Experience with more than 100 total artificial heart implants

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Objective: The SynCardia Total Artificial Heart (SynCardia Systems Inc, Tucson, Ariz) has been used as a bridge to cardiac transplantation in 930 patients worldwide and in 101 patients in our program. Our experience with SynCardia Total Artificial Heart implantation documents its indications, safety, and efficacy.

Methods: Data regarding preoperative condition, mortality, and morbidity have been reviewed and analyzed.

Results: From January 1993 to December 2009, 101 patients had bridge to transplant procedures with the SynCardia Total Artificial Heart. Ninety-one percent of cases were Interagency Registry for Mechanically Assisted Circulatory Support profile 1, and the remaining 9% of cases were failing medical therapy on multiple inotropic medications. The mean support time was 87 days (median, 53 days; range, 1–441 days). Pump outputs during support were 7 to 9 L/min. Adverse events included strokes in 7.9% of cases and take-back for hemorrhage in 24.7% of cases. Survival to transplantation was 68.3%. Causes of death of 32 patients on device support included multiple organ failure (13), pulmonary failure (6), and neurologic injury (4). Survival after transplantation at 1, 5, and 10 years was 76.8%, 60.5%, and 41.2%, respectively. The longest-term survivor is currently alive 16.4 years postimplantation.

Conclusions: These patients were not candidates for left ventricular assist device therapy and were expected to die. The SynCardia Total Artificial Heart offers a real alternative for survival with a reasonable complication rate in appropriate candidates who otherwise might have been assigned to hospice care. (J Thorac Cardiovasc Surg 2012;143:727-34)

Total artificial heart (TAH) implantation as a bridge to transplantation was attempted in 1969[1] and 1981.[2] In 1985, we implanted the Jarvik-7 (Symbion Inc, Salt Lake City, Utah) in a patient for the first successful bridge to transplant followed by long-term survival.[3] Since that era, approximately 15,000 mechanical circulatory support devices have been implanted in patients, including more than 930 SynCardia Total Artificial Heart (TAH-t) (SynCardia Systems Inc, Tucson, Ariz) implants worldwide. The SynCardia TAH-t became the only TAH ever approved by the Food and Drug Administration (FDA) in 2004 and by the Centers for Medicare & Medicaid Services in 2008. There are now 20 TAH implanting centers in Europe, 15 TAH implanting centers in the United States, and 1 TAH implanting center in Australia. An additional 18 centers in Europe and 12 centers in the United States are in the process of credentialing. The increase in activity has been based on several factors, including the availability this year in Europe and Australia of a 6-kg driver that permits hospital discharge. Before that, the majority of implants in the world were supported by 36 large 180-kg consoles. There were no other drivers. Patients have now spent more than 20,000 days out of hospital with the SynCardia TAH-t, and 1 patient surviving as an outpatient for 1327 days recently underwent successful transplantation.

Another factor that may be responsible for the increased number of implants has been recognition of the limitations of left ventricular assist device (LVAD) therapy. Recent publications establish the predictive value of risk scales such as the Lietz–Miller Score,[4] SOFA score,[5] HeartMate II risk score,[6] right ventricular failure score,[7] and Muenster score.[8] These scores have shown that patients with Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profile 1, ''crash and burn,''[9] may have a several-fold increased risk with LVADs. In the multicenter trial with the SynCardia TAH-t,[10] we analyzed 43 prognostic factors by univariate and multivariate analyses and compared these with multivariate analyses for LVADs and biventricular assist devices (BiVADs). We found that a history of smoking and a prothrombin time greater than 16 seconds were the only predictors of a bad outcome for TAH-t recipients at any time postoperatively.[11] Factors that had been found to be predictors of mortality with LVADs in the risk factor scoring systems included thrombocytopenia, ventilator support, renal dysfunction,

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Abbreviations and Acronyms

BiVAD	= biventricular assist device
BSA	= body surface area
ECMO	= extracorporeal membrane oxygenation
FDA	= Food and Drug Administration
INTERMACS	= Interagency Registry for Mechanically Assisted Circulatory Support
LVAD	= left ventricular assist device
NYHA	= New York Heart Association
PTFE	= polytetrafluoroethylene
TAH	= total artificial heart
TAH-t	= temporary total artificial heart

hepatic dysfunction, previous surgery, and right-sided heart failure.[4-8] These were not significant predictors for the TAH. A previously published comparative study from our center documented survival to transplantation of 75% for TAH recipients, 57% for LVAD recipients, and 38% for BiVAD recipients.[12] The working hypothesis is that the TAH rescues patients who would have a higher risk with an LVAD.

Finally, some situations seem best suited for TAH, including failed cardiac transplantation (acute or chronic), massive myocardial infarction, acquired ventricular septal defect, diffuse mural thrombosis, failed Fontan, severe hypertrophic cardiomyopathy, and catastrophic intraoperative cardiac damage.

Three programs have implanted more than 100 TAHs in patients: La Pitie Salpetrier has implanted more than 200 TAHs,[13] Bad Oyenhausen (L. Arusoglu, MD, personal communication, October 2011) has implanted more than 100 TAHs, and our program has implanted more than 100 TAHs. Another source of data on TAH results is available from INTERMACS,[14] but at this early stage of enrollment into the registry it may be biased by the large number of recent start-up programs in the United States and by the learning curve effect, particularly with respect to patient selection. This has not been true in all new programs, for instance, the Virginia Commonwealth University has a series of 27 consecutive TAH survivals to transplantation (M. Hess, MD, and V. Kasirajan, MD, personal communication, October 2011).

Our series started in 1985 with the Jarvik-7 and in 1993 with the SynCardia TAH-t in an investigational device exemption study aimed at obtaining FDA approval. The SynCardia TAH-t history, use, sizing, function, indications, and anticoagulation, and our previous results up to 55 implants have been reported.[15-17] We present the experience with the SynCardia TAH-t from 1993 to 2009.

MATERIALS AND METHODS

The current study began in January 1993 and ended in December 2009. It includes 101 consecutive patients from University Medical Center (Tucson, Ariz), with 65 patients previously reported as part of a multiinstitutional investigational device exemption study from 1993 to 2002.[10] Thirty-six more patients from University Medical Center were added between 2002 and 2009. Indications and exclusions for implantation in that study have been reported.[10] Inclusion criteria were as follows: patient eligible for cardiac transplantation, New York Heart Association (NYHA) functional class IV, body surface area (BSA) 1.7 to 2.5 m^2 or T10 distance from sternum to anterior vertebral body by computed tomography scan of 10 cm or greater, either cardiac index of 2 L/min/m^2 or less and systolic pressure 90 mm Hg or less and central venous pressure 18 mmHg or more, or on 2 of the following: dopamine 10 μg/kg/min or greater, dobutamine 10 μg/kg/min or greater, epinephrine 2 μg/kg/min or greater, other drugs at maximum levels, intra-aortic balloon pump, or cardiopulmonary bypass. Exclusion criteria were as follows: use of any ventricular assist device, pulmonary vascular resistance of 8 Wood units or greater (640 dynes/sec/cm^5), dialysis in previous 7 days, serum creatinine 5 mg/dL or greater, cirrhosis with total bilirubin 5 mg/dL or greater, and cytotoxic antibody 10% or greater. After the completion of that study, we liberalized our criteria, accepting some patients for implantation who were too sick to meet the ''eligible for cardiac transplantation'' criteria.

A polytetrafluoroethylene (PTFE) neopericardium was constructed to cover the TAH in 70 of these patients.[18] The rationale was to facilitate explantation. The implantation technique has been reported.[19] The same anticoagulation strategy, including multiple tests and combined anticoagulation and antiaggregant therapies, was used in all patients.[16]

Adverse events were defined according to the FDA investigational device exemption trial[10] and have been published.[20] They are essentially the same as those published by INTERMACS.[21] The definitions of some of the events were broad. For instance, ''bleeding'' included perioperative use of 8 units or more of packed red blood cells, any reoperation for bleeding, any postoperative thoracic drainage of more than 200 mL/h 4 hours or more postoperatively, and any transfusion of 3 units or more of blood within a 24-hour period after the first 48 postoperative hours. Neurologic events included any transient ischemic attack, cerebral vascular event or seizure, any abnormal cerebral imaging study, and any other cause of neurologic deficit (eg, ischemic damage from cardiac arrest). Stroke is defined as a neurologic deficit lasting more than 24 hours. Infection is defined as a positive culture or clinical sepsis with negative culture. Infections were defined as serious if they were related to death or delayed transplantation.

RESULTS

This institutional review board–approved study began in 1993 with our first transplant of the SynCardia TAH-t, called the ''CardioWest TAH.'' The last patient included in the series underwent transplantation in December 2009. The longest-term survivor is currently alive 16.4 years postimplantation. All transplantations were performed at the University Medical Center in Tucson, Arizona. Demographics are shown in Table 1. There were 101 patients with a mean age of 48 years (median, 52 years; range, 14–70 years). Eighty-five percent were male, and 75% were white. Patients had an average weight of 86 kg and a BSA of 2.05 m^2. Nine patients had a BSA of 1.77 m^2 or less. Forty-one patients were on mechanical ventilation, 26 patients were on mechanical circulatory support, 26 patients had experienced a recent cardiac arrest, and 4 patients were on extracorporeal membrane oxygenation. SynCardia