Arabia FA, et al. Interagency Registry for Mechanically Assisted Circulatory Support Report on the Total Artificial Heart. J Heart Lung Transplant 2018;37:1304–1312.

[www.jhltonline.org/article/S1053-2498(18)31434-7/fulltext](http://www.jhltonline.org/article/S1053-2498(18)31434-7/fulltext)

**Abstract:**

**BACKGROUND:** We sought to better understand the patient population who receive a temporary total artificial heart (TAH) as bridge to transplant or as bridge to decision by evaluating data from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database. METHODS: We examined data related to survival, adverse events, and competing outcomes from patients who received TAHs between June 2006 and April 2017 and used hazard function analysis to explore risk factors for mortality.

**RESULTS**: Data from 450 patients (87% men; mean age, 50 years) were available in the INTERMACS database. The 2 most common diagnoses were dilated cardiomyopathy (50%) and ischemic cardiomyopathy (20%). Risk factors for right heart failure were present in 82% of patients. Most patients were INTERMACS Profile 1 (43%) or 2 (37%) at implantation. There were 266 patients who eventually underwent transplantation, and 162 died. Overall 3-, 6-, and 12-month actuarial survival rates were 73%, 62%, and 53%, respectively. Risk factors for death included older age (p 1⁄4 0.001), need for pre-implantation dialysis (p 1⁄4 0.006), higher creatinine (p 1⁄4 0.008) and lower albumin (p o 0.001) levels, and implantation at a low-volume center (≤10 TAHs; p o 0.001). Competing-outcomes analysis showed 71% of patients in high-volume centers were alive on the device or had undergone transplantation at 12 months after TAH implantation vs 57% in low-volume centers (p 1⁄4 0.003).

**CONCLUSIONS**: Patients receiving TAHs have rapidly declining cardiac function and require prompt intervention. Experienced centers have better outcomes, likely related to patient selection, timing of implantation, patient care, and device management. Organized transfer of knowledge to low-volume centers could improve outcomes. “

COMMENTS BY BARBARA WILKEY, MD

The TAH-t (SynCardia) is available in two sizes, 50 mL stroke volume and 70 mL stroke volume. The 70 mL TAH is approved for bridge to transplant (BTT) in the Unites States, Canada and Europe. It is currently undergoing clinical trial for destination therapy (DT) in the United States. The 50 mL TAH is in clinical trial for BTT in the US but approved for BTT in Europe and Canada.

Each ventricle of TAH has one inflow and one outflow Synhall tilting disc valve and a pneumatic drive system. Patients who could be considered for the TAH-t include those with irreversible biventricular failure, allograft failure, allograft rejection, allograft vasculopathy, decompensated right heart failure on LVAD support, failure to wean from ECMO, architectural features that affect LVAD insertion ability, recurrent ventricular tachycardia and/or ventricular fibrillation, post infarct VSD, type A dissection with coronary artery dissection, end stage congenital heart disease, valvular problems with single or biventricular failure and those with cardiac tumors.

Implantation of the TAH-t is done on cardiopulmonary bypass through median sternotomy with bicaval cannulation. After initiation of cardiopulmonary bypass the aorta and pulmonary artery are transected just above the semilunar valves and native ventricles are excised approximately one cm below the atrial-ventricular groove. The AV valve leaflets are cut out and the coronary sinus is oversewn. Interatrial communication, if present, is closed. Inflow connecting grafts are then sewn to each atrium and outflow grafts are sewn to the pulmonary artery and aorta. The suture lines are pressure tested and the ventricles are then connected.

Preoperative considerations for TAH-t candidates are similar to standard patients with refractory heart failure. Intraoperative monitoring should include an arterial line, central line and transesophageal echocardiography (TEE). Swan Ganz catheters cannot be used intraoperatively or postoperatively. Indeed, the distal end of the central line should not go past the SVC-innominate junction as entanglement in the AV valve could cause cardiac arrest. TEE is useful for deairing and confirmation of proper valve function. TAH-t recipients are at risk of caval and pulmonary vein compression from the device itself. The post implant TEE exam must include evaluation of flow through these structures. Intraoperative transfusion is common and delayed closure of the chest can be done if there is significant concern for continued bleeding in the intensive care unit. When bleeding does subside, patients are placed on anticoagulation and antiplatelet therapy for thrombus prevention.

This article for December’s issue is a retrospective study using data from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) to evaluate the characteristics of patients who received TAHs-t (70 mL) between 2006 and 2017. During the review period 450 patients received the TAH-t. Forty three percent of these patients were classified as INTERMACS profile 1 at the time of implantation, 37% were INTERMACS profile 2, and the remaining 20% were INTERMACS profile 3-7. Ninety percent of subjects were male and mean age at the time of implantation was 50 years old. Eighty-two percent of patients had characteristics of RV failure which the authors defined as dialysis, extracorporeal membranous oxygenation, ventilator support or dependence, severely reduced right ventricular ejection fraction, temporary mechanical support, and either moderate or severe tricuspid regurgitation.

Overall, of the 450 implanted patients 266 received heart transplants, 162 died on support and the remaining 22 died from withdrawal of support. At the twelve month mark the rate of transplantation was 53%, mortality 34% and survival on the device 13%. Survival was highest in patients with INTERMACS profile 3. The highest risk for morality was in the first three months. Multisystem organ failure was the cause of death in 36% of patients, neurologic injury in 18% and withdrawal of support in 12%. Risk factors for early mortality were pre-implant dialysis and older age. Risk factors for late mortality were elevated creatinine and low serum albumin levels. Center experience was also a predictor of outcome. Centers that had performed less than or equal to ten implants had a 12 month survival of 36.7% versus 64.8% for those with more experience.

Early adverse events were defined as those in the first three months. The most common early adverse events bleeding and infection. After this time period infection and minor device malfunctions (no harm to patient) were the most common adverse events. At six months risk of some sort of infection was almost 70%, 28% had a minor device malfunction, 23% had a stroke and 20% of patients had a major gastrointestinal bleed. 109 patients were discharged with the TAH-t, 91% of which were discharged to home.

The authors desired to compare outcomes of the TAH-t with biventricular ventricular assist device (bi-VAD) support but due to the variability in bi-VAD support they were not able to do so. The authors did make several comparisons between outcomes in left ventricular assist device (LVAD) recipients however the data is not fully comparable as indications for implantation and illness level at the time of implantation can differ between the two devices. It was noted that patients who received TAHs-t had a more severe INTERMACS profile than those who received LVAD over the same time period, mortality was higher in the TAH-t than LVAD, and of discharged patients more TAH-t patients were discharged home than LVAD patients.

In conclusion, patients receiving the TAH-t are generally critically ill. Higher survival is seen when the device is implanted in younger patients without renal dysfunction in higher volume centers. Low serum albumin is also a risk factor for mortality. Mortality is highest in the first three months. The most common adverse events are infection, bleeding, neurologic events, and minor device malfunction.

INTERMACS Profiles

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| 1 | Critical Cardiogenic Shock |
| 2 | Progressive Decline |
| 3 | Stable But Inotrope Dependent |
| 4 | Resting Symptoms |
| 5-7 | Less Sick |

References

1. [www.syncardia.com](http://www.syncardia.com)
2. Yaung J, Arabia FA, Nurok M. Perioperative Care of the Patient with the Total Artificial Heart. Anesth Analg 2017;124:1412–22.
3. Arabia FA, et al. Interagency registry for mechanically assisted circulatory support report on the total artificial heart. J Heart Lung Transplant 2018;37:1304–1312.