

TandemHeart Device as Rescue Therapy in the Management of Acute Heart Failure

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ABSTRACT

Background: The TandemHeart device (THD) is a pump system that can be deployed percutaneously (PC) or via conventional surgical (CS) cannulation; it is capable of supporting one or both ventricles. It is a versatile system designed for use as a rescue device in acute heart failure and as a bridge to decision in moribund patients.

Methods: Retrospective analysis was conducted on all patients who underwent a THD implant; either PC or CS; at our institution. Univariate analysis was done using Fisher's exact and Chi-square tests for categorical variables and Wilcoxon Rank Sum test for continuous ones.

Results: 51 adult patients were identified: 10 PC and 41 CS. Mean age was 58.9 ± 12.8 years, and 31% were female. In hospital mortality was 61%. Univariate predictors of death were prolonged support (74% versus 46%, $P = .04$) and higher lactic acid levels (5.3 ± 4.9 versus 2.3 ± 1.9 mmol/L, $P = .012$). The length of stay (LOS) for survivors was 59.8 ± 30.0 days.

Conclusion: Uni- or bi-ventricular unloading can be successfully achieved using the THD, either trans-thoracically or percutaneously, with an acceptable complication profile.

INTRODUCTION

Acute severe cardiogenic shock is associated with high mortality from multi-system organ failure and sepsis, which precludes permanent LVAD placement [Khalife 2007; Gregoric 2008, 2009; Kiernan 2010; Thomas 2010]. In these patients, short-term extracorporeal pulsatile or nonpulsatile ventricular assist devices (VADs) and extracorporeal membrane oxygenation (ECMO) are viable options, particularly after intra-aortic balloon pump (IABP) and high-dose inotropes have failed to reestablish hemodynamic stability [Entwistle 2003; Khalife 2007; Gregoric 2008, 2009; Kiernan 2010; Thomas 2010]. The severe structural remodeling in patients with chronic congestive heart failure is a strong predictor of the natural course of the disease [Neragi-Miandoab 1999] and the severity of such remodeling should be evaluated prior to making decisions on a long-term plan.

Some of these patients will either eventually recover or be bridged to a long-term VAD [Bruckner 2008; Busch 2008;

Gregoric 2009; Neragi-Miandoab 2012]. In addition, a significant percentage of patients may develop right ventricular (RV) failure in the acute stage following LVAD implantation. The THD can be used to bridge patients whose candidacy for permanent LVAD placement is not certain and who need temporary support until the work up has been completed. THD has been used to support isolated RV failure following LVAD implantation and in patients with isolated RV failure following an inferior MI [Kiernan 2010; Neragi-Miandoab 2012]. Additional indications for THD include: fulminant myocarditis resistant to inotropic agents, failure of IABP to stabilize hemodynamics [Khalife 2007] and, in very high risk patients, percutaneous coronary intervention (PCI) [Vranckx 2009].

Among the implantation techniques for VADs is the closed percutaneous technique (PC) [Bara 2007], which requires trans-septal cannulation of the left atrium or direct central cannulation of the pulmonary vein and aorta as well as right atrium and pulmonary artery, as indicated [Pitsis 2007; Bruckner 2008]. Currently, three percutaneous VADs are available for clinical use: the TandemHeart, Centrimag, and Impella system [Neragi-Miandoab 2012]. Here we report our institutional experience with emergent THD rescue therapy for refractory shock with diverse etiologies. Limited data exists on the use of this system for acute refractory heart failure syndromes.

METHODS

Retrospective analysis was conducted on all patients at our institution with signs of profound cardiogenic shock who underwent THD implantation for short-term cardiac assistance between 2007 to 2011. All patients were in severe uni- or bi-ventricular failure despite maximal medical therapy. We looked at factors associated with in-hospital mortality. Univariate and multivariate analysis was done using Fisher's exact and Chi-square tests for categorical variables and Wilcoxon Rank-Sum test for continuous ones.

RESULTS

We identified 51 adult patients who had undergone THD placement; 10 were performed percutaneously and 41 surgically. The mean age of patients was 58.9 ± 12.8 years, and 31% were female. Indications for support included postcardiotomy shock ($n = 13$, 25.4%), acute MI ($n = 19$, 37.2%), RV failure after LVAD ($n = 13$, 25.4%), acute heart failure syndrome ($n = 4$, 7.8%) and others ($n = 2$, 3.9%). Roughly half of the patients ($n = 24$, 47%) had been transferred from other

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Table 1. Patient Characteristics

Variable	Mean	SD	Median	Minimum	Maximum
Age	59.9	13.97	63.5	39.0	78.0
Creatinine	1.83	.68	1.75	0.9	2.7
T-bili	5.02	7.94	2.0	0.5	26.3
INR	1.68	0.67	1.50	0.9	3.0
Lactic acid	3.76	3.2	1.95	1.1	9.1
Cardiac Index	2.17	0.81	2.06	1.24	3.61
Support, days	17.2	7.5	18.0	2.0	26.0
Vent, days	7.4	4.6	6.0	1.0	16.0
LOS	36.0	8.0	36.0	30.0	42.0

Table 2. Type of Support

	n	%
BIVAD	10	19.61
LVAD	14	27.45
RVAD	27	52.94

institutions in acute cardiogenic shock. Additional patient characteristics are illustrated in Tables 1 and 2. Postoperative complications are shown in Table 3.

With a 100% follow-up, the in-hospital mortality was 61%; 15 patients (29.4%) survived explantation but died prior to discharge. An additional 6 patients (11.7%) died while on support. The univariate predictors of death were prolonged ventilatory support (74% versus 46%, $P = .04$) and higher lactic acid levels (5.3 ± 4.9 versus 2.3 ± 1.9 mmol/L, $P = .012$). Patients who had percutaneous implantation of THD were more likely to have been on IABP (70% versus 24%, $P = .006$) or ventilatory support (80% versus 46%, $P = .056$). Patients who died in-hospital were older (61.5 ± 12.4 versus 54.9 ± 30.0 , $P = .064$) and were more likely to have undergone PC implantation of THD (80% mortality for PC and 56% for CS). However, these differences weren't statistically significant, which may be attributable to the limited statistical power. There was no survival difference between patients who were transferred from other institutions compared to in-house patients ($P = .42$). Mean length of support was 9 ± 6 days (range 1-26 days). Of the 20 surviving patients, 15 (29.4%) recovered and were discharged from the hospital, and 5 (9.8%) were bridged to a long-term mechanical assist device (with overall survival 39%). The length of stay (LOS) for survivors was 59.8 ± 30.0 days.

DISCUSSION

The superiority of ventricular assist devices to IABP in reducing preload and improving the cardiac index and end-organ function is well established [Windecker 2007;

Table 3. Complications Following Implantation of TandemHeart Device

	n	%
Sepsis	8	16
Bleeding	12	23.5
Respiratory failure requiring tracheostomy	9	17.6
Cerebrovascular accident	5	9.8
Acute renal failure requiring hemodialysis	17	33.3
Gastrointestinal bleeding	6	11.7
Ventricular fibrillation and cardiac arrest	4	7.8
Lower extremity ischemia	3	7.8

Kar 2011]. THD can provide short-term left and isolated right or biventricular support in this setting [Thomas 2010]. The percutaneous THD is a left atrial-to-femoral artery bypass system [Chandra 2007]. Thomas et al. in 2010 published a series of 37 patients with compromised LV function (NYHA III-IV) who required THD support prior to complex coronary and valvular interventions. The authors reported that 71% of their patients survived to hospital discharge. Gregoric et al. (2009) used percutaneous THD as a prophylactic approach in patients with critical AS who had undergone surgical aortic valve replacement, and had a high weaning rate and favorable survival. The same authors used THD in patients with advanced HF and had immediate significant improvement on the cardiac index. End-organ function and overall condition improved in all patients, thus decreasing the preoperative risk factors for implantation of a long-term device [Gregoric 2008].

Early implantation of THD may allow for rapid off loading of the left ventricle and improve outcomes [Gregoric 2009]. The majority of patients in the Thomas and Gregoric studies had PCI only, and THD played a prophylactically supportive role during the procedure. While prophylactic placement of THD expands its application, the survival following this approach cannot be compared with other results in the literature that used THD as a salvage approach in patients with severe cardiogenic shock. The cohort in this study included patients with severe acute cardiogenic shock who required hemodynamic support on an emergency basis; the other patients received THD for RV failure following LVAD implantation.

Using percutaneous THD, Kar et al. (2006) reported a survival rate of 61%; 11 patients with cardiogenic shock and 7 patients who had undergone high-risk PCI. The mean duration of support following high-risk PCI was 5.5 days. The same authors reported using THD in a series of 117 patients with acute cardiogenic shock; of these, 80 patients had ischemic cardiomyopathy and 37 patients had non-ischemic cardiomyopathy. After THD implantation, the cardiac index, systolic blood pressure, and mixed venous oxygen saturation improved significantly. Urine output, pulmonary capillary wedge pressure, lactic acid levels, and creatinine levels

improved, reflecting recovery of end-organ function. Mortality rates at 30 days and 6 months were 40.2% and 45.3%, respectively [Kar 2011]. We believe that the 6 month mortality rates reflect not only high perioperative mortality but also comorbidities and underlying conditions. Based on this, we recommend using the perioperative mortality rate and the survival rate as the only parameters (end points) in evaluating the efficacy of THD and short-term VADs.

Brinkman et al. (2009) reported using THD in 22 patients with cardiogenic shock. Indications for insertion included bridge to decision (BTD) or salvage and bridge to transplant (BTT). Ten of 11 BTT patients were successfully bridged; in 7 of 11 BTD patients, support was withdrawn. The authors recommended using THD as a BTD mode, which allows time for a more complete evaluation of neurologic and end-organ status. Our patient population is similar to the patients in the Brinkman study. Of 20 surviving patients in our series, 15 patients (29.4%) recovered and were discharged from the hospital, and 5 (9.8%) were bridged to a long-term mechanical assist device (overall survival 39%); another 15 patients (29.4%) survived explantation but died in the hospital. Some authors have reported a more favorable outcome and weaning rate with THD [Burkhoff 2006; Pitsis 2007]; however, all of our patients had advanced HF and were in severe acute cardiogenic shock. Although there is a high weaning rate with the use of THD in these settings, the etiology of the disease, the patient's condition at the time of THD placement and the severity of the cardiogenic shock should all be considered when comparing outcomes following THD implantation.

CONCLUSION

The THD is a versatile system for use as a rescue device as a bridge to decision or recovery in patients with acute cardiogenic shock. Uni- or bi-ventricular off-loading, either trans-thoracic or percutaneously, can be achieved with an acceptable complication profile. A clinically significant survival advantage was observed in patients supported via conventional surgical cannulation. This may be due to better flow achieved with conventional surgical compared to percutaneous implantation. Prolonged ventilatory support and severity of lactic acidosis both emerged as significant predictors of death. An extended LOS can also be expected in surviving patients following THD placement.

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