Tissue Expander as a Routine Component of 50cc Total Artificial Heart Implantation for Bridge to Transplant

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Definitive therapy of advanced heart failure, as classified by the American College of Cardiology/American Heart Association guidelines, is complicated because of the lack of donor organs for transplantation.[1] This shortage has established a need for alternative heart failure therapies. In 2004, the Food and Drug Administration approval of a 70cc total artificial heart (TAH; SynCardia Systems Inc, Tucson, AZ) served as a valuable new treatment option offering a bridge to transplant, although patients await a donor heart.

Recent studies demonstrated that the 70cc TAH has been successfully placed in 1300 patients worldwide and has served as a successful bridge to transplant in 79% of patients.[2] However, the invasive removal of the atria and ventricles during placement of the TAH carries risks. Hematologic risks include hemopericardium and coagulopathy, which may further result in either pulmonary or neurological embolic events. The implanted device itself is not without risk given reported instances of infections, leaks, and malfunctioning-related kinking of either the TAH components surgical anastomoses or the drive lines. Despite the seriousness of the complications related to the 70cc TAH, these risks can be acceptably minimized with patient education relating to proper TAH care and with an appropriate social support network.

Given the ability to manage and prevent device complications after implantation, a critical pretransplant complication that must be assessed before TAH placement is proper device fit within the patient's thoracic cavity given the varying intrathoracic space related to body habitus and age-related difference. Although a body surface area of 1.7 to 2.5 cm^2 has been correlated with sufficient intrathoracic space for the 70cc TAH, quantitative approaches derived from computed tomographic (CT) or magnetic resonance examinations have also been used for noninvasive estimation. The 2 most common approaches are the T10 measurement and left ventricle end-diastolic diameter. The T10 measurement is the distance between the T10 vertebral body and inner table of the sternum obtained from a single-axial CT or magnetic resonance image, with a T10 measurement of ≥10 cm being sufficient to accommodate the 70cc TAH. The left ventricle end-diastolic diameter measurement is acquired in the axial plane, with a distance >6 cm from the septal and lateral endocardial borders predictive of a successful fit of the 70cc TAH after implantation. Recently, a more promising technique is virtual transplantation, which uses CT image fusion software to determine the position of the TAH within the thoracic space.[3]

Despite the noninvasive techniques to determine if the patient's intrathoracic space will accommodate the 70cc TAH, patients with smaller chest cavities were left with little recourse if the 70cc was too large for implantation. A solution is the recent Food and Drug Administration approval of the smaller 50cc TAH (SynCardia Systems Inc) that serves to ameliorate the issue related to device fit in patients with smaller thoracic cavities while providing the same therapeutic bridge to transplant.[4] A notable issue with the smaller 50cc TAH is that the device may be significantly smaller compared with the patient's normal anatomy, resulting in deformations and shrinkage of the pericardium after device placement. The predominant concern is that the 50cc TAH may be too small compared with the patient's normal pericardium volume, resulting in fibrosis of the pericardial tissue to cover the smaller device. Although pericardial shrinking does not complicate the patient's course during the bridge to therapy, the atrophied pericardium will be too small to contain a transplanted donor heart matched for size and weight, resulting in either pericardial removal or resection.

Case Presentation

Our patient is a 23-year-old man with nonischemic cardiomyopathy related to a familial titinopathy related to a mutation of the Titin gene, which was also expressed in the patient's father. The patient was determined to be American College of Cardiology/American Heart Association stage D with a left ventricular ejection fraction of <15%. The patient underwent both left ventricular assist device placement (Heartmate II; Thoratec, Pleasanton, CA) and right ventricular assist device placement (Centrimag; Thoratec); however, he was unable to be listed for heart transplant because of persistent leukocytosis. The clinical team subsequently pursued TAH implantation as a bridge to transplant. Noninvasive investigation using image-guided metrics deemed that the patient's thoracic cavity may not accommodate the standard 70cc TAH given virtual implantation modeling and that the left ventricle end-diastolic diameter measurement was 5.6 cm. Given the expected

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(*Circ Heart Fail*. 2017;10:e003765. DOI: 10.1161/CIRCHEARTFAILURE.116.003765.)

surgical complications of placing a device that may not successfully fit in the patient's intrathoracic cavity, formal institutional approval was given for compassionate use of a 50cc TAH. During surgical placement of the smaller 50cc TAH, an excessive amount of intrathoracic space was noted between the TAH and the patient's pericardial sac. To prevent the expected atrophy of the pericardial sac around the smaller 50cc TAH, a small breast tissue expander was placed between the 2 components of the 50cc TAH. The expander filled the space normally containing the ventricular apices (Figure 1A through 1D). Also, the implant filled the space without producing strain on the pericardial sac, preventing pericardial tearing and pressure necrosis. Postoperatively, noninvasive assessment of the breast implant was performed as a component of clinical chest CT exams. CT imaging demonstrated the implant to be persistently well seated between the 70cc TAH components with no postoperative movement or settling of the expander or displacement of the TAH components. The pericardium also retained a position similar to shape before heart explantation. Unfortunately, the patient expired 552 days after placement of the 50cc TAH because of complications related to gall stone pancreatitis resulting in multiorgan failure and septic shock after an open cholecystectomy. Postmortem evaluation demonstrated that the breast implant was retained in appropriate position and was intact (Figure 2A through 2C). The implant produced the planned effect of preventing pericardial atrophy by serving as a space filler resulting in the development a fibrotic, thickened pericardium after TAH placement.

Discussion

We report a first-in-human successful placement of a silicone breast tissue expander into the pericardial sac during surgical placement of a 50cc TAH as a bridge to transplant. The technique was performed to use the breast implant as a space filler within the pericardial sac because of the small size of the 50cc TAH. Our findings demonstrated that the expander allowed the pericardium to keep its normal size and shape while decreasing the risk of complications related to either pericardial removal or tearing of the pericardium during donor transplantation. In conclusion, given the recent approval of the 50cc TAH as a treatment for heart failure in patients with small intrathoracic cavities, we expect that the routine use of tissue expanders may provide a preventive technique to reduce complications related to pericardial shrinkage during explant and heart transplant.

Disclosures

R.G. Smith has a financial relationship with SynCardia Systems, Inc. The other authors report no conflicts.

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KEY WORDS: artificial heart ■ atrophy ■ breast implant ■ computerized tomography ■ heart failure

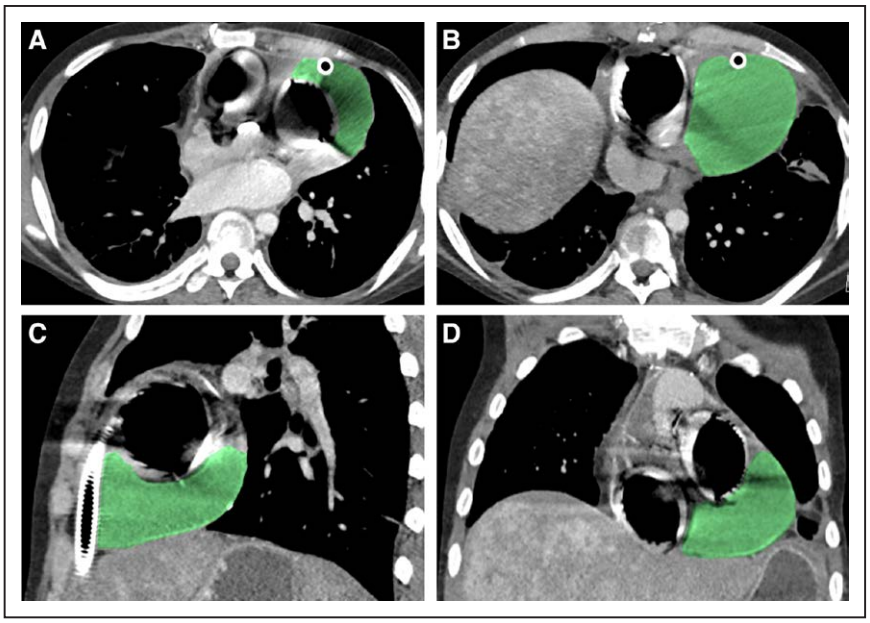

Figure 1. Contrast-enhanced chest computed tomographic (CT) images after implantation of the 50cc SynCardia total artificial heart. Superior axial (**A**) and inferior axial (**B**) views demonstrate placement of a small breast implant (green) within the pericardial sac between the 2 components of the artificial heart. Note that the implant does not deform the normal structure of components and drive line. Coronal (**C**) and sagittal (**D**) views demonstrate that the breast implant appropriately fills the pericardial space with no changes in expected confirmation of the pericardium.

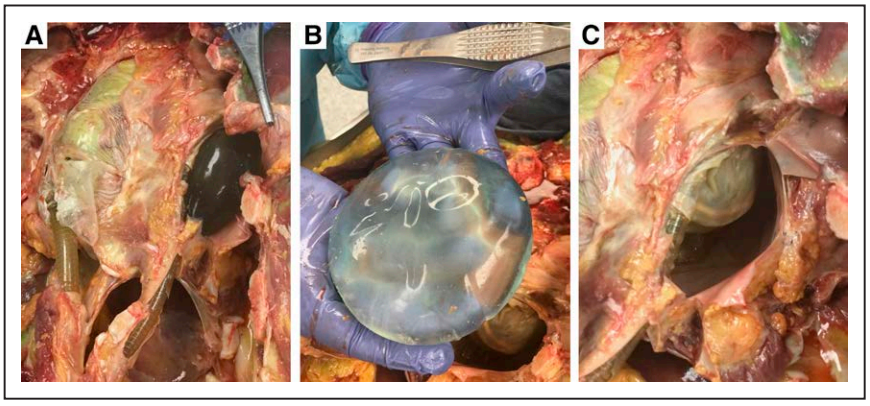

Figure 2. Postmortem pictures during removal of the breast implant from the pericardial sac. **A**, Tissue expander in situ demonstrates the expander in expected position after postmortem opening of the pericardial sac. **B**, The tissue expander was found to be intact with no evidence of tears or degradation after explantation. **C**, In situ the tissue expander produced successful pericardial space expansion, while the pericardial sac acquired a thickened, fibrous appearance with no decrease in size.