

The CentriMag ventricular assist device in acute heart failure refractory to medical management

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BACKGROUND: The CentriMag ventricular assist device (VAD) has gained popularity in the last several years as rescue support for patients with decompensated heart failure. We have used the CentriMag VAD as a bridge to decision device. We describe our experience with device placement, use and outcomes.

METHODS: This is a retrospective study of all patients who underwent CentriMag placement at our institution from January 2007 to August 2009. Sixty-three patients had placement of a CentriMag device, with 43% ($n = 27$) of these being placed due to failure of medical management. These cases were the focus of our study.

RESULTS: Primary diagnoses were ischemic cardiomyopathy ($n = 17$), dilated cardiomyopathy ($n = 7$) or other ($n = 3$). Mean age was 47.1 (range 7 to 72) years. Prior to implant, 85% of patients were on intra-aortic balloon pump (IABP) support, 70% were on vasopressors, and 44% were on more than one inotrope. INTERMACS score was 1 in 67% of patients and 2 in 33% of patients. Six patients were bridged to a long-term device, 8 to transplantation and 10 to recovery. Eighty-nine percent (24 of 27) of patients survived to explant and 74% (20 of 27) survived to hospital discharge, with a 1-year survival of 68%. Thromboembolic complications occurred in 10 patients, including 6 strokes. Compared with patients who survived to discharge, those who died had a significantly higher body mass index (30.8 vs 24.1 kg/m², $p = 0.003$). Survivors to discharge demonstrated significant improvements in hepatic and renal function over the course of device support while non-survivors did not.

CONCLUSIONS: The CentriMag demonstrates promising results when used in patients with acute heart failure refractory to medical management.

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Industrialized nations have witnessed significant increases in life expectancy associated with advances in medical care. However, the incidence of various age-related comorbidities has increased in parallel. In 2006, congestive heart failure affected an estimated 5.8 million adults (2.6%) in the USA, including 5% to 10% of those aged 60 to 80 years.¹ Furthermore, the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial demonstrated a 75% 1-year mor-

tality rate for New York Heart Association Class IV heart failure patients managed with optimal medical therapy.²

Heart transplantation remains the optimal treatment for end-stage heart failure, but other strategies are necessary due to a limited donor supply. Although long-term implantable ventricular assist devices (VADs) are used successfully as a bridge to transplant or for destination therapy, their use is limited by high morbidity and mortality in inappropriate candidates and high costs.^{3–5} As a result, strict patient criteria have been developed for their use.³ In emergent settings, mechanical circulatory support (MCS) may be required in the absence of time to perform such an evaluation. In such cases, a short-term device is utilized to provide circulatory support and restoration of end-organ function

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while either myocardial recovery occurs or evaluation for a long-term approach may be undertaken. Various short-term devices, including extracorporeal membrane oxygenation (ECMO), the Biomedicus, Abiomed BVS5000 and CentriMag, as well as percutaneous VAD technology, have all been used in these scenarios as a bridge to decision, each with their benefits and drawbacks.⁶ The CentriMag is our device of choice because of its ease of insertion with snared cannulae, as well as the advantages of its bearingless magnetically levitated pump system, which allows for fewer moving parts and resulting reductions in friction, wear and hemolysis.

Herein we describe our experience with the CentriMag in patients with acute heart failure refractory to medical management with the goal of demonstrating improvements in end-organ function while myocardial recovery or evaluation for a long-term device or transplantation proceeds.

Methods

All CentriMag placements at our institution were analyzed retrospectively. From January 2007 until August 2009, 63 patients underwent surgical CentriMag placement, primarily for cardiac support. Of these devices, 27 were placed for failure of medical management and are the focus of this study. Eleven were placed for right ventricular failure after long-term LVAD and 25 for post-cardiotomy shock/graft failure after heart transplantation. Failure of medical management was defined as unstable hemodynamics with impaired end-organ perfusion despite maximal medical therapy, including multiple inotropes and vasopressors with or without intra-aortic balloon pump (IABP) counterpulsation. Data were collected via chart review and survival data were supplemented with the Social Security Death Index.

Data collection

Data collected included demographics such as patient age, gender and body mass index; prior cardiac procedures; and pre-operative factors, such as IABP use, inotrope and vasopressor requirement, need for mechanical ventilation, indication for CentriMag support and INTERMACS level. Operative data included type of device placed, concomitant procedures and use of cardiopulmonary bypass. Complications included thromboembolic phenomena, bleeding requiring open chest management or re-exploration, and cannula malpositioning requiring operative intervention. Daily flow rates were recorded at 24-hour intervals from the time of arrival to the intensive care unit. Laboratory markers of end-organ function collected included blood urea and nitrogen, creatinine and liver function tests. Outcomes included reason for explant (recovery, transplantation, long-term device placement or death) and survival status at discharge and last known follow-up.

Statistical analysis

Continuous variables are represented as the mean with ranges and categorical variables as frequency and percentage. Continuous variables were compared using Student's *t*-test and categorical variables were compared using the chi-square test or Fisher's exact

test as appropriate. $p < 0.05$ was considered statistically significant. All reported *p*-values are 2-sided. Kaplan-Meier analysis was used to calculate survival rates and the log-rank test was used to determine statistical significance. All data were analyzed using STATA or EXCEL software programs.

Results

Demographics

From January 2007 until August 2009, 63 patients underwent surgical CentriMag device placement, primarily for cardiac support. Of these devices, 43% ($n = 27$) were placed for failure of medical management, including 26 biventricular VADs (BiVADs) and 1 LVAD (Table 1). Mean age was 47.1 (range 7 to 72) years. Mean length of support was 15.9 (range 2 to 48) days and mean follow-up was 412 (range 3 to 1,103) days. Seventy percent of patients ($n = 19$) were transferred from an outside hospital.

Primary diagnoses included ischemic cardiomyopathy in 63% ($n = 17$), dilated cardiomyopathy in 26%⁷ or other in 11%.³ Of those with ischemic cardiomyopathy, 13 had an acute myocardial infarction, and 8 underwent percutaneous coronary intervention just prior to CentriMag placement. One case of dilated cardiomyopathy was secondary to adriamycin toxicity, whereas the others were either of the famil-

Table 1 Demographics

	<i>n</i> (range or %)
Age (years)	47.1 ^a (7–72)
Female	4 (15%)
Transferred from outside hospital	19 (70%)
Re-operation	5 (19%)
Ischemic cardiomyopathy	17 (63%)
Acute myocardial infarction	13
Percutaneous coronary intervention	8
Dilated cardiomyopathy	7 (26%)
Length of disease <6 months	21 (78%)
Ventilator-dependent	20 (74%)
Pre-operative IABP	23 (85%)
Pre-operative MCS	3 (11%)
Vasopressor support	19 (70%)
Two or more inotropes	12 (44%)
INTERMACS 1	18 (67%)
Length of support (days)	15.9 ^a (2–48)
Length of follow-up (days)	412 ^a (3–1,103)
Device	
BiVAD	26 (96%)
LVAD	1 (4%)
RVAD	0
ECMO spliced into RVAD	6 (22%)

BiVAD, biventricular assist device; ECMO, extracorporeal membrane oxygenator; IABP, intra-aortic balloon pump; MCS, mechanical circulatory support; LVAD, ventricular assist device; RVAD, right ventricular assist device.

^aMean value.

ial or idiopathic types. The three final cases included 1 patient with myocarditis, 1 with likely rejection at 3 years after heart transplant, and 1 who had an acute myocardial infarction due to transplant coronary artery disease at 10 years after heart transplant.

Five patients had prior cardiac procedures, including 2 prior coronary artery bypass grafting procedures in 1 patient, simultaneous coronary artery bypass grafting (CABG) and aortic valve replacement in 1, mitral valve repair in 1, CABG and subsequent heart transplantation in 1, and HeartMate II implantation and subsequent heart transplantation in 1. Before VAD placement, 85% of patients were on IABP support, 70% were on vasopressors, and 44% were on more than one inotrope. Three patients had MCS already in place at the time of CentriMag implantation, including 1 patient on Abiomed support, 1 with a Tandem Heart and 1 with an Impella device. INTERMACS score was 1 in 67% ($n = 18$) of patients and 2 in 33% of patients.⁹

Operative details and post-operative management

VAD insertion was performed via a median sternotomy as described previously.⁷ CentriMag placement was performed without cardiopulmonary bypass whenever possible at the discretion of the operating surgeon. In general, cardiopulmonary bypass was not utilized unless the patient was in extremis at the start of the procedure. LVAD inflow was performed via the left ventricle when myocardial recovery was possible (either via the left ventricular apex or the left atrium and the mitral valve). Anti-coagulation with intravenous heparin with a target prothrombin time (PTT) of 60 to 80 seconds was started when the chest tube output decreased, usually after Day 3 post-operatively. All patients were extubated if they met standard criteria and 7 patients were out of bed with the device.

Twenty-six BiVADs and 1 LVAD were placed for failure of medical management. Forty-four percent of cases ($n = 12$) were performed without cardiopulmonary bypass. Of the 15 patients in whom cardiopulmonary bypass was utilized, 1 was placed on bypass for simultaneous coronary artery bypass grafting (biventricular VAD implantation was planned pre-operatively as a bridge to recovery). In 17 patients, LVAD inflow was via cannulation of the left ventricular apex, and in 10 patients it was done via left atrial cannulation. In 2 cases utilizing left atrial cannulation, the cannulae were passed into the left ventricle via the mitral valve. One of the aforementioned patients had undergone Abiomed placement at an outside hospital for decompensation after an acute myocardial infarction. The patient was transferred to our institution, and the next day underwent device exchange to a CentriMag. The same cannulae as for the Abiomed were utilized with the exception of the LVAD inflow cannula, which was converted from the left atrium to the left ventricle. Six patients had an extracorporeal membrane oxygenation (ECMO) device spliced into the RVAD circuit for poor oxygenation or cooling.

The decision of whether to explant or exchange the device for a long-term device was made based on the clin-

ical situation of the patient. In general, CentriMag support was continued until near complete end-organ recovery was ensured. At this point, the potential for cardiac recovery was addressed. When the heart was considered recoverable, CentriMag support was continued; otherwise, heart transplant or device exchange was considered.

At our institution, cardiac function is monitored with periodic echocardiography and, if significant improvements in function are seen, a weaning study is performed. Flow is decreased to 3 liters/min at the bedside to confirm hemodynamic stability. If this is tolerated, then the patient is taken to the catheterization laboratory and a full assessment is performed with echocardiography, with or without Swan-Ganz catheter placement. After heparinization, flow is further decreased to as low as 1 liter/min. This weaning study is tailored based on the expected severity of ventricular dysfunction as determined by clinical observation. Final functional assessment is based on clinical judgment in combination with these measurements. In patients who recover, re-sternotomy is performed and the cannulae removed and purse-strings tied. When a patient is expected to need a long period of support (such as those with blood type O awaiting transplant), the device is exchanged to a long-term device to facilitate hospital discharge as well as to decrease complications.

Flow rates and complications

Average LVAD flow indices (flow per body surface area) of ≥ 2.6 liter/min/m² were maintained over the course of support. Thirteen patients required open chest management at the time of device insertion or re-exploration for bleeding due to coagulopathy. Device-related operative complications occurred in 1 patient, in whom significant bleeding at the aortic and pulmonary arterial cannulation sites was noted and repaired at the time of implantation. The patient died from an embolic stroke 23 days later. Thirty-seven percent¹⁰ of patients had thromboembolic complications, including 5 embolic strokes as determined by neurologic exam and computed tomography. Two patients developed aortic thrombi and 1 developed left atrial thrombi requiring operative removal. One patient developed extensive blotchy erythema of the hands and knees, presumed to be embolic in nature. The patient was determined to be a transplant candidate and underwent device exchange to a HeartMate II and subsequent transplant. Two patients had sternal wound infection episodes.

Outcomes

Eighty-nine percent of patients (24 of 27) survived to explant. Of these, 6 patients were bridged to a long-term mechanical assist device, 8 to transplantation and 10 to recovery (Figure 1). Of the 6 patients bridged to a long-term device, 3 received a HeartMate I, 2 received a HeartMate II, and 1 received a Thoratec internal BiVAD. Four of these patients were bridged to transplantation and are alive at last follow-up. One was bridged to recovery and survived approximately 1 year. One required CentriMag RVAD reinsertion. The device was subsequently explanted but the

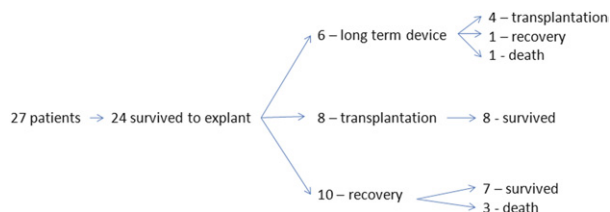


Figure 1 Outcomes.

patient succumbed to persistent right ventricular failure and sepsis. Of the 8 patients bridged to transplantation, all survived to discharge and 7 are alive at last follow-up. Of the 10 patients bridged to recovery, 3 had a concomitant CABG, 2 had CABG and mitral valve replacement, and 1 had an unroofing of an anomalous left main coronary artery. In addition, 2 aortic valve thrombectomies and 1 left atrial thrombectomy were performed. Three patients did not survive to discharge. Seven patients survived to discharge and are alive at last follow-up. Overall, 74% of patients (20 of 27) survived to hospital discharge, with a 1-year survival rate of 68%.

Survival to discharge was significantly higher when failure of medical management was the indication for CentriMag support compared with right ventricular failure after long-term LVAD or post-cardiotomy shock/graft failure (20 of 27 [74%] vs 14 of 35 [40%], $p = 0.016$). Similarly, long-term survival differed by indication for CentriMag placement (log-rank, $p = 0.0016$; Figure 2).

Pre-implant predictors of survival

No difference was observed in the pre-operative use of IABP counterpulsation, inotropes or vasopressors between survivors to discharge and non-survivors. Non-survivors had a significantly elevated body mass index compared with survivors (30.8 vs 24.1 kg/m², $p = 0.003$). In addition, non-survivors demonstrated a trend toward older age and a more frequent diagnosis of ischemic cardiomyopathy (86% [6 of 7] in non-survivors vs 55% [11 of 20] in survivors). Excluding those with pre-operative MCS, non-survivors (to discharge) also demonstrated a trend toward a lower pre-implant cardiac index and lower pre-implant blood urea and nitrogen and creatinine levels as well as a trend toward higher pre-implant white blood cell counts and liver function tests (Table 2). All 3 patients with pre-operative MCS survived to discharge.

Measures of end-organ function

When excluding those with pre-operative MCS, survivors to discharge demonstrated significant improvements in end-organ function (Table 3), as shown by blood urea and nitrogen (36.1 mg/dl vs 17.1 mg/dl, $p = 0.001$), creatinine (1.65 vs 1.14 mg/dl, $p = 0.037$) and aspartate transaminase (146 vs 53 U/liter, $p = 0.021$) levels. Those patients who did not survive to discharge demonstrated no significant changes in end-organ function, although there was a strong trend toward improved hepatic enzymes (Table 3).

Discussion

In this study we have described our experience with short-term MCS in the setting of acute cardiogenic shock refractory to maximal medical management and IABP counterpulsation. CentriMag placement was described in the setting of acute heart failure decompensation, right ventricular failure after long-term LVAD placement, post-cardiotomy shock and graft failure after heart transplantation.^{6,8–11} As the options for long-term right ventricular support are limited and patients with post-cardiotomy shock and graft failure have typically undergone prolonged procedures on cardiopulmonary bypass, the decision to place a short-term device in these latter 3 scenarios has become fairly clear. However, it may not be as straightforward in the first instance.

Various screening scales, including one from our own institution, have demonstrated poor outcomes for long-term VAD implantation as a bridge to transplant in patients with various pre-operative risk factors.³ Several criteria, including patient age, neurologic status, end-organ function, comorbidities, compliance and social support structures should be evaluated via a multidisciplinary team approach prior to proceeding with long-term VAD implantation for destination therapy or as a bridge to transplant. The REMATCH trial, which culminated in Food and Drug Administration approval of the HeartMate VE device for destination therapy, demonstrated a significant survival benefit with VAD implantation over optimal medical management in patients with New York Heart Association Class IV heart failure and contraindications to heart transplantation.² Cost analysis, however, demonstrated the financial burden of such treatment.⁴ Furthermore, significant cost differentials were noted between survivors and non-survivors (to discharge from the index hospitalization), both in the REMATCH and post-REMATCH era.^{4,5} Thus, appropriate patient selection is essential for cost-effective strategies and optimal patient outcomes with regard to MCS.

In general, patients with decompensated heart failure are not good candidates for implantable VADs from a risk profile standpoint. On the other hand, the CentriMag VAD has several advantageous features in this situation: it can be

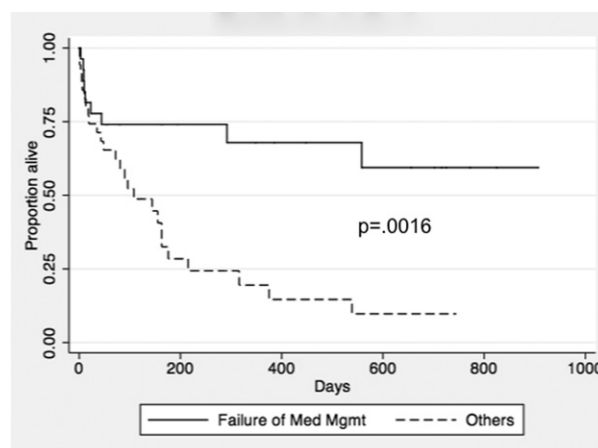


Figure 2 Survival by indication.

Table 2 Predictors of Survival

Pre-implant variable	Overall (n = 27)	Non-survivors (n = 7)	Survivors (n = 20) ^a	p-value
BMI (kg/m ²)	25.8	30.8	24.1	0.003 ^b
Age (years)	45.926	53.143	43.400	0.194
Diagnosis of ICM	17 (63%)	6 (86%)	11 (55%)	0.204
WBC (10 ⁹ /liter)	13.592	16.471	12.406	0.131
Total bilirubin (mg/dl)	2.317	3.457	1.819	0.309
AST (U/liter)	227.348	414.143	145.625	0.137
ALT (U/liter)	174.043	214.286	156.438	0.648
INR	1.710	2.433	1.413	0.182
Creatinine (mg/dl)	1.542	1.271	1.653	0.189
Arterial pH	7.395	7.386	7.398	0.845
Albumin (g/dl)	3.378	3.314	3.406	0.779
Hematocrit (%)	36.313	39.271	35.094	0.192
BUN (mg/dl)	33.667	27.714	36.118	0.311
Platelets (10 ⁹ /liter)	244.348	281.714	228.000	0.335
CI (liters/min/m ²)	2.232	1.818	2.391	0.231
Wedge pressure (mm Hg)	27.688	25.800	28.545	0.689
CVP (mm Hg)	17.250	16.250	17.583	0.825
PA systolic (mm Hg)	43.400	42.571	43.846	0.833
PA diastolic (mm Hg)	23.900	23.714	24.000	0.941
MAP pressure (mm Hg)	70.911	69.660	71.357	0.853
Heart rate (beats/min)	101.000	103.400	100.000	0.789

ALT, alanine aminotransferase; AST, aspartate aminotransferase; BMI, body mass index; BUN, blood urea nitrogen; CI, cardiac index; CVP, central venous pressure; ICM, ischemic cardiomyopathy; INR, International Normalized Ratio; MAP, mean arterial pressure; PA, pulmonary artery; WBC, white blood cell count.

^aThree patients with pre-CentriMag mechanical circulatory support were excluded from all laboratory value and hemodynamics analyses.

^bStatistically significant.

inserted easily and quickly; it offers various options of configuration (LVAD, RVAD or BiVAD); it can be used with ECMO when an RVAD is present; and it provides excellent flow of up to 10 liters. Previous studies have demonstrated successful use of this device in various patient populations, including those with acute cardiogenic shock,

post-cardiotomy shock, right ventricular failure after long-term LVAD placement and graft failure.^{6,8–11} Improvements in hemodynamic variables and hepatic enzymes over the course of device support have been demonstrated.⁸ In addition, differences in pre-implant bilirubin have been shown to correlate with survival.⁹

Table 3 Changes in End-organ Function

	Overall (n = 27)			Non-survivors (n = 7)			Survivors (n = 17) ^a		
	Pre	Post	p	Pre	Post	p	Pre	Post	p
WBC (10 ⁹ /liter)	13.6	12.4	0.301	16.5	14.8	0.618	12.4	11.4	0.321
Total bilirubin (mg/dl)	2.3	3.6	0.184	3.5	6.2	0.259	1.8	2.5	0.494
AST (U/liter)	227.3	61.2	0.053	414.1	80.4	0.237	145.6	53.3	0.021
ALT (U/liter)	174.0	44.3	0.023	214.3	42.7	0.219	156.4	45.0	0.064
INR	1.71	1.28	0.229	2.43	1.32	0.387	1.41	1.26	0.150
BUN (mg/dl)	33.7	22.5	0.018	27.7	34.9	0.309	36.1	17.1	0.001
Creatinine (mg/dl)	1.54	1.24	0.174	1.27	1.50	0.628	1.65	1.14	0.037
Arterial pH	7.40	7.44	0.178	7.39	7.40	0.821	7.40	7.46	0.131
Albumin (g/dl)	3.38	3.05	0.038	3.31	2.89	0.236	3.41	3.05	0.107
Hematocrit (%)	36.3	28.1	<0.001	39.3	27.9	0.013	35.1	28.2	0.002
Platelets (10 ⁹ /liter)	244.3	188.3	0.055	281.7	196.4	0.074	228.0	184.9	0.238

Bold p-values indicate statistical significance. AST, aspartate aminotransferase; ALT, alanine aminotransferase; BUN, blood urea nitrogen; Pre, pre-implant; Post, post-implant; WBC, white blood cell count.

^aThree patients with pre-CentriMag MCS were excluded from the analyses.

In this study, body mass index was strongly associated with survival to discharge. In addition, trends were noted between other pre-implant variables and survival. Older age, an ischemic etiology of heart failure, poor pre-implant hepatic function and lower pre-implant cardiac index were associated with a trend toward decreased survival to discharge. Although our study was likely underpowered to detect significance with regard to these variables, the findings suggest that optimization of the timing of device placement when possible is critical for successful outcomes. It is unclear why a trend toward worse pre-implant renal function was seen in the survivors. This warrants further study.

Those who survived to discharge demonstrated significant improvements in renal and hepatic function over the course of CentriMag support, whereas non-survivors did not. These findings support the use of an inexpensive short-term device in patients with acute decompensation and reserving implantable VAD utilization for those patients with recovery of end-organ function, as we have shown that outcomes are poor in those who do not demonstrate such recovery.

The CentriMag device was mainly instituted as the initial form of support to serve as a bridge to decision. However, 3 patients had their MCS device already in place prior to CentriMag implantation, whether in the form of a percutaneous or surgical VAD. The majority of our patients suffered from an ischemic etiology of heart failure. Percutaneous VAD support via an Impella or Tandem Heart may be implemented in the cardiac catheterization laboratory in the event of decompensation during percutaneous coronary intervention. Although these devices allow for stabilization in such an event and allow additional time for patient evaluation and decision-making, somewhat limited flow rates may require conversion to a surgical device. If, at this juncture, complete evaluation of end-organ and neurologic function is incomplete, the CentriMag serves as a useful next step in this scenario of "bridge to bridge." In the setting of a previous surgical device, such as the Abiomed, device exchange may be as straightforward as simply reconnecting the pre-existing cannulae from the prior device to the CentriMag, as was the case in 1 patient in our experience (although in this case the left atrial cannulation site was converted to the left ventricle for improved decompression).

In general, biventricular support was preferred to fully support the critically ill patient. The inability to evaluate certain parameters, such as the need for multiple transfusions and the subsequent development of pulmonary edema, and the negative impact of prolonged inotropic support of the right ventricle before delayed RVAD implantation, have led some to more liberal institution of BiVAD support in critically ill patients.¹² We believe that with strict adherence to post-operative management protocols, the morbidity associated with BiVAD use can be reduced and is outweighed by the benefit of earlier RVAD support.

Ten patients (37%) had thromboembolic complications. None of these were related to the pump or the tubing, but rather to the cannulae. Five of 6 embolic strokes occurred in patients with left ventricular apical cannulation. Both pa-

tients requiring aortic valve thrombectomy had left ventricular apical cannulation as did the patient who developed blotchy erythema of the hands and knees leading to device exchange. Left ventricular apical thrombus was confirmed intra-operatively. The patient undergoing left atrial thrombectomy had left atrial cannulation, although the cannula was passed through the mitral valve to the left ventricle. Improvements in cannulae, cannulation methods and anticoagulation protocols may decrease the incidence of these complications. After analysis of our entire experience with this device, we abandoned the strategy of cannulating the left ventricle via the left atrium and the mitral valve.

Limitations of this study include those inherent in a retrospective analysis utilizing chart review, such as incomplete data, the potential for inaccuracies in data, and selection bias. In addition, due to differences in clinical practice across centers, extrapolation of results may be of limited value. Further, due to the low number of patients, especially in the non-survivor group, the study had limited power to detect with statistical significance improvements in end-organ function.

In conclusion, use of the CentriMag device appears to be a safe and effective method of ventricular support in the setting of acute cardiac decompensation. We achieved a 74% survival to explant and 68% 1-year survival in a cohort of extremely ill patients requiring multiple pharmacologic agents and IABP counterpulsation. In light of the extremely poor prognosis of such patients with medical management, the CentriMag VAD can be used as a salvage, resuscitation and maintenance device for bridge-to-decision therapy.

Disclosure statement

The authors have no conflicts of interest to disclose.

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