



# Quality of life and rehabilitation after total artificial heart

Megan M. Streur<sup>1</sup>, Jennifer A. Beckman<sup>2</sup>, Cynthia M. Dougherty<sup>1</sup>, Song Li<sup>2</sup>, Claudius Mahr<sup>2</sup>

<sup>1</sup>Department of Biobehavioral Nursing and Health Informatics, School of Nursing, <sup>2</sup>Division of Cardiology, Department of Medicine, University of Washington, Seattle, WA, USA

*Correspondence to:* Megan M. Streur, PhD, ARNP. Department of Biobehavioral Nursing and Health Informatics, School of Nursing, University of Washington, 1959 NE Pacific Street, Seattle, WA 98195, USA. Email: mstreur@uw.edu.



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Over the past several decades, tremendous effort has been expended to improve survival, reduce adverse events, optimize device functionality, and improve device portability for patients with the total artificial heart (TAH) (1). In contrast, there is a paucity of data on quality of life (QOL), psychological outcomes, functional capacity, and rehabilitation outcomes. Patients with TAH may live with the device for extended periods of time, making it critically important to define the impact of TAH on patient-centered outcomes. To ensure patients and families make informed decisions regarding TAH implant, clinicians have the responsibility to provide evidence-based information that may impact the patient's decision to receive the TAH.

A growing body of literature describes patient-centered outcomes following left ventricular assist device (LVAD) implant, including QOL, depression, anxiety, and symptoms of post-traumatic stress disorder (PTSD). Data from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database reveals that patients with LVAD experience rapid and sustained QOL improvement as early as 3 months post-LVAD that extends through 5 years of follow-up (2). Longitudinal TAH-specific QOL data has yet to be reported (3), representing a noteworthy knowledge gap. In the absence of TAH specific data, the assumption could be made that QOL and psychological outcomes in patients with TAH may follow a similar trajectory to patients with an LVAD. However, differences between LVAD and TAH recipients, including clinical characteristics, disease severity, adverse event profiles, and device features, make the veracity of this assumption questionable. We identified only one cross-sectional, single-center study that described QOL among

11 TAH patients (4), and none delving into symptoms of anxiety, depression, or PTSD.

To move the science forward, carefully designed longitudinal studies are needed to describe QOL, psychological, and functional outcomes of TAH recipients, identify patients' most prominent concerns, and determine whether subsets of patients are at increased risk for poor patient-centered outcomes. Patient-reported outcomes are inherently prone to selection bias [e.g., illness severity or adverse events (stroke) can influence which patients self-report] and survival bias. Thus, it is imperative to employ strategies to avoid selection bias when possible, and to utilize statistical methods that account for the non-random missing data that result from unpreventable selection and survival bias (5).

Participation in exercise-based cardiac rehabilitation increases functional capacity, improves QOL, and reduces hospitalizations for the general heart failure population (6). Prospective, randomized controlled trials of exercise training interventions in the TAH population have not been published. Exercise training studies in the VAD (LVAD and BiVAD) population demonstrate a mean increase in peak  $\text{VO}_2$  of 2.2 mL/kg/min in exercise versus control groups following completion of exercise-based interventions (7). Exercise training has equivocal effects on QOL and psychological outcomes for patients with VAD, likely related to small samples sizes (7). Extrapolation of exercise training data from patients with VAD suggests that TAH recipients may gain modest improvement in exercise capacity from participating in exercise, with potential improvement in QOL. However, TAH-specific device features (e.g., fixed heart rate and limited fill-volume reserve) result in a limited ability to increase cardiac output

and peak  $VO_2$  in response to exercise (8). Therefore, the potential benefits of exercise in the TAH population are unclear, with the most likely benefits being the prevention of skeletal muscle wasting and improvement of skeletal muscle oxygenation, QOL, and psychological outcomes. The safety of supervised, symptom-limited exercise testing for TAH recipients has been demonstrated in 2 small, single-center studies (8,9). Longitudinal, controlled trials that evaluate the effects of exercise-based cardiac rehabilitation on mortality, functional capacity, QOL, and hospitalizations are lacking in the TAH population, representing a significant knowledge gap that is critical to the development of physical activity guidelines for patients with a TAH.

Frailty is an important prognostic indicator in end-stage heart failure, characterized by decreased physiologic reserve, unintentional weight loss, fatigue, weakness, impaired gait speed, and/or limited physical activity (10). In the setting of end-stage heart failure there is significant overlap between age-related frailty and disease-related frailty, including cachexia, fatigue, and weakness, which presents a conundrum for clinicians attempting to utilize measures of frailty to predict outcomes and determine appropriate candidates for advanced surgical interventions (e.g., LVAD, TAH, heart transplantation). Although current evidence supports frailty as an indicator of poor prognosis following LVAD and heart transplantation, there is evidence suggesting that disease-related frailty may be partially reversed through exercise training and nutritional optimization both pre- and post-surgery (10). This suggests that implementation of cardiac rehabilitation in the period between TAH and transplant would favorably improve patient outcomes both pre- and post-transplantation. Unfortunately, the deficiency of evidence regarding the effects of exercise-based rehabilitation on mortality and functional outcomes in TAH recipients renders it impossible to determine whether disease-related frailty can be mitigated in the TAH population prior to transplantation.

In conclusion, there is a dearth of research related to QOL and cardiac rehabilitation in patients with a TAH. These significant knowledge gaps limit the ability to address and improve patient-centered outcomes. Cardiac rehabilitation holds the most promise for improving patient-centered outcomes after TAH. Thus, longitudinal, randomized controlled trials on the effects of cardiac rehabilitation are a priority in order to establish physical

activity guidelines for patients with TAH.

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## Footnote

*Conflicts of Interest:* The authors have no conflicts of interest to declare.

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