First North American 50 cc Total Artificial Heart Experience: Conversion from a 70 cc Total Artificial Heart

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The 70 cc total artificial heart (TAH) has been utilized as bridge to transplant (BTT) for biventricular failure. However, the utilization of 70 cc TAH has been limited to large patients for the low output from the pulmonary as well as systemic vein compression after chest closure. Therefore, the 50 cc TAH was developed by SynCardia (Tucson, AZ) to accommodate smaller chest cavity. We report the first TAH exchange from a 70 to 50 cc due to a fit difficulty. The patient failed to be closed with a 70 cc TAH, although the patient met the conventional 70 cc TAH fit criteria. We successfully closed the chest with a 50 cc TAH. *ASAIO Journal* 2016; 62:e43–e45.

Key Words: patient match, total artificial heart, transplant

The SynCardia Total Artificial Heart (TAH) is a biventricular, pneumatic, pulsatile blood pump designed to replace both cardiac ventricles. The 70 cc TAH has demonstrated excellent clinical outcomes with biventricular failure. Bridge to transplant (BTT) rates with a TAH have been reported as 79%.[1] However, TAH placement has been limited to large patients because forced closure in smaller patients results in pulmonary or systemic vein compression decreasing TAH output. To accommodate smaller patients SynCardia developed a 50 cc TAH. We report the first utilization of the 50 cc TAH in North America in a patient with a mal-fitting 70 cc TAH implanted, despite meeting conventional chest cavity size criteria during preoperative planning.

Case Description

A 53 year old female with a prior orthotopic heart transplant in 1990, secondary to postpartum cardiomyopathy, was diagnosed with chronic rejection and severe allograft vasculopathy, and was listed for retransplant. Following sudden cardiac arrest, the patient received a biventricular assist device (BiVAD; Jostra RotaFlow, Maquet, Jostra Medizintechnik AG) as a bridge to decision; a 70 cc TAH was subsequently implanted for long-term support. Her body surface area (BSA) was ≥1.7 m^2, and distance from the inner table of the sternum to the anterior vertebra at the level of T-10 on computed tomography (CT) scan was ≥10 cm. Therefore, implantation of the 70 cc TAH was performed in a standard fashion.[2,3] However, the sternum could not be closed without the left anterior chest wall impinging on the TAH despite multiple attempts. There was evidence of left pulmonary vein compression coupled with a compromised cardiac output to 3 L/min. Ultimately the chest remained with an open-chest, which resulted in normal filling volumes of the left and right ventricles of a 70 cc TAH. Furthermore, we aimed to reduce the tissue edema using continuous renal replacement therapy.

Despite extensive fluid removal, partial resection of the left costal cartilage before the chest closure, manipulation of the drivelines and mobilization of the pericardium and diaphragm to create space for the 70 cc TAH, the chest could not be closed without hemodynamic compromise. Her end organ function including neurological function was maintained during this process. After two further attempts to close the chest, we decided to explant the 70 cc TAH and to implant the new 50 cc TAH on postoperative day (POD) 14. The hemodynamic variables pre- and post-50 cc TAH implant are in **Table 1**. In consideration and preparation for this, we first performed a three-dimensional (3D) virtual implant (performed at Arizona State University *via* SynCardia) based on the CT scan data analyzed by Mimics software (Materialise, Leuven, Belgium) confirming that the new, smaller device would fit.[4] Basically, 3D reconstructions of preoperative chest CT images were generated and TAHs were projected over the native. The relationship between the devices and the atria, ventricles, chest wall, and diaphragm were assessed.

The 50 cc TAH was implanted as previously described for 70 cc TAH.[2,3] Both atrial cuffs were replaced. The new 6 cm pulmonary artery outflow graft and 2.5 cm aortic outflow graft were sewn to freshly trimmed great vessels. The diaphragm was plicated anteriorly to keep the IVC open. The right ventricle driveline was secured using Merselene tapes to the left costal cartilage of the 7th rib. The new drivelines were tunneled lateral and inferior to the left costal margin, a couple cm distant from the previous insertion sites. The chest was closed successfully without hemodynamic compromise.

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Written informed consent was obtained from the patient for publication of this case report and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief.

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Table 1. Hemodynamic Variables and TAH Settings Before (70 cc TAH) and After 50 cc TAH Placement

	Hemodynamic Variables					Total Artificial Heart Settings						
	BP (mm Hg)	CVP (mm Hg)	Norepinephrine (mcg/kg/min)	Vasopressin (units/min)	Lactate	HR (/min)	LCO (l/min)	RCO (l/min)	LDP (mm Hg)	RDP (mm Hg)	LV Vacuum (mm Hg)	RV Vacuum (mm Hg)
70 cc TAH	111/55	9	1	0.04	0.6	120	6.5	6.6	200	100	−24	−24
50 cc TAH	102/66	14	7	0.04	1.6	130	4.6	4.7	210	100	−20	−20

BP, blood pressure; CVP, central venous pressure; HR, heart rate; LCO, left cardiac output; LDP, left drive pressure; LV vacuum, left ventricle vacuum; RCO, right cardiac output; RDP, right drive pressure; RV vacuum, right ventricle vacuum; TAH, total artificial heart.

The postoperative course was remarkable for respiratory failure requiring tracheostomy as well as persistent renal failure requiring dialysis. The patient was hemodynamically stable, but ultimately died of sepsis 6 weeks postop. No autopsy was obtained.

Discussion

The 50 cc TAH is a much-needed option for smaller patients who do not meet criteria for the 70 cc TAH due to small chest cavities or native hearts. This smaller device resolves most fit issues while providing 5–6 L/min of support. The TAH has been associated with comparable patient survival to the available BiVAD.[5] The fourth Interagency Registry for Mechanically Assisted Circulatory Support report cited improved 3- and 6-month survival rates in patients with biventricular dysfunction supported with a TAH *versus* a BiVAD[6] (at 85% *vs.* 70% at 3 months, and at 68% *vs.* 62% at 6 months, respectively). SynCardia 70 cc TAH recipients also experienced significantly fewer neurologic events compared with BiVAD recipients[6] suggesting possible reduction in thromboembolic events due to design elements of the TAH.

As the 70 cc TAH is a relatively large device, the major physical criteria for the 70 cc TAH include a BSA >1.7 m^2. However, even if BSA is <1.7 m^2, the device can be implanted depending on an left ventricular end-diastolic diameter (LVEDD) >70 mm and a distance from the anterior surface of the sternum to the T10 vertebral body >10 cm. Although our patient met the major criteria, her chest lacked the space for a 70 cc TAH. The changes in her intrathoracic geometry were likely a result of the multiple cardiothoracic procedures before the 70 cc TAH implantation, tissue edema from various resuscitation processes, and modest enlargement of the failing cardiac graft.

A discrepancy between the size of the device and the anterior-posterior distance in the patient's mediastinum at T-10 may cause the device to compress the IVC and pulmonary veins reducing filling of the TAH upon chest closure. Furthermore, patients with a low BSA who receive a TAH have been shown to have an increased risk of mortality.[7] Inadequate fit despite guidelines for 70 cc TAH placement has been reported as the cause of low cardiac index in some patients.[1] The fit criteria for this 50 cc TAH will also need to be established. Furthermore, considerations in TAH size selection based on a preoperative 3D virtual model would help guide surgeons to anticipate fit problems in the operating room.

The TAH provides good clinical outcomes in patients with postheart transplant cardiomyopathy, especially biventricular failure from allograft vasculopathy and chronic rejection. Receiving a TAH allows to discontinue the immunosuppressive agents. Unfortunately, this patient developed sepsis potentially due to the prolonged open chest period and residual immunosuppressive therapy. A TAH also provides sufficient restoration of hemodynamic function immediately after implantation. Our experience thus far suggests that the 50 cc TAH provides adequate support.

The TAH has been utilized for various patients including complex congenital cardiac disease population.[8] It will be utilized as destination therapy (DT). Now with the birth of 50 cc TAH, a larger group of patients with small chest size will be eligible for BTT and potentially DT. Further clinical experience with this new sized TAH will continue to define its role for patients with severe biventricular heart failure.

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