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ORIGINAL ARTICLE

Ethical Analysis of Withdrawing Total Artificial Heart Support

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Abstract

Objectives: To describe the characteristics of patients who undergo withdrawal of total artificial heart support and to explore the ethical aspects of withdrawing this life-sustaining treatment.

Patients and Methods: We retrospectively reviewed the medical records of all adult recipients of a total artificial heart at Mayo Clinic from the program's inception in 2007 through June 30, 2015. Management of other life-sustaining therapies, approach to end-of-life decision making, engagement of ethics and palliative care consultation, and causes of death were analyzed.

Results: Of 47 total artificial heart recipients, 14 patients or their surrogates (30%) requested withdrawal of total artificial heart support. No request was denied by treatment teams. All 14 patients were supported with at least 1 other life-sustaining therapy. Only 1 patient was able to participate in decision making.

Conclusion: It is widely held to be ethically permissible to withdraw a life-sustaining treatment when the treatment no longer meets the patient's health care–related goals (ie, the burdens outweigh the benefits). These data suggest that some patients, surrogates, physicians, and other care providers believe that this principle extends to the withdrawal of total artificial heart support.

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HISTORICAL PERSPECTIVE

Replacing an ailing heart with a man-made organ has been the dream of scientists since the time of Leonardo da Vinci and the Renaissance.[1] In 1964, Dr Michael DeBakey and colleagues appealed to President Lyndon B. Johnson to establish a total artificial heart (TAH) program, which was ultimately allocated approximately $160 million in federal funding.[2] This ambitious endeavor was to parallel President Kennedy's space program, with the objective of developing a fully functional TAH before the lunar landing.[1,3] In April 1969, a mere 3 months before Neil Armstrong landed on the moon, Dr Denton Cooley implanted the first human TAH, which supported a man for 64 hours until he received a heart transplant.[1]

In 1982, Dr William DeVries implanted the first TAH intended as destination therapy at the University of Utah.[2] Justifiably, this pioneering case received prominent and exuberant international news coverage, with reporters packing the hospital auditorium. A fact receiving little publicity was that the surgeons had given the patient, Dr Barney Clark, a dentist, a "key" to the compressor of his TAH.[4] Dr Willem Kolff, founder of University of Utah's artificial heart program, explained, "if the man suffers and feels it isn't worth it anymore, he has a key that he can apply… I think it is entirely legitimate that this man whose life has been extended should have the right to cut it off if he doesn't want it, if life ceases to be enjoyable…."[4] Dr Clark survived 112 days, never leaving the hospital and never using his key, eventually dying "with peace and dignity" from circulatory collapse and secondary multiorgan system failure.[5,p17]

MEDICAL INDICATIONS AND THE STATE OF THE ART

Approximately 400,000 patients die of heart failure in the United States annually.[6] Only 2000 to 2500 hearts are transplanted annually, a number that has remained approximately the same for 20 years.[1] Mechanical circulatory

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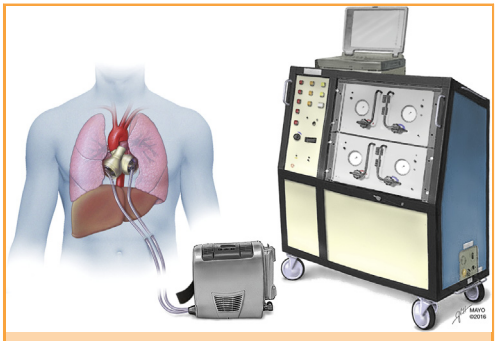

FIGURE. Total artificial heart and driver consoles. (Used with the permission of Mayo Foundation for Medical Education and Research.)

support devices such as TAHs and ventricular assist devices (VADs) have the potential to address, in part, the mismatch between the demand for and the availability of hearts for transplant.

A TAH implantation requires excision of the native heart, leaving atrial remnants to which cuffs can be secured (Figure). Vascular grafts are sutured to the pulmonary artery and aorta. A pneumatically driven diaphragm directs blood through 2 artificial ventricles in a pulsatile manner, with 4 mechanical valves ensuring unidirectional flow. Percutaneous drive lines tether hospitalized patients to a washing machine–sized air compressor terminal, also known as "big blue."[7] As an alternative, a portable driver (Freedom; SynCardia Systems LLC) weighing approximately 6 kg allows patients to walk around and even to leave the hospital.

Indications for TAH implantation include severe biventricular heart failure, intractable arrhythmia, septal defects or myocardial aneurysms, previous valve prosthesis or congenital heart disease, infiltrative or restrictive cardiomyopathy, cardiac malignancies, and cardiac graft failure (heart transplant recipients awaiting a second allograft).[1,7] The TAH was implanted in 4 patients in the 1980s as a permanent therapy, or destination therapy, before US Food and Drug Administration (FDA) approval for this application of the TAH was withdrawn.[8] Since the 1990s, the TAH has been approved only as a bridge to transplant, although in 2015 the FDA approved a clinical trial with the TAH as destination therapy.[8,9]

More than 1300 SynCardia temporary TAHs have been implanted, with 80% successfully bridging the patient to transplant. One-year survival with the device is 70%,[10] with the longest successful bridge to transplant being more than 3.5 years.[11] The annual number of TAH implantations remains in the double digits; the Interagency Registry for Mechanically Assisted Circulatory Support recorded 278 SynCardia temporary TAH implantations between 2008 and 2014.[12]

ETHICAL QUESTIONS RAISED BY THE TAH

Although the TAH touches the lives of a relative few, many ethical considerations accompany its use. A patient undergoing TAH implantation consents and submits to a lethal alteration in his or her anatomy, whereby the native heart is explanted and replaced with a mechanical device. Infection, hemorrhage, thrombosis, and multiorgan failure may occur in patients with a TAH, all of which would preclude heart transplant. One-fifth of TAH recipients do not survive to transplant,[10] yet their experience is seldom described in the medical literature. Several questions related to TAH use remain to be answered, such as under what circumstance is withdrawal of TAH support—leading to certain, near-instantaneous death—ethically and legally permissible? And when a patient's circulation is entirely reliant on implanted mechanical support, is the patient required to continue TAH support even if the treatment becomes more burdensome than beneficial?

The aim of this study was to describe the characteristics of patients who underwent TAH implantation at Mayo Clinic and from whom TAH support was withdrawn. We also aimed to evaluate the ethical and legal permissibility of withdrawing this life-sustaining therapy (LST) from patients who no longer desire it.

PATIENTS AND METHODS

We searched our electronic patient database for the medical records of all patients who have undergone TAH implantation at Mayo Clinic in Scottsdale, Arizona, and Rochester, Minnesota, since inception of the TAH program in 2007 through June 30, 2015. We reviewed the records of all patients identified to further identify those who did not receive a heart transplant and who requested,

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