Virtual Implantation Of Mechanical Circulatory Support Devices

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Abstract

Our group previously described successful use of virtual implantation of the 70cc Total Artificial Heart (TAH) to predict safe placement in small-size patients not meeting standard fit criteria. With the new 50cc TAH, there is an opportunity for broader use of the TAH device in pediatric patients with biventricular heart failure. The proposed fit criteria for the 50cc TAH (BSA 1.2-1.6 m2) has not been tested in actual patients. The study objective was to determine the efficacy of virtual implantation of the 50cc and 70cc TAH in a cohort of pediatric heart failure patients and compare virtual fit results with proposed fit criteria.
Acknowledgements:

The authors would like to acknowledge Todd Pietila, BSc from Materialise, Inc. (Plymouth, Michigan) for assistance in the development of this technique, creation of images/videos, and enhancement of quantitative applications.

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Introduction

The temporary total artificial heart (TAH-t) (SynCardia Systems Inc, Tucson, AZ) is the only available artificial heart in the United States and has been implanted in greater than 1000 patients worldwide (reference). Unfortunately, small adults and children with biventricular heart failure have not routinely been able to benefit from the technology due to size limitations. The currently available 70cc TAH-t has been successfully used in pediatrics but placement within the small thoracic cavity is challenging (reference fix). In order to expand the use of the TAH-t, SynCardia has developed a smaller 50cc TAH-t device which by comparison is 30% smaller by volume than the 70cc TAH-t.

We propose that there are patients outside both the predefined BSA criteria for the 70 cc and 50 cc TAH-t that may be eligible for device placement if virtual implantation is used for device sizing. Prior to the initiation of the 50 cc trial, to determine feasibility, we performed a retrospective analysis of 15 consecutive patients being evaluated for mechanical circulatory support (MCS) as a bridge-to-transplant (BTT). We than compared the virtual implantation results with the proposed age (10-18 years) and BSA (1.2-1.85m²) eligibility criteria for the 50 cc clinical trial as well as the age (>18 years) and BSA (>1.7m²) criteria established for the 70 cc TAH-t.

Methods

A retrospective chart review was performed in patients that were evaluated for transplantation. Fifteen transplant-eligible patients (ages 3-34 years of age; BSA 0.67-1.98 m²) identified underwent virtual implantation of the TAH-t devices. Only patients with a CT scan of the chest as part of their transplant evaluation were included in the study. The Institutional Review Board at Cincinnati Children’s Hospital Medical Center approved this study.
The patients were divided into 3 groups based on recommended BSA for each device. Group 1 had a BSA <1.2 m², group 2 had a BSA >1.2 m² and <1.7 m², and group 3 had a BSA >1.7 m². The 70cc TAH-t has a wider cardiac output range therefore, all patients had virtual implantation performed of the 70cc TAH-t first. Patients that did not fit the 70cc TAH-t were then assessed for appropriate fit of the 50cc TAH-t. This methodology allowed for all patients to be assessed for optimal device size, regardless of their BSA. The results of the virtual implantation were then compared to BSA criteria for each device.

The 50cc and 70cc TAH-t devices were individually scanned using a 360-slice CT scanner (Toshiba Aquilion, Tustin, California) and the 2-dimensional CT images were used to generate a surface-rendered 3D reconstruction and then was imported into the software interface and used for virtual implantation. The 3D surface-rendered TAH-t was imported into Mimics Innovation Suite 3D visualization software (Materialise Inc., Belgium). A chest CT for each patient was imported and segmentation of bones, soft tissue, and vessels was performed. The ventricular masses were removed below the level of the atrioventricular (AV) and semilunar valves and the device was evaluated for fit within the chest cavity. Intrathoracic structures were closely evaluated for potential device overlap and compression.

Results

Fifteen patients were evaluated: 7 adults (>18 years), 4 adolescents (age 13-18) and 4 children (3-12 years). The patients were divided into 3 groups by their size (Table). A majority of the patients were managed medically and did not require MCS. Five patients (33%) required MCS as a BTT with two of those patients undergoing a 70cc TAH-t procedural implantation. Of the 15 patients that underwent virtual implantation, 14 patients were predicted to be candidates for successful placement of either a 70cc or 50cc TAH-t device. By comparison, 12 of 15
patients would have fit a device by BSA criteria alone. In our cohort, 33% of patients would have had their management altered based on preoperative virtual implantation assessment (Figure). Two patients had a successful virtual implantation despite not meeting BSA criteria for either device and an additional two patients could potentially be upsized to a 70cc TAH-t. Of particular interest, two patients with a BSA <1.2m² could have been candidates for the 50cc TAH-t placement based on virtual implantation. There was only one patient predicted to “not fit” and that child had a BSA of 0.67m². Two patients had actual 70cc TAH-t procedural placement, with one patient having successful virtual implantation despite failing BSA criteria⁴. One patient had heightened concerns for 70cc TAH-t placement after failing virtual implantation despite meeting BSA criteria; however, this patient did fit the 50cc TAH-t virtually.

**Discussion**

The availability of virtual implantation will increase the number of patients that are eligible for use of both sizes of the TAH-t compared to BSA criteria alone. With both virtual fit and the introduction of the 50cc TAH-t, the TAH-t has the potential to become a popular intracorporeal MCS device in both pediatric and adult centers. The present study demonstrates that in many cases the predetermined BSA criteria will be an adequate guide for successful device placement but there may be patients that would benefit from virtual implantation. An example would be in a patient with restrictive cardiomyopathy the atria may be large and when the device is implanted it may be positioned more in the left chest cavity. In this case not only is the BSA not predictive of fit but the measurement from the sternum to vertebra would not predict fit either.

Patients with complex congenital heart disease will also benefit greatly from preoperative virtual implantation. In these cases, discovering novel approaches for implantation will be just as
important as assessing proper fit within the chest. For example, patients who have undergone Fontan palliation have only one atrioventricular valve. In these cases a capacitance chamber must be constructed in order to adequately connect the TAH-t\textsuperscript{7}. Virtual implantation offers the ability to test several surgical approaches for device placement prior to the patient even entering the operating room.

This study was limited by a single center experience in a small patient cohort. Additionally, the assessment by virtual implantation was retrospective and no actual 50cc TAH-t device was implanted to confirm the predicted results of the virtual implantation because it was not available during the study. However, two 70cc TAH-t devices were placed successfully as predicted by virtual implantation\textsuperscript{4}.

**Conclusion**

In conclusion, virtual compatibility testing allows device consideration for fit to be individualized, and represents a movement away from using generalized assumptions about heart size, chest wall anatomy, and spatial relationships of cardiothoracic structures to determine fit. The SynCardia 50cc TAH-t trial is the first device trial to use virtual techniques to establish safer compatibility criteria.
Table 1: Demographics of BSA Groups

<table>
<thead>
<tr>
<th>Characteristics (Median, Range)</th>
<th>Group 1 BSA&lt;1.2m²</th>
<th>Group 2 BSA &gt;1.2m²-&lt;1.7m²</th>
<th>Group 3 BSA ≥1.7m²</th>
<th>ALL</th>
</tr>
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<tbody>
<tr>
<td>N</td>
<td>3</td>
<td>8</td>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>7 (3-13)</td>
<td>16.5 (10-29)</td>
<td>28.5 (20-34)</td>
<td>18 (3 - 34)</td>
</tr>
<tr>
<td>Gender (% male)</td>
<td>100%</td>
<td>37.5%</td>
<td>75%</td>
<td>60%</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>122 (101.6-150)</td>
<td>153.3 (140-166.5)</td>
<td>155.5 (158.8-168)</td>
<td>154 (101.6 – 168)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>26.3 (16.5-33.2)</td>
<td>52.2 (42.3-62.3)</td>
<td>74.5 (62.9-93.5)</td>
<td>56.1 (16.5 - 93.5)</td>
</tr>
<tr>
<td>BSA (m²)</td>
<td>0.88 (0.67-1.18)</td>
<td>1.49 (1.28-1.64)</td>
<td>1.84 (1.71-1.98)</td>
<td>1.54 (0.67 - 1.99)</td>
</tr>
<tr>
<td>T10-sternum (cm)</td>
<td>8.3 (6.9-9.6)</td>
<td>9.3 (7.1-12.4)</td>
<td>12.4(10.2-12.9)</td>
<td>9.5 (6.9 - 12.9)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>CMP</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>CHD – Other</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>CHD – Fontan</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Chronic Rejection</td>
<td>0</td>
<td>1</td>
<td>0</td>
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BSA = body surface area; CMP = cardiomyopathy; CHD = congenital heart disease
Figure 1: Comparison of TAH-t Sizes. The 70cc TAH-t device (left) is approximately 30% larger by volume than the new 50cc TAH-t device (right).

Figure 2: Virtual Implantation of the 50cc TAH: Demonstrates appropriate attachment points and successful placement within the thoracic cavity.
Figure 3: Diagram representation of decision tree for groups by BSA. Assessment was performed for both TAH-t devices in patients with a BSA <1.2m² (A), BSA >1.2m² but <1.7m² (B), and BSA ≥1.7m² (C) by virtual implantation.
Figure 4: This is a visual example of virtual implantation assessment of TAH-t devices in a patient with a BSA >1.7m² and thoracic deformity. First, the patient chest and intrathoracic structures are 3D reconstructed from CT data (A). As mentioned, this patient had significant thoracic deformity caused by severe scoliosis (B). The 70cc TAH-t was first assessed and did not virtually fit in the chest, likely due to thoracic deformity, despite meeting BSA criteria (C). Next, the 50cc TAH-t device was tested and demonstrated appropriate fit within the thoracic cage (D).
References:


