

Clinical Experience Using the Levitronix CentriMag System for Temporary Right Ventricular Mechanical Circulatory Support

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Background: Short-term mechanical circulatory support may be lifesaving in patients with right ventricular (RV) failure related to post-cardiotomy cardiogenic shock (PCCS), cardiac transplantation (CTx), and long-term therapy with a left ventricular assist device (LVAD). This study evaluates our clinical experience using the CentriMag (Levitronix LLC, Waltham, Mass) system for temporary mechanical RV support.

Methods: A retrospective review was performed of 29 patients (mean age, 57 ± 14 years) in whom the CentriMag system was used for RV support from September 2005 to March 2008.

Results: The indication for RV support was PCCS in 7 (24%), CTx in 10 (35%), and LVAD placement in 12 (41%). The mean support time was 8 ± 8 days. The device was successfully weaned in 3 PCCS patients (43%), 7 CTx patients (70%), and 7 LVAD patients (58%). Complications included major infection (pneumonia, sepsis, or LVAD pocket infection) in 13 (45%), arrhythmia in 13 (45%), reoperation for bleeding in 10 (35%), stroke/encephalopathy in 3 (10%), and air embolism in 1 (3%). Early mortality (< 30 days or before discharge) occurred in 14 patients (48%) of which 9 (31%) died with the device in place. Late death occurred in 2 of 15 patients (13%) who survived to discharge. There were no device failures.

Conclusions: The CentriMag system provides effective temporary mechanical circulatory support for RV failure. Ease of implantation and a high rate of successful device weaning justify the use of the CentriMag system for temporary RV support. *J Heart Lung Transplant* 2009;28:971-6. Copyright © 2009 by the International Society for Heart and Lung Transplantation.

Right ventricular (RV) failure is a clinical problem associated with a high mortality that may occur in a variety of settings, including post-cardiotomy cardiogenic shock (PCCS),¹ cardiac transplantation (CTx),² and after long-term therapy with a left ventricular assist device (LVAD).³ Short-term mechanical circulatory support (MCS) for RV dysfunction may prove lifesaving in such situations.

We recently began using the CentriMag (Levitronix LLC, Waltham, MA) for temporary RV support because of its ease of implantation and unique design (Figure 1).

This device has a magnetically levitated rotor that eliminates the need for bearings or seals and results in less friction and heat generation in the blood path. Because the rotor surface is completely washed by blood, the risk of blood stagnation and turbulence is minimized, resulting in less hemolysis and thrombosis. Such new-generation devices may minimize morbidity and mortality in these often-moribund patients, especially when used early after the onset of RV dysfunction before high-dose inotropic agents are required. This study reports our clinical experience with the CentriMag system for temporary mechanical RV support.

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METHODS Patients

Approval was obtained from the University of Pittsburgh Medical Center Internal Review Board. All data for patients receiving MCS at the University of Pittsburgh is prospectively entered into a database. We performed a retrospective review of patients who underwent implantation of the CentriMag for RV support from September 2005 through March 2008. The study excluded 6 patients because the device required exchange in the operating room for extracorporeal membrane oxygenation support due to deterioration in

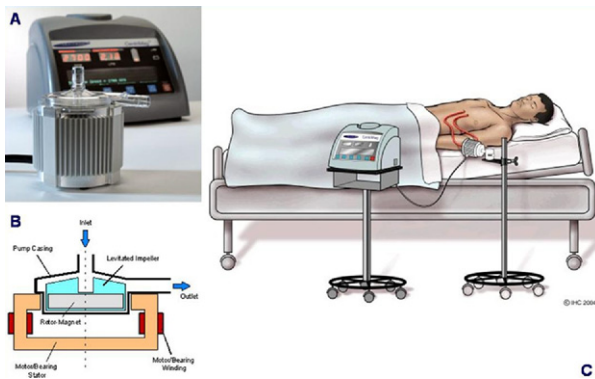


Figure 1. (A) Levitronix CentriMag rotor and bearingless pump. (B) A schematic representation of the pump and (C) console as seen in clinical use. Reprinted with permission from Levitronix LLC. Copyright IHC 2004.

pulmonary function. One patient who underwent placement of the CentriMag for RV failure after CTx required replacement less than 12 hours after the device was weaned and removed. A detailed record review collected demographic, procedural, and outcome data. Adverse events after device implantation were defined according to Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) guidelines.⁴

Device Placement

The diagnosis of RV failure was made if there was significant RV dysfunction seen by transesophageal echocardiography despite adequate inotropic support and inhaled nitric oxide. All patients underwent implantation of the CentriMag system through a midsternotomy with cardiopulmonary bypass (CPB) support, or in patients with an LVAD, shortly after CBP was weaned.

For the inflow, the right atrial appendage was cannulated with a 24F to 28F angled, wire-reinforced cannula secured with 2 multipledgeted, 2-0 Tevdek (Teleflex Medical, Mansfield, MA) purse-string sutures. For the outflow, the pulmonary artery was directly cannulated with a 20F to 22F elongated 1-piece arterial cannula (Medtronic Inc, Minneapolis, MN) secured with two 3-0 Tevdek purse-string sutures. Cannulas were tunneled sub-cutaneously to exit along the right costal margin.

The CentriMag pump head and tubing were primed on the back table with normal saline, deaired, and attached to the inflow and outflow cannulas. The speed of the pump was then gradually increased to achieve adequate flows of 4 to 6 liters/min, with caution exercised to avoid pulmonary overflow by monitoring the pulmonary artery diastolic pressures. CPB was weaned in sequence with increasing the CentriMag pump flow. In patients with a long-term LVAD, the LVAD was also initiated as CBP was weaned. Once satisfactory flows were established, the patient was

separated from CPB completely and protamine sulfate was administered.

Primary closure of the sternum was accomplished in 18 patients (62%). If primary closure was not possible due to excessive edema, the skin was approximated over the open sternum or an Esmarch dressing was used to cover the defect by attaching it to the wound with skin staples in a circumferential manner, followed by an Ioban antimicrobial incise drape (3M Corp, St. Paul, MN).

Device Weaning and Removal

A weaning transthoracic echocardiogram was obtained in the intensive care unit after 48 hours of support to evaluate RV function. Low-dose inotropic support with milrinone ($\leq 0.25 \mu\text{g}/\text{kg}/\text{min}$) or epinephrine ($\leq 0.05 \mu\text{g}/\text{kg}/\text{min}$) was initiated before attempting to wean the device. Signs consistent with RV recovery included increased amplitude of the pulmonary arterial waveform, no need for escalation of inotropic support, maintenance of a low central venous pressure, and improved RV systolic function on echocardiography.

If RV function recovered, the patient was scheduled for elective removal of the CentriMag system in the operating room with transesophageal echocardiographic guidance. Patients who did not demonstrate RV recovery after 7 to 14 days but were deemed acceptable candidates for CTx underwent exchange of the CentriMag for a Thoratec Paracorporeal Ventricular Assist Device (PVAD; Thoratec Corp, Pleasanton, CA) for long-term RV support. Thereafter, RV function was reassessed monthly. Weaning was considered to have failed in these patients.

Anti-coagulation

No anti-coagulation was used for the first 12 to 24 hours post-operatively. Appropriate blood products were administered to normalize the coagulation profile as needed. Once bleeding was less than 50 ml/hour from each chest tube for 4 to 6 hours, a heparin infusion was initiated and gradually increased to achieve an activated partial thromboplastin time (aPTT) of 59 to 72 seconds. In patients with significant thrombocytopenia, anti-coagulation was withheld even if chest tube output was acceptable. Patients with a normal platelet count but with documented heparin antibodies received a bivalirudin infusion targeting the same aPTT range.

Statistical Analysis

Statistical analysis was performed using Stata 10 software (StataCorp LP, College Station, TX). Descriptive statistics are reported as mean \pm standard deviation. Actuarial survival estimates were calculated using Kaplan-Meier life-table analysis.

RESULTS

A total of 29 patients who received a CentriMag RVAD met the inclusion criteria. Demographic data are summarized in Table 1. The indication for RV support was PCCS in 7 patients (24%), RV failure after CTx in 10 (35%), and after LVAD therapy in 12 (41%).

The mean support time was 8 ± 8 days (range, 0–38 days). The overall rate of successful device weaning was 66%: 3 of 7 PCCS patients (43%), 7 of 10 CTx patients (70%), and 7 of 12 LVAD patients (58%; Figure 2). Significant post-operative adverse events included major infection in 13 (45%), arrhythmia in 13 (45%), repeat operation for bleeding in 10 (35%), stroke/encephalopathy in 3 (10%), and air embolism in 1 (3%). These events are reported according to indication for RV support in Table 2. There were no device failures. Weaning failed in 3 patients in the LVAD group, and replacement of the CentriMag with a Thoratec PVAD was required. Two of these patients were successfully bridged to transplantation.

Early death (<30 days or before discharge) occurred in 14 patients (48%), of which 9 (31%) died with the device in place. Late death occurred in 2 of 15 patients (13%) who survived to discharge. Causes of death in these patients are summarized in Table 2. There were

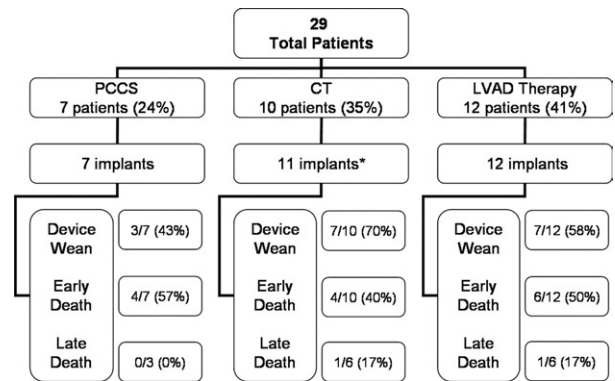


Figure 2. Flow diagram demonstrates outcomes according to the indication for right ventricular (RV) support. PCCS, post-cardiotomy cardiogenic shock; CT, cardiac transplantation; LVAD, left ventricular assist device. *One patient underwent reinstitution of CentriMag RVAD support with in 12 hours of device removal.

no differences in overall survival based on the indication for support (Figure 3).

DISCUSSION

This article augments the growing literature demonstrating that the Levitronix CentriMag system provides effective temporary MCS in a variety of clinical settings (Table 3).⁵⁻¹³ This study focused on the role the CentriMag might have in a diverse patient population with a specific indication. Primary RV failure, a problem that is often underappreciated, can occur in a variety of settings after cardiac surgery. The incidence of RV failure varies from < 1% for most elective reconstructive cardiac surgical procedures to $\geq 30\%$ for patients after placement of a long-term LVAD.^{2,14,15} Although most RV failure is reversible with appropriate medical

Table 1. Peri-operative Characteristics of Patients Receiving Right Ventricular Support With the Levitronix CentriMag According to Indication for Support

Characteristic ^a	PCCS (n = 7)	CTx (n = 10)	LVAD (n = 12)
Age, years	67 ± 13	61 ± 7	47 ± 14
Sex			
Male	5 (71)	9 (90)	8 (75)
Female	2 (29)	1 (10)	4 (25)
Primary diagnosis			
Ischemic cardiomyopathy	5 (71)	6 (60)	4 (33)
Nonischemic cardiomyopathy	0 (0)	3 (30)	6 (50)
Other ^b	2 (29)	1 (10)	2 (17)
Comorbidities	2 (29)		
Diabetes	5 (71)	1 (10)	3 (25)
Hypertension	4 (57)	4 (40)	3 (25)
Intra-aortic balloon pump		2 (20)	3 (25)
Type of LVAD			
HeartMate XVE	1 (8)
Thoratec PVAD	4 (33)
HeartMate II	5 (42)
VentrAssist	2 (17)
Length of CentriMag support, days	3 ± 2	8 ± 11	9 ± 2

CTx, cardiac transplantation; LVAD, left ventricular assist device; PCCS, post-cardiotomy cardiogenic shock; PVAD, paracorporeal ventricular assist device.

^aCategoric data are presented as number (%); and continuous data as mean ± standard deviation.

^bThese included valvular heart disease, congenital heart disease, massive pulmonary embolism, and post-partum cardiomyopathy.

Table 2. Adverse Events and Death

Variable	PCCS (n = 7) No. (%)	CTx (n = 10) No. (%)	LVAD (n = 12) No. (%)
Adverse event			
Re-op for bleeding	1 (14)	4 (40)	5 (42)
Major infection	2 (29)	3 (30)	8 (67)
Arrhythmia	2 (29)	4 (40)	7 (58)
Stroke/encephalopathy	1 (14)	0 (0)	2 (17)
Air embolism	0 (0)	0 (0)	1 (8)
Causes of early death			
MSOF/sepsis	0 (0)	2 (20)	3 (25)
LV failure	1 (14)	1 (10)	0 (0)
Stroke	0 (0)	0 (0)	1 (8)
Care withdrawn	3 (43)	1 (10)	2 (17)
Causes of late death			
Stroke	0 (0)	0 (0)	1 (8)
Care withdrawn	0 (0)	1 (10)	0 (0)

CTx, cardiac transplantation; LVAD, left ventricular assist device; MSOF, multisystem organ failure; PCCS, post-cardiotomy cardiogenic shock.

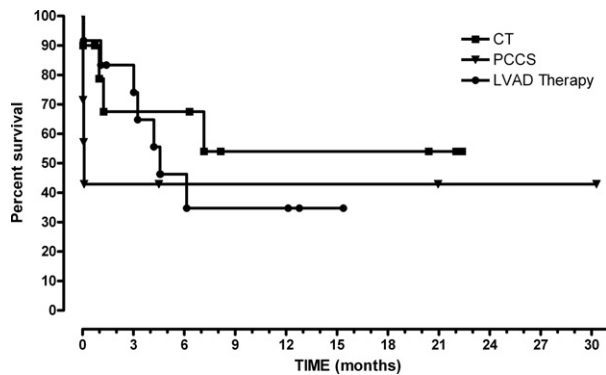


Figure 3. Kaplan-Meier survival according to indication for right ventricular support. CT, cardiac transplantation; PCCS, post-cardiotomy cardiogenic shock; LVAD, left ventricular assist device.

management, persistent RV failure despite inotropic support is an ominous sign associated with significant mortality.¹ Temporary MCS of the RV in this setting can be lifesaving.

Patients with RV failure are extremely ill, require high-dose inotropic/vasopressor support, and are coagulopathic due to hepatic congestion. The ideal device for providing RV support is easy to implant and explant, provides adequate RV support, requires minimal anti-coagulation, and is relatively inexpensive. Currently available devices for temporary RV support, including Medtronic Biomedicus, Abiomed AB5000 (Abiomed, Danvers, MA), and the Thoratec PVAD, have limited applicability in the setting of acute RV failure due to one or more of the following problems: adverse effect on blood elements such as hemolysis and platelet damage (Biomedicus), relatively higher cost (Thoratec PVAD, Abiomed AB500), or greater complexity of implantation

Table 4. Comparative Characteristics of Various Mechanical Circulatory Support Devices Available for Temporary Right Ventricular Support

Characteristic	Medtronic BioMedicus	Abiomed AB5000, Thoratec PVAD	Levitronix CentriMag
Blood element damage	High	Low	Low
Cost	Low	High	Moderate
Complexity of implant	Low	High	Low
Anti-coagulation need	High	High	Low
Safe duration of use	Days	Months	Weeks

PVAD, paracorporeal ventricular assist device.

(Thoratec PVAD, Abiomed AB500). The Thoratec PVAD and the Abiomed AB5000 both require the anastomosis of an outflow graft to the pulmonary artery, which adds complexity to the procedure and increases the potential for bleeding complications. All of these devices require prompt anti-coagulation after implantation.

The CentriMag system provides numerous advantages compared with other devices (Table 4), primarily related to its magnetically levitated rotor and lack of bearings or seals. This unique design allows rotation of the rotor with less friction and wear. Lower heat generation results in less thermal damage to blood components, less hemolysis, and a reduced risk of thrombus generation. Other advantages include ease of priming and implantation. Direct cannulation of the pulmonary artery reduces the time required for implantation and the need for more specialized training.

Although the device is licensed for only 14 days of continuous use, the literature demonstrates it has been used for more than 6 weeks without device-related complications.⁵ We have had a similar experience with the device functioning without complications for 38

Table 3. Review of the Literature Describing Levitronix CentriMag^a Use

First author	Year	No.	Indication	Support, R/L/B	Support time, days	Weaned, No. (%)	Early death, No. (%)
DeRobertis ⁵	2006	12	PCCS	3/6/3	8	5 (42)	7 (58)
		6	BTD	0/3/3	26	0 (0)	5 (83)
Santise ⁶	2006	2	PGF	0/0/2	5	1 (50)	0 (0)
Whitson ⁷	2007	1	BTD ^b	0/0/1	7	1 (100)	0 (0)
John ⁸	2007	12	BTD ^c	0/0/12	8	2 (17)	3 (25)
Maat ⁹	2008	3	BTD ^d	0/1/2	6	0 (0)	1 (33)
Shuhaiber ¹⁰	2008	7	PCCS	0/2/5	8	3 (43)	4 (57)
		9	BTD	0/4/5	17	0 (0)	7 (78)
		6	PGF	1/1/4	9	2 (33)	3 (50)
		5	LVAD	5/0/0	18	0 (0)	5 (100)
DeRobertis ¹¹	2008	16	BTD	0/6/10	47	2 (13)	3 (19)
Clough ¹²	2008	2	PCCS	0/1/1	16	2 (100)	0 (0)
Gregoric ¹³	2008	1	PCCS	0/1/0	14	0 (0)	1 (100)

B, biventricular; L, left ventricular; BTD, bridge to decision; LVAD, left ventricular assist device; PCCS, post-cardiotomy cardiogenic shock; PGF, primary graft failure; R, right ventricular.

^aNo device failures were documented.

^bSeptic shock related to *Aspergillus*.

^cIncludes 2 patients with PCCS.

^dPediatric patients.

days. Additionally, given the lower risk of thrombosis, we have successfully used the device for right-sided support without anti-coagulation for more than 72 hours without device thrombosis.

Because of these numerous advantages and the unique versatility of the CentriMag system, many centers have now found it to be efficacious both for RV and LV support, especially as a bridge-to-decision mechanism to triage moribund patients.^{8,10,12} Our experience with the CentriMag for RV support has been relatively equally distributed amongst patients with RV failure related to PCCS, CTx, and LVAD therapy.

Primary RV failure after routine cardiac surgery is an uncommon event in the current era of advanced cardiac anesthesia support but carries a significant mortality rate when it occurs. Although most reports describing PCCS MCS have dealt primarily with LV failure, some have addressed RV failure using centrifugal pumps or the Abiomed system.^{1,16}

A recent report by DeRobertis et al⁵ described use of the CentriMag system in 12 PCCS patients, comprising LV support in 6, RV support in 3, and biventricular support in 6. The average duration of support was 8 days, and 5 patients were successfully weaned. The early mortality rate for these patients was 42%. Of the 3 patients who underwent isolated RV support, only 1 was successfully weaned. Another was bridged to transplant but then died, and the third died with the device in place. Although these are commendable results in an extremely compromised group of patients, they are comparable to results from previous reports with the Biomedicus and AbioMed systems, where successful weaning and overall survival were generally both less than 50%.^{1,16} Our experience with the CentriMag for RV support for PCCS was similarly poor, with an overall weaning rate of only 43% and an early mortality of 57%.

We attribute this poor outcome not only to the general level of illness of these patients but also to unrecognized LV dysfunction that often accompanies RV dysfunction and at times may be underappreciated. The potential need for biventricular support in these extremely ill patients must be addressed by the surgeon at the time of surgery, with the attendant risks and benefits considered with each individual patient and family. In this situation, patient selection is important in ensuring adequate success with temporary mechanical RV support.

Another important group of patients who have benefited from mechanical RV support are those with RV dysfunction after CTx. Because of a declining pool of acceptable donors, there is a growing trend toward the use of marginal donor hearts.¹⁷ As a consequence, it is not uncommon to experience primary graft failure presenting as isolated RV dysfunction or biventricular failure. Previous reports have documented successful use of the CentriMag system for biventricular support

after CTx.^{6,10} Our experience with the CentriMag system in the setting of RV failure after CTx suggests that it provides adequate temporary RV support, with a weaning rate of 70% and an early mortality of 40%. The effect of RV failure and the requirement for MCS places patients at a higher risk for post-operative complications such as sepsis and multiorgan failure, which accounted for many of the deaths in this cohort. These results represent a significant improvement compared with the nearly uniform mortality associated with RV failure after CTx without temporary MCS.

The high rate of successful weaning experienced with these patients is likely a result of early identification of RV dysfunction in the setting of adequate medical management. We use continuous hemodynamic monitoring of the central venous and pulmonary artery pressures, recognizing that low pulmonary artery pressures in the setting of high right atrial pressures often indicate a greater degree of ventricular dysfunction and an inability to generate contractile force. In addition, we routinely use intraoperative transesophageal echocardiography for evaluation of right heart function and maintain a low threshold for instituting mechanical support when important RV dysfunction is identified. Early mechanical support also has allowed primary chest closure at the time of CTx in 68% of patients who would otherwise have required keeping the chest open, with the attendant risk of infectious complications.

A unique group of patients in whom temporary RV support is often necessary are patients in whom RV failure develops at the time of or shortly after LVAD therapy, which may occur in 20% to 40%.^{2,14,15} LVAD therapy has been demonstrated to be efficacious in bridging patients with end-stage heart failure to CTx; however, this process can be limited by the development of severe RV failure that may be related to pre-existent RV failure and exacerbated by increased pre-load, transient elevation of pulmonary vascular resistance related to CPB, and LV decompression with septal shift.¹⁵ In such patients, temporary RV mechanical support may allow for RV recovery and ultimately long-term support with an LVAD alone. Unfortunately, the development of severe RV failure requiring mechanical RV support after LVAD placement adversely affects the overall bridging success rate, prolongs the length of hospital stay, and increases device-related death and overall hospital cost.^{3,18}

A recently published experience in which the CentriMag was used for RV support in 5 patients after LVAD therapy demonstrated an early mortality rate of 100%.¹⁰ Three of the 5 patients had RV support instituted more than 72 hours after initiation of LVAD support, suggesting that delayed institution of RV support may portend a poor outcome. Similarly, another study that used the Abiomed system in which support was instituted

within 24 hours yielded a bridging success rate of 70% vs only 57% if support was delayed.¹⁸

At our center during the study period, 22 of the 79 patients (28%) who received MCS therapy for heart failure had significant biventricular failure necessitating immediate biventricular support. The remaining 57 patients (72%) received LVAD support as the primary therapy; of these, 12 (21%) required additional temporary RV support and 3 (25%) ultimately required permanent RV support. Our overall experience with the CentriMag in these patient demonstrates an excellent weaning rate of 58%. We attribute this success largely to early initiation of RV support at the time of LVAD placement, which occurred in 11 patients (92%). The early mortality for these patients was 50%, which is better than that observed in previous studies. We attribute this improvement to a higher weaning rate related to early implementation of support.

In conclusion, we have demonstrated that the CentriMag system provides effective temporary mechanical circulatory support for acute RV failure in a variety of clinical settings, with higher rates of RV recovery and survival than previously reported. Device-specific advantages, such as ease of implantation, reduced mechanical damage to blood elements, and lower need for anti-coagulation, make it a particularly attractive device for temporary RV support. Encouraging rates of successful weaning when used for RV failure after CTx and after long-term LVAD therapy justify its continued use in these settings. Early institution of support appears to contribute to improved weaning rates, especially when used after LVAD therapy.

Nonetheless, the development of RV failure has a profound effect on survival, regardless of the clinical scenario. Furthermore, successful outcomes in such challenging situations require an experienced team of medical professionals. We recommend that patients who develop significant RV failure at centers that lack an experienced MCS program be transferred to a tertiary referral center that has such experience. A better understanding of the pathophysiology of RV dysfunction and the means by which to prevent it will be essential to improving outcomes in this extremely high-risk cohort of patients.

DISCLOSURE STATEMENT

The authors have no relevant disclosures to report.

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