 4 groups based on the cause of RCS: failure of medical management (FMM), PCS, graft failure post–heart transplantation (GF), and right ventricular failure postimplantable LVAD (RVF-p-iLVAD), including 71, 37, 22, and 13 patients, respectively. FMM was defined as persistent INTERMACS profile 1 or 2 status despite aforementioned medical management for various causes of CS, excluding PCS, GF, and RVF-p-iLVAD. The average age was 52±16 years, and 70.6% were in INTERMACS profile 1, indicating that these patients were young and acutely ill (Table 1). Among 158 device runs, bi-ventricular assist device (BiV AD) was most frequently used (105 patients; 66.5%), followed by isolated RV AD (n=41; 26.0%; this included the use of CentriMag RV AD in the presence of a pre-existing implantable LVAD) and isolated LV AD (12; 7.6%; Table 2). In patients who received LVAD, the LVAD inflow cannula was inserted in the LV apex in 60 (51.3%), the left atrium in 47 (30.2%), and the left ventricle through the left atrium traversing the mitral valve in 10 (8.5%) patients. The LVAD outflow cannula was inserted through a Dacron graft sewn in the ascending aorta in 41 (35%) of the cases, and the aorta was directly cannulated in the remaining patients. Overall, cardiopulmonary bypass support was required in 87 (55.1%) of the cases.

Outcomes
The device support resulted in significant hemodynamic improvement (Table 3). Lactic acidosis improved. Biochemical improvement of end-organ function was not observed for ≤24 hours after initiation of support. Median overall duration of support was 14 days (IQR, 8–26), 14 days (IQR, 8–27) in BiVAD, 15.5 days (IQR, 8–22) in LVAD, and 12 days (IQR, 7–22) in RVAD.

All patients completed 1-year follow-up. Overall survival rate was 69.2% at 30 days and 48.6% at 1 year (Table 4; Figure 2). The CentriMag VAD was explanted because of myocardial recovery in 30.1%, whereas 14.7% underwent device exchange to an implantable VAD, and 17.5% underwent heart transplantation (Figure 3). FMM and GF groups had higher survival compared with the PCS group (P=0.002; log-rank) at 1 year (Figure 4). In the FMM group, 1-year survival of acute myocardial infarction (AMI; n=32) and other causes (n=39) were 53.3% and 60.9%, respectively. Multivariable analysis indicated that only history of hypertension impacted 1-year survival (Table 5).

Complications
INTERMACS-defined major bleeding occurred in 32.9% (Table 6). Mediastinal bleeding was the most frequent cause of bleeding, and 20.9% of patients required mediastinal re-exploitation. Cerebrovascular accident occurred in 13.9% of patients. This was more frequent when the left side of the heart was cannulated: 16.2% in BiVAD, 16.7% in LVAD, and 7.3% in RVAD. The sternum was left open in 33% of cases to achieve hemostasis. There was no CentriMag pump failure or thrombosis. However, there were 2 cases of thrombus formation within the

<table>
<thead>
<tr>
<th>Table 1. Preoperative Patient Characteristics P/D1</th>
</tr>
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<tbody>
<tr>
<td>Overall</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>n</td>
</tr>
<tr>
<td>Age, y, mean±SD</td>
</tr>
<tr>
<td>Male sex, %</td>
</tr>
<tr>
<td>Whites, %</td>
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<tr>
<td>BMI, kg/m², mean±SD</td>
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<tr>
<td>CAD, %</td>
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<tr>
<td>Hypertension, %</td>
</tr>
<tr>
<td>Hyperlipidemia, %</td>
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<tr>
<td>Diabetes mellitus, %</td>
</tr>
<tr>
<td>INTERMACS 1, %</td>
</tr>
<tr>
<td>Intubated, %</td>
</tr>
<tr>
<td>CVVH, %</td>
</tr>
<tr>
<td>IABP, %</td>
</tr>
<tr>
<td>ECMO, %</td>
</tr>
<tr>
<td>No. of pressors, median (IQR)</td>
</tr>
<tr>
<td>No. of pressors and inotropes, median (IQR)</td>
</tr>
</tbody>
</table>

AMI indicates acute myocardial infarction; BMI, body mass index; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CVVH, continuous veno-venous hemofiltration; DCM, dilated cardiomyopathy; ECMO, extracorporeal membrane oxygenation; FMM, failure of medical management; GF, graft failure; IABP, intra-aortic balloon pump; ICM, ischemic cardiomyopathy; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; IQR, interquartile range; PCS, postcardiotomy shock; and RVF-p-iLVAD, right ventricular failure postimplantable left ventricular assist devices.
Table 2. Operative Data

<table>
<thead>
<tr>
<th>Configuration</th>
<th>n=158</th>
<th>%</th>
</tr>
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<tbody>
<tr>
<td>BVAD</td>
<td>105</td>
<td>66.5</td>
</tr>
<tr>
<td>LVAD</td>
<td>12</td>
<td>7.6</td>
</tr>
<tr>
<td>RVAD</td>
<td>41</td>
<td>26.0</td>
</tr>
<tr>
<td>Insertion with CPB use</td>
<td>87</td>
<td>55.1</td>
</tr>
<tr>
<td>Initial VAD flow, L/min, mean (SD), range</td>
<td>5.3 (±1.2), 2–8</td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Hemodynamics and Laboratories

<table>
<thead>
<tr>
<th></th>
<th>Before VAD</th>
<th>After VAD</th>
<th>Difference</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP, mean±SD</td>
<td>98.0±19.5</td>
<td>96.1±19.6</td>
<td>1.8</td>
<td>0.49</td>
</tr>
<tr>
<td>DBP, mean±SD</td>
<td>62.9±13.5</td>
<td>74.5±18.0</td>
<td>−11.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>MAP, mean±SD</td>
<td>75.4±13.2</td>
<td>80.2±13.5</td>
<td>−4.8</td>
<td>0.008</td>
</tr>
<tr>
<td>HR, mean±SD</td>
<td>98.3±20.4</td>
<td>85.2±17.5</td>
<td>−13.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>CVP, mean±SD</td>
<td>15.4±5.4</td>
<td>12.1±4.0</td>
<td>3.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mean PAP, mean±SD</td>
<td>26.7±8.6</td>
<td>25.2±7.3</td>
<td>1.5</td>
<td>0.23</td>
</tr>
<tr>
<td>Lactic acid, mean±SD</td>
<td>3.39±2.56</td>
<td>2.07±1.02</td>
<td>1.3</td>
<td>0.077</td>
</tr>
<tr>
<td>pH, mean±SD</td>
<td>7.32±0.6</td>
<td>7.32±0.8</td>
<td>−0.003</td>
<td>0.96</td>
</tr>
<tr>
<td>Cr, mean±SD</td>
<td>2.10±3.6</td>
<td>3.06±3.7</td>
<td>0.03</td>
<td>0.70</td>
</tr>
<tr>
<td>BUN, mean±SD</td>
<td>32.2±20.2</td>
<td>30.0±19.0</td>
<td>2.26</td>
<td>0.021</td>
</tr>
<tr>
<td>Hemoglobin, mean±SD</td>
<td>10.9±3.1</td>
<td>10.0±3.2</td>
<td>0.8</td>
<td>0.0006</td>
</tr>
<tr>
<td>AST, mean±SD</td>
<td>283.2±578.4</td>
<td>467.2±1383.7</td>
<td>−184.0</td>
<td>0.18</td>
</tr>
<tr>
<td>ALT, mean±SD</td>
<td>151.4±434.3</td>
<td>174.5±514.9</td>
<td>−23.1</td>
<td>0.58</td>
</tr>
</tbody>
</table>

ALT indicates alanine transaminase; AST, aspartate aminotransferase; BUN, blood urea nitrogen; Cr, creatinine; CVP, central venous pressure; DBP, diastolic blood pressure; HR, heart rate; MAP, mean arterial pressure; PAP, pulmonary arterial pressure; SBP, systolic blood pressure; and VAD, ventricular assist device.

Discussion

This is the largest series reported on CentriMag VAD use. The present study demonstrated wide applicability of this device as bridge-to-decision therapy in a variety of RCS patients using different device combinations and various anatomic configurations. CentriMag VAD support resulted in significant hemodynamic improvement, usually immediate normalization of cardiac output. The overall survival was 69.2% at 30 days and 48.6% at 1 year.

Since Mueller et al reported their experience on 11 patients with the CentriMag VAD in 2004, several small case series have been published from throughout the world. In a multicenter study of 38 patients with RCS, CentriMag devices were implanted in a left (n=8), right (n=12), or biventricular (n=18) configuration. The mean duration of support was 13 days (IQR, 1–60 days). Here, the survival rate at 30 days was 49%. Even the largest series published before our study included only 42 patients. In this series, indications for support in 42 patients were failure to wean from the cardiopulmonary bypass in the setting of PCS (n=23), GF (n=4), RVF-p-iLVAD (n=10), and refractory heart failure after AMI (n=5). Overall survival to discharge rate was 57.3%. Unique insertion techniques have also been reported, including a minithoracotomy approach and a percutaneous approach. Of note, compatibility of the system to different cannulas allows connection to other types of VADs, such as Berlin Heart Excor and PVAD. CentriMag VAD has also been used in the pediatric population as well as within ECMO configurations. When compared with previous reports, the present study is particularly relevant and unique because it provides a comprehensive evaluation of the device performance, from hemodynamics to outcomes, in the largest patient population.

Comparing our survival data with those reported in literature on MCSD use as bridge to decision is not straightforward because of differences in patient illness severity as well as in their demographics. In the present study, we used the INTERMACS profile to describe the acuity of RCS rather than other descriptions such as the use of intra-aortic balloon pump, vasoactive drips, or endotracheal intubation. Overall, 70.6% of our patients were in INTERMACS profile 1, defined as patients with life-threatening hypotension, despite rapidly escalating inotropic support, with evidence of critical organ hypoperfusion, often confirmed by worsening acidosis and lactate levels, so called crash and burn.

We categorized the causes of RCS into 4 groups: FMM (mostly consisted of RCS complicating AMI and acute decompensated heart failure), PCS, GF, and RVF-p-iLVAD. Historical outcomes of FMM may be best represented by that of RCS complicating AMI. The incidence of CS in patients with AMI ranges from 5% to 15% with some decline in the past years. Although numerous registries have confirmed the survival advantage of early revascularization since the compression by the cannula (50% incidence compared with 4.3% with left atrial cannulation and 5.0% with LV apical cannulation) and thus was abandoned. Another patient had a massive systemic air embolism because of a LVAD inflow cannula fracture. The cannula size was 28F rather than the routine size of 31F to accommodate small body size of the patient.
Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock trial in 1999, the overall in-hospital mortality rates for CS remain at \approx 50\% and approach 100\% in patients with the worst hemodynamics. Intra-aortic balloon pump support in this group of patients failed to improve outcome according to a recently completed randomized study. Thus, it seems logical to investigate more powerful MCS modalities in this patient population. We have previously reported our initial CentriMag V AD experience in patients with FMM, including RCS complicating AMI and acute decompensated heart failure. In the current study, we have expanded our cohort to include 71 patients. Patients with FMM continued to have the best survival compared with other groups. The outcome, 30-day and 1-year survival of 67\% and 57\%, is comparable with, if not more satisfactory than, previously published series using other devices. Recently, Kar et al\(^2\) reported their experience with TandemHeart pV AD (CardiacAssist, Inc, Pittsburgh, PA) of 117 patients. Their survival rate at 30 days was 60\%. Anderson et al\(^3\) also presented data on the AB5000 (ABIOMED Inc, Danvers, MA), another surgically placed LVAD. Their 30-day survival was 46\%. Of note, patients with AMI had a higher chance of myocardial recovery compared with the rest of FMM patients (36\% versus 14\%) although 1-year survival was inferior.

One subgroup of patients with persistently unsatisfactory outcomes is that of PCS. The prevalence of PCS ranges from 0.2\% to 6\% dependent on the definition. Once MCS is required, mortality ranges from 60\% to 75\%, which has not changed over time. These patients often develop RCS after a prolonged cardiopulmonary bypass run. In addition, they frequently develop multisystem organ dysfunction and require massive blood transfusions because of severe postsurgical bleeding. Although our 30-day survival of 54.1\% is one of the best outcomes reported, it remains lower than that of other subgroups. The simple cannulation procedure of the CentriMag VAD seems beneficial particularly in PCS setting, in which patients are exposed to prolonged bypass runs as well as multiple manipulations of the heart and great vessels during the index operation. In addition, flexibility in univentricular versus biventricular support and in cannulation site allows the device to be configured ideally for a given patient. These features are also advantageous in patients with GF, which often manifests as the inability to be weaned from cardiopulmonary bypass follow orthotopic heart transplant. In the presence of profound LV dysfunction, we think it is crucial to decompress the left ventricle for 2 reasons: to facilitate LV recovery and to prevent thrombus formation within the stagnant LV cavity. Although VA ECMO has recently been used with excellent results, there have been anecdotal experiences of massive thrombus formation in the left heart extending into the pulmonary veins when VA ECMO support was used for patients with profound LV dysfunction. For late GF, defined as GF after post-transplant day 7, CentriMag BiV AD was inserted in patients who were expected to be listed for retransplantation. Otherwise, circulation was temporarily supported with VA ECMO.

Lastly, RVF occurs in 20\% to 40\% of implantable LVAD recipients, and RVAD support is required in \approx 5\% of cases. The CentriMag RVAD is widely used in this setting. The 1-year survival in our cohort was just >50\%, which is likely reflective of the unfavorable prognostic nature of patients with PCS.

### Table 4. Outcomes

<table>
<thead>
<tr>
<th></th>
<th>FMM</th>
<th>Overall</th>
<th>All</th>
<th>AMI</th>
<th>Others</th>
<th>PCS</th>
<th>GF</th>
<th>RVF-p-iLVAD</th>
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</thead>
<tbody>
<tr>
<td><strong>Survival</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>n</td>
<td>143</td>
<td>71</td>
<td>32</td>
<td>39</td>
<td>37</td>
<td>22</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>30-d survival, %</td>
<td>69.2</td>
<td>76.1</td>
<td>78.1</td>
<td>74.4</td>
<td>54.1</td>
<td>77.3</td>
<td>69.2</td>
<td></td>
</tr>
<tr>
<td>Survival to discharge, %</td>
<td>57.3</td>
<td>66.2</td>
<td>62.5</td>
<td>69.2</td>
<td>32.4</td>
<td>72.7</td>
<td>53.8</td>
<td></td>
</tr>
<tr>
<td>1-y survival, %</td>
<td>48.6</td>
<td>57.3</td>
<td>53.3</td>
<td>60.9</td>
<td>23.6</td>
<td>58.0</td>
<td>53.8</td>
<td></td>
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<tr>
<td><strong>Destination at 1 y</strong></td>
<td></td>
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<td></td>
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<tr>
<td>Myocardial recovery, %</td>
<td>30.1</td>
<td>23.9</td>
<td>37.5</td>
<td>12.8</td>
<td>37.8</td>
<td>40.9</td>
<td>23.1</td>
<td></td>
</tr>
<tr>
<td>Implantable VAD, %</td>
<td>14.7</td>
<td>22.5</td>
<td>28.1</td>
<td>17.9</td>
<td>2.7</td>
<td>13.6</td>
<td>7.7</td>
<td></td>
</tr>
<tr>
<td>Heart transplant, %</td>
<td>17.5</td>
<td>25.4</td>
<td>6.3</td>
<td>41.0</td>
<td>2.7</td>
<td>22.7</td>
<td>7.7</td>
<td></td>
</tr>
</tbody>
</table>

Kaplan–Meier estimates. AMI indicates acute myocardial infarction; FMM, failure of medical management; GF, graft failure; PCS, postcardiotomy shock; and RVF-p-iLVAD, right ventricular failure postimplantable left ventricular assist device (VAD).

### Figure 2. Survival curve. The event of interest was death regardless of whether they were on CentriMag ventricular assist device (VAD) or not.
refractory RVF-p-iLVAD implantation rather than limitations in CentriMag RVAD technology.²⁷

### Surgical Versus Percutaneous Implantation of VADs in RCS

Although surgical insertion is more invasive than a percutaneous approach, this disadvantage may be offset by the beneficial features of surgical VADs that facilitate longer support times than percutaneous VADs. The longest support period in this study was 145 days with BiVAD. Importantly, while on the device support our patients participate in ambulatory rehabilitation, another advantage over percutaneous VADs.⁹ An additional important feature of the CentriMag VAD is its capability to support both ventricles when required. Fitzpatrick et al²⁸ showed that early planned institution of BiVAD resulted in improved outcomes compared with delayed conversion of an LVAD to a BiVAD. This principle has been implemented in our practice as reflected by a 66.5% use of BiVAD configuration, even after excluding those who received a CentriMag RVAD for RVF-p-iLVAD. In terms of cannula placement site, the RVAD inflow, its outflow, and LVAD outflow were almost always at the right atrium, the pulmonary artery, and the ascending aorta, respectively. The LVAD inflow was chosen based on individual’s pathophysiology. In general, the LV apex was preferred, whereas the left atrium was occasionally selected to minimize surgical insult. Regardless of the cannulation site, the insertion procedure remains simple, an important feature of a bridge-to-decision device. The only difference is that LV apical cannulation generally requires support with cardiopulmonary bypass.

### Complications of Surgical Implantation

Mediastinal bleeding was the most frequent cause of bleeding, frequently requiring mediastinal re-exploration. Bleeding was often attributed to the preoperative use of antiplatelet agents, prolonged bypass run, and shock liver. However, the cannulation sites, especially the ones for the LVAD, were occasionally identified as the source in our early experience. We have, therefore, modified our cannulation technique to reinforce these

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**Figure 3.** Competing outcomes with myocardial recovery change to durable mechanical circulatory support device (MCSD), and heart transplantation as competing/intermediate events and event of concern is death. VAD indicates ventricular assist device.

**Figure 4.** Survival curve stratified by groups. The event of interest was death regardless of whether they were on CentriMag VAD or not. FMM indicates failure of medical management; GF, graft failure after heart transplantation; PCS, postcardiotomy shock; and RVF-p-iLVAD, right ventricular failure postimplantable left ventricular assist device (VAD).
sites. The LV apical cannulation site is secured with the liberal use of felt pledgets and strips with purse string sutures for patients with fragile ventricular muscle such as post-AMI. This site is further reinforced with a polytetrafluoroethylene peri-cardial membrane, and the space around the cannulation site is filled with Bioglue (CryoLife, Inc, Kennesaw, GA). Whenever feasible, the LVAD outflow graft is inserted in the ascending aorta through a Dacron graft sewn in end-to-side fashion (rather than direct cannulation). Another important complication was cerebrovascular accident when compared with implantable LV ADs. Its incidence appeared consistent during the support (incidence ≥3 pressors and inotropes 0.49 0.17–1.36 0.13). in a recent multicenter study were bleeding (21%), infection (5%), respiratory failure (3%), hemolysis (5%), and neurological dysfunction (11%).

We believe in the important value of the MCSD Heart Team, which consists of surgeons, cardiologists, intensivists, specialized nurse practitioners, and members from other disciplines. The team provides daily ICU rounds and a weekly roundtable discussion for all patients supported on MCSDs. Implementation of the Heart Team has resulted in improved patient care, reflected by shorter ICU and hospital stays in patients with implantable LVADs (unpublished data). The Heart Team approach not only provides comprehensive daily patient care but also facilitates early initiation of the comprehensive work-up to assess patient’s candidacy for heart replacement therapy as well as decision-making regarding appropriate timing for the transition to the next destination.

There are limitations in our study. Comparing our survival data with those reported in the literature on MCSD use as bridge-to-decision devices is not straightforward because of differences in patient illness severity as well as in their demographics. This also originates from lack of more strict definitions or classifications of RCS. Appropriate categorization of patients in cardiogenic shock seems to be a limitation in using the INTERMACS profiles, which are subjective. In addition, the present study contains inherent limitations related to its retrospective nature.

In summary, we conclude that bridge-to-decision therapy with CentriMag VAD is feasible in a variety of RCS settings. This device facilitates flexible configurations and prolonged circulatory support with ambulatory rehabilitation. PCS patients continue to have inferior survival.

### Disclosures

Drs Jorde and Naka receive consultant fee from Thoratec. The other authors report no conflicts.

#### Table 5. Multivariable Analysis for Survival

<table>
<thead>
<tr>
<th>Cause</th>
<th>OR</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cause</td>
<td></td>
<td></td>
<td>0.40</td>
</tr>
<tr>
<td>PCS</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMM*</td>
<td>1.89</td>
<td>0.60–5.94</td>
<td></td>
</tr>
<tr>
<td>GVf†</td>
<td>4.20</td>
<td>0.65–27.3</td>
<td></td>
</tr>
<tr>
<td>RVF–p–ILVAD</td>
<td>2.86</td>
<td>0.48–16.9</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>0.98</td>
<td>0.94–1.02</td>
<td>0.27</td>
</tr>
<tr>
<td>Male sex</td>
<td>1.60</td>
<td>0.56–4.56</td>
<td>0.38</td>
</tr>
<tr>
<td>CAD</td>
<td>0.71</td>
<td>0.23–2.16</td>
<td>0.55</td>
</tr>
<tr>
<td>Hypertension</td>
<td>2.83</td>
<td>0.92–8.68</td>
<td>0.069</td>
</tr>
<tr>
<td>CVWH</td>
<td>0.33</td>
<td>0.12–1.94</td>
<td>0.038</td>
</tr>
<tr>
<td>≥3 pressors and inotropes</td>
<td>0.49</td>
<td>0.17–1.36</td>
<td>0.13</td>
</tr>
</tbody>
</table>

#### Table 6. Complications

<table>
<thead>
<tr>
<th>n</th>
<th>All device runs (158)</th>
<th>BiVAD (105)</th>
<th>LVAD (12)</th>
<th>RVAD (41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of support</td>
<td>20.5 (±20.6)</td>
<td>21.1 (±20.8)</td>
<td>18.8 (±17.1)</td>
<td>19.5 (±21.4)</td>
</tr>
<tr>
<td>in days, mean</td>
<td>(8.0–26.0)</td>
<td>(8.0–27.0)</td>
<td>(7.5–22.0)</td>
<td>(7.0–22.0)</td>
</tr>
<tr>
<td>Hemorrhagic, %</td>
<td>Mediastinal re-exploration</td>
<td>20.9</td>
<td>21.9</td>
<td>16.7</td>
</tr>
<tr>
<td>GI bleeding</td>
<td>9.5</td>
<td>11.4</td>
<td>0</td>
<td>7.3</td>
</tr>
<tr>
<td>Major bleed</td>
<td>32.9</td>
<td>34.3</td>
<td>16.7</td>
<td>34.2</td>
</tr>
<tr>
<td>Neurological, %</td>
<td>CVA</td>
<td>13.9</td>
<td>16.2</td>
<td>16.7</td>
</tr>
<tr>
<td>Infection, %</td>
<td>UTI</td>
<td>24.8</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>27.9</td>
<td>22.9</td>
<td>33.3</td>
<td>39</td>
</tr>
<tr>
<td>Mediastinitis</td>
<td>3.8</td>
<td>3.8</td>
<td>8.3</td>
<td>2.4</td>
</tr>
<tr>
<td>Bacteremia</td>
<td>16.5</td>
<td>13.3</td>
<td>8.3</td>
<td>2.8</td>
</tr>
</tbody>
</table>

BiVAD indicates biventricular assist device; CVA, cerebrovascular accident; GI, gastrointestinal; IQR, interquartile range; LVAD, left ventricular assist device; RVAD, right ventricular assist device; and UTI, urinary tract infection.
References


CLINICAL PERSPECTIVE

Mortality for refractory cardiogenic shock remains high. In this patient cohort, there have been mixed results with regard to the use of mechanical circulatory support devices as a bridge-to-decision therapy. Among available mechanical circulatory support devices, CentriMag ventricular assist device (VAD; Thoratec Corp, Pleasanton, CA) is gaining popularity for this indication. This single-center retrospective study included the largest number of patients (n=143) supported with surgically implanted CentriMag VAD in various settings of refractory cardiogenic shock: failure of medical management in 71 patients, postcardiotomy shock in 37, graft failure postheart transplantation in 22, and right ventricular failure postimplantable left VAD in 13. This VAD allowed various configurations to accommodate the need of individual patient. Survival was 69% at 30 days and 49% at 1 year. The next destination after the CentriMag VAD was myocardial recovery in 30%, device exchange to an implantable VAD in 15%, and heart transplantation in 18%. Bridge-to-decision therapy with surgical CentriMag VAD is feasible in a variety of refractory cardiogenic shock settings. This comprehensive summary of our experience provides outcomes of patients who require mechanical support for refractory cardiogenic shock in the current era and sets a standard against which outcomes of a short-term mechanical circulatory support device, percutaneous or surgical, should be compared.
Bridge-to-Decision Therapy With a Continuous-Flow External Ventricular Assist Device in Refractory Cardiogenic Shock of Various Causes

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