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Review Article

A Review of Ethical Considerations for Ventricular Assist Device Placement in Older Adults

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ABSTRACT: This article reviews some of the complex ethical issues that accompany the diffusion of ventricular assist devices (VADs) for heart failure patients, with a particular emphasis on issues unique to older adults. In doing so, the ethical issues are centered on three decision points: (a) patient selection; (b) informed consent (i.e., initiation of the device); and (c) end of life (i.e., deactivation of the device.) It is contended that, with the technological improvements in heart failure treatments and new indications, the decision making process for VAD placement and deactivation has become more clinically and ethically challenging, particularly for older adults. Areas for potential future research are identified.

Key words: Ethics, older adults, ventricular assist devices, mechanical support, heart failure

Heart failure, once bluntly described as "a disorder of the elderly," (1) has been characterized as a worldwide epidemic that disproportionately affects older adults to an extent far greater than most other diseases (2-4). Estimates suggest that heart failure is the most common cause of hospitalization for people 65 years of age or older, with the median age of all heart failure hospitalizations being 75 years old (1). The rates of prevalence for heart failure increases precipitously from less than 1% for persons 50 years-old or younger to about 10% for individuals that are 80 years of age or older. The trend in incidence and prevalence is expected to continue, in large part due to the growing aging population (1).

Of greater concern and consequence is the impact that heart failure has on individuals and society, with 5.4% of the total health care budget (~$30 billion) designated to heart failure health care expenditures (5). On an individual level, heart failure negatively impacts patients' quality of life and limits their activities of daily living and functional or exercise capacity (6,7). Estimates suggest that more than 100,000 patients have severe heart failure (American College of Cardiology, Stage D) (8).

While optimal medical management can help patients with mild-to-moderate heart failure (and, on occasion, help some patients with severe heart failure) (9-11), heart failure symptoms often become refractory to medical management in its late stages, occasioning the development and diffusion of advanced cardiac therapies to supplement or replace medical management and improve cardiac function (4,12). These therapies—ranging from noninvasive implantable cardioverter defibrillators (ICDs) to life-changing cardiac transplantation or invasive mechanical circulatory support devices—have had great success in prolonging life and ameliorating symptoms associated with advanced heart failure (3,13,14).

One such advanced cardiac therapy is the ventricular assist device (VAD). The VAD, a type of mechanical pump that supports ventricular unloading, was initially approved to "bridge" the patient to cardiac

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transplantation by stabilizing organ function and enabling subsequent transplantation. The shift from pulsatile technology to smaller, more durable, continuous-flow devices and improved clinical outcomes facilitated the increasing use of VAD implantation as a "destination" therapy (VAD-DT) for patients who were not candidates for transplantation (10,15).

This article reviews some of the complex ethical issues that accompany the diffusion of VADs, with a particular emphasis on issues unique to older adults. In doing so, the ethical issues are centered on three decision points: (a) patient selection, (b) informed consent (i.e., initiation of the device) and (c) end of life (i.e., deactivation of the device.) It is contended that, with the technological improvements in heart failure treatments and new indications, the decision making process for VAD placement and deactivation has become more clinically and ethically challenging, particularly for older adults (16). Explicit recognition of ethical considerations at each of the decision points must be undertaken.

Patient Selection

Patient selection: Intended use of the device

Early in the history of VAD implantation, VADs were traditionally reserved for critically ill patients with end-stage heart failure and impending cardiogenic shock and/or multiorgan failure (3). On account of improved design modifications and improved patient outcomes, VADs are currently used for patients that are less critically ill. VADS have become increasingly conceptualized as standard of care for managing end-stage heart failure, particularly for older Americans. This conceptualization is based on actuarial survival statistics indicating that survival with VAD implantation exceeds 80% at 1-year and 66% at 2 years. Without surgical intervention, the 1-year mortality estimate for patients with end-stage heart failure exceeds 50% (10,17,18).

VAD placement can be put into a particular tripartite taxonomy according to the intended use of the device to accommodate Centers for Medicare and Medicaid Services (CMS) reimbursement criteria: bridge-to-recovery (VAD-BTR), bridge-to-transplant (VAD-BTT), or destination therapy (VAD-DT) (Table 1). For patients for whom the intended use of the device is VAD-BTT, the VAD is implanted with the expectation that the patient will, in a short time after recovery from VAD implantation, receive a transplant. Approximately 23.7% of VAD patients, averaging 52.7 years old, receive a VAD as a BTT (18). For the small subset of cases where the VAD is implanted as a bridge-to-recovery (~0.8%), it is intended to be used as a short-term, removable intervention for patients with temporary, severe heart failure (e.g., myocarditis) (19). The VAD will be removed if and when cardiac functional improvement is demonstrated.

VAD-DT is a unique category of purposes and patients and has particular relevance to older adults, given that the average age of VAD-DT patients is 61.7 (18). The device is intended to be used as a destination therapy when the end-stage heart failure patient is ineligible for cardiac transplantation and has failed to respond to optimal medical management. Here, the device is placed as a long-term intervention with the goal of prolonging life for about 2-5 years and ameliorating heart failure symptoms as an end-stage therapy. While cardiac transplantation is the ideal life-prolonging therapy for end-stage heart failure patients, it is not usually an option for older adults because most transplant centers use recipient age as an eligibility criterion for transplantation (20). In fact, advanced age is the most common contraindication to cardiac transplantation (18). Essentially, this means that older Americans with heart failure may only have VAD-DT available to them as the one therapeutic modality that could prolong their lives and improve their quality of life. Between 2009 and 2010, the number of VAD-DT implants increased over 7-fold in the U.S. This trend is expected to continue with the 2010 approval of the HeartMate II continuous flow device (Thoratec Corporation, Pleasanton, Calif.) (18).

Patient selection: General considerations

A principle clinical challenge is to select patients that are ill and unresponsive to optimal medical management, so as to benefit from an invasive intervention, while simultaneously selecting patients that are not so severely illness that implantation of the device will not increase survival (21). While recipient eligibility criteria for cardiac transplantation have been well-established by professional organizations through detailed published guidelines (22), there are no widely-used consensus guidelines for VAD implantation. Medical and surgical criteria, however, have been developed to assist in optimal patient selection (www.cms.gov)(10,13,23-30).

Based on data from multi-site clinical trials, CMS formulated inclusion criteria for destination therapy patients for reimbursement. The coverage criteria for destination therapy include patients who have end-stage heart failure and are ineligible for cardiac transplantation and who meet all of the following conditions: (a) NYHA Class IV symptoms of heart failure that have not responded to optimal medical management for at least 45 of the last 60 days or who have been balloon-pump dependent for 7 days, or IV inotrope dependent for 14 days; (b) a left ventricular ejection fraction less than

25%; (c) demonstrated functional limitation with a peak oxygen consumption of 14 ml/kg/min or less unless the patient is balloon pump or inotrope dependent or physically unable to perform an exercise test; and (d) appropriate body size for the device (www.cms.org). The American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines for the Diagnosis and Management of Heart Failure in Adults opines that VAD-DT is appropriate for patients that have an estimated 1-year-survival of less than 50% or an overall life expectancy of less than 2 years (26). More specific guidelines are needed for appropriate referrals of potential VAD candidates (28).

Table 1. A Summary of Ethical Considerations for Ventricular Assist Device Placement in Older Adults

Ethical Consideration		Key Points
Patient Selection	Intended Use of the Device	1. VAD placement can be put into a particular tripartite taxonomy to accommodate CMS reimbursement criteria: bridge to transplant (BTT), destination therapy (DT), and bridge to recovery. 2. VAD-DT is particularly relevant for older Americans.
	General Considerations	1. At present, there are no widely-used consensus statements for VAD implantation. 2. Patient profiles and clinical outcomes are tracked to simplify risk assessments. 3. Advanced age coincident with end-stage heart failure is often accompanied by deconditioning, which may exacerbate surgical and recovery processes.
	Psychosocial Considerations	1. Psychosocial contraindications for VAD-DT remain somewhat nebulous. 2. Systematic studies examining isolated psychosocial factors associated with poor outcomes for VAD implantation are lacking.
Informed Consent	Predictive models	1. The erratic clinical trajectory for heart failure complicates advance care planning and prognostication efforts. 2. The predictive utility of some risk stratification models has been questioned. 3. A limitation of several predictive models is that they focus on mortality, often excluding consideration of other clinical outcomes that are relevant to patients and arguably integral to informed consent.
	Quality of life	1. Large-scale clinical trials have demonstrated the efficacy of VADS in three domains: prolonging survival, maintaining organ function, and improving quality of life. 2. Limitations of the evidence on quality of life include: missing data, small sample sizes, few domains of study, and one-time snapshots of patient experiences. 3. Mixed method approaches of study are needed. 4. Results underscore the limitations in measuring physiologic age in risk calculations for VAD implantation.
Deactivation	Ethical Permissibility	1. An ethical consensus is taking shape that suggests that VADs can be deactivated in many circumstances. 2. Countervailing ethical considerations exist that would be grounds for questioning the authenticity of the patient's desire to deactivate the VAD.
	Advance care planning	1. The erratic, nonlinear clinical trajectory of heart failure can frustrate proactive advance care planning efforts. 2. The optimal time to talk about patient preferences is in the ambulatory setting with the patient's cardiologist. 3. VAD-associated factors that can affect patients' perspectives of quality of life should be discussed.

Essential to optimal patient selection is identifying and excluding patients from consideration that have unacceptably high operative risk. To this end, The Interagency Registry for Mechanical Assisted Circulatory Support (INTERMACS) tracks patient profiles and clinical outcomes in the United States for patients who receive a VAD in order to simplify risk assessments (Table 1). A report of INTERMACS data focused on destination therapy patients suggested that cardiogenic shock, concomitant surgery, and poor renal function were associated with higher post-operative mortality (18). Predictive and risk stratification models are available to assist in prospectively determining perioperative risk and mortality estimates but, as discussed below, they are subject to serious limitations.

Patient selection: Psychosocial considerations

Psychosocial criteria for VAD candidacy are primarily institution-specific and psychosocial contraindications for VAD-DT remain somewhat nebulous. Before 2002, VADs were primarily used as a BTT device. As such, the VAD candidates were judged by similar criteria to that of transplant candidates. If patients were not candidates for transplants, they were generally not considered eligible for VAD implantation (31). This is because the patients were expected to receive a cardiac transplant. Organs are a non-renewable, scare resource, leading to the development of definitive allocation criteria that are clinically refined. The Food and Drug Administration's (FDA's) approval of the device as a destination therapy and the subsequent proliferation of VAD-DT use have led to a relaxing of psychosocial standards. Often, when patients are not considered a transplant candidate on account of advanced age, nonadherence, or other psychosocial contraindications, they are considered appropriate VAD-DT candidates. The justification provided is that, since VADs are not scare resources in the same way that organs for transplant are, the allocation considerations need not be as regimented (31).

As a result, the minimal psychosocial requisites for VAD-DT remain an open question. Who should be ineligible to receive a VAD-DT on the basis of psychosocial considerations? Should the psychosocial criteria for VAD-DT be different than VAD-BTT criteria? More generally, should the psychosocial criteria be different for transplantation than device implantation? VAD programs currently use institution-specific practices for defining VAD psychosocial assessment parameters, which may borrow heavily from the transplantation literature with regard to questions of adherence, social support, substance abuse, and insight. Social stability (broadly defined to include personal support, a 24-hour care plan, and housing), no close relatives with substance abuse problems, younger age, no repeated alcohol-treatment failures, good adherence with medication regimens, no current polydrug use, and no existing severe mental disorders have all been associated with good transplantation outcomes (32-39).

Yet, at present, is unclear whether and how these psychosocial variables are associated with good outcomes in the context of VAD implantation. Systemic studies examining isolated psychosocial factors associated with poor outcomes in the context of VAD implantation are lacking (Table 1). It is equally unclear whether and how such variables should be measured in the context of VAD placement. Could standardized instruments used for assessing transplant candidates, like the Psychosocial Assessment of Candidates for Transplantation (PACT) or the Stanford Integrated Psychosocial Assessment for Transplant (SIPAT), be modified for VAD implantation to ensure consistent practices with VAD candidates? Are criteria absolute (i.e., one "passes" or "fails") (40)? Should the psychosocial criteria be weighed equally, or should some factors be considered more important? Answers to such questions would greatly assist in determining the minimal psychosocial requisites for VAD-DT placement and, more broadly, determining psychosocial parameters for assessing VAD candidates.

On the other hand, several studies have examined quality of life measures, functional capacity, and caregiver burdens that indirectly address psychosocial considerations for VAD implantation. These studies are discussed more fully in the following sections but, suffice it to say here, this evidence suggests that a key component of the psychosocial assessment is (and should be) a social support network because of its ability to influence perception of quality of life and self-care.

Patient selection: Older adults

There are some patient selection factors that are of particular relevance for older adults. For instance, while neurocognitive functioning is important for patients of any age, it is of greater importance for older adults because of the potential for impaired self-care (16,23,41). Once the patient is discharged home, they initiate self-care, including system checks, battery recharging, power changes, driveline dressing changes, alarm recognition and management.

A history of stroke, neuropathy, dementia, or other cognitive changes may impact the patient's ability to manipulate and manage the device, including operation and maintenance of it (42). Cognitive impairments that affect a patient's ability to recognize alarms or direct others to care may preclude VAD placement as a viable

option. Because of the causal connection between maintenance of the device and drive-line, pump-pocket, and pump infections, the candidate for VAD placement must be able to care for him or herself and be attentive to potential problems.

Advanced age coincident with end-stage heart failure is often accompanied by deconditioning cachexia, poor nutritional status, osteoarthitis exercise intolerance, which may exacerbate surgical and post-surgical complications and post-operative recovery processes (16)(Table 1). One study indicated that device implantation in patients who were 70 years of age or older was associated with above a 2-fold increased morality risk (18,43). It should be noted that, although concerns have been raised about the ability of older patients to perform activities for device maintenance, some studies have suggested that older patients will adapt to the technology over time (43).

Informed Consent

When initiating any surgical intervention, the risk/benefit calculation must be medically and surgically acceptable to the physician and the patient or surrogate must agree that initiation of the treatment is most in keeping with the patient's values, goals, and preferences. Shared decision making has been touted as the ethically preferable mode of informed decision making to facilitate an open, back-and-forth dialogue between the physician and the patient about the patient's values, preferences, and goals. Shared decision making is rooted in evidence highlighting the benefits of patient involvement on patient satisfaction and adherence with therapy (44). A healthy therapeutic alliance between patient and the clinical team is of great significance in the VAD context, perhaps more so than with many other interventions. This is because the stability and longevity required in the clinician and VAD patient relationship has major importance: "The patient is dependent upon the VAD team for survival, and the VAD team is dependent upon good outcomes for survival of the VAD program" (31).

Aside from improving patient satisfaction and adherence and helping to foster a therapeutic alliance, shared decision making ideally can begin important advance care planning conversations. More specifically, when initiating a therapy, the likelihood and degree of benefit should be commensurate with that of the risks, the weighing of which should be conducted prior to initiating the intervention and continually reassessed to formulate goals and clinical endpoints (45,46). When patients provide important values and preferences in these initial shared decision making conversations, the information conveyed can serve as starting point for a more detailed conversation that can take place after VAD placement if there is a negative shift in a patient's performance status.

An ethical and practical challenge is to identify necessary components of the shared decision making dialogue and the process in which the exchange of information between the patient and physician should occur. In what follows, several components that have been cited in the literature as important for informed consent discussions are outlined. A few of these components are constrained by the evolving status of evidence surrounding VAD implantation. For instance, as will be discussed more fully below, the clinical variability in patients' trajectories, experiences, and burdens leave wide uncertainties around estimates of survival and post-operative experiences for a particular individual, thereby limiting prognostication efforts. This has implications for informed consent processes.

Informed consent: Predictive models and risk stratification

The clinical trajectory for heart failure is nonlinear, marked by periods of unpredictable exacerbation with precipitous declines in functional capacity, frequently followed by recovery to near baseline functioning (47). The erratic pattern of heart failure not only complicates advance care planning, but also complicates the development of multivariable models that could provide refined prognostic information for patients with heart failure (48). Several prediction and risk stratification models are available for predicting death or adverse outcomes for heart failure patients, as well as VAD candidates specifically (7,24,49-63) and can assist in predicting survival and patient outcomes. However, they have limitations and leave wide uncertainties around estimates of survival for a particular individual (48).

Physicians need to convey risk in discussions with patients and surrogates so that these decision makers can make informed decisions. Accurate and validated predictive models are essential assets in formulating physicians' risk assessment (64-66). The Destination Therapy Risk Score (DTRS) is a widely-applied predictive model. Unlike many other risk models available that are derived from retrospective analysis of single-center experiences, this model is uniquely comprehensive in that it is derived from a multi-institutional dataset (64). Recently, this predictive model has been found to be a poor mortality risk discriminator for VAD-BTT recipients and only modestly successful at stratifying destination therapy patients with new-generation continuous flow devices (24,64,67). Other predictive models, such as the Heart Failure Survival Score (HFSS) and the Seattle Heart Failure Model

(SHFM) need revalidation for current patient populations on newer device therapies (28). Thus, the predictive utility of some risk stratification models has been questioned (Table 1).

A limitation of several predictive models is that they focus on mortality, often excluding consideration of other clinical outcome measures that are highly relevant to patients and arguably integral to informed consent discussions (Table 1). For instance, studies have found that patients often prefer improved quality of life and symptom relief over quantity of lif (48,68-70). In discussions with VAD candidates, many patients will likely want to know their prognosis, but they may also express interest in gauging anticipated social functioning, quality of life, and caregiver burdens with and without VAD implantation. With the exception of a few notable predictive models that are aimed at identifying nonmortality patient-centered outcomes for particular heart failure patients (50), this predictive information is largely left to clinical intuition informed by available data that may not be patient-specific. The available data can be culled from the existing literature on quality of life post- VAD implantation, which is discussed in the following section.

Informed consent: Quality of life determinants

Quality of life is a subjective, multidimensional assessment of one's ability to engage in life activities and derive continued satisfaction from doing so. It includes consideration of physical, mental, and social functioning (71). The early application of VADs focused on mitigating adverse events and complications such as drive-line, pump-pocket and pump infections, sepsis, stroke, and multi-organ dysfunction (e.g., respiratory, hepatic, renal). Design modifications, including patient-desired features such as the miniaturization and silencing of VADs, have invigorated clinicians and physicians and created a significant uptake in device implantation (3). As duration of support is extended and the criteria for VAD-candidacy expands, instruments and measures of assessing and optimizing quality of life and functional and exercise capacity have become (and will continue to become) a greater focus of research (15).

Large-scale clinical trials have demonstrated the efficacy of VADs in three principle domains: prolonging survival, maintaining organ function, and improving quality of life (10,13)(Table 1). Several studies have been conducted examining patients' perceptions of quality of life (10,13,43,62,63,72-88).

In studies conducted immediately post-implantation, patients report being more satisfied with their lives, their health, and their quality of life, compared to their pre-implantation experience (78). These VAD patients experience relatively low amounts of stress and low symptom distress and functional disability (78). While most reports have generally examined quality of life outcomes within a couple of weeks or 1-3 months post-implantation, other studies have described outcomes well after device implantation and demonstrate similar results. In one oft-cited study, patients' perceptions of health status and quality of life were generally good and considered stable between 1 month and 1 year after VAD implantation (79).

Dew and colleagues compared two groups of patients: patients who had a ventricular assist device followed by explantation and transplantation and patients who did not require VAD support before transplantation. The two groups reported similar levels of physical and emotional functioning (73,89). Notable improvement in quality of life has been associated with the elapse of time (78).

Factors identified as predictive of a good quality of life are related to ambulation, self-care, psychological health, and discharge from the hospital (73,79,80). In at least one study, psychological factors were considered the strongest predictor of patient satisfaction and a global perspective of quality of life (80). Discharge from the hospital has been found predictive of decreased family-related stress (73). Outpatients have also reported feeling less of a burden to their families compared to VAD inpatients and transplant candidates (73).

It should be noted that, within these same studies, patients have reported some stressors and anxiety. Moderate levels of stress and acceptable ratings of coping ability were noted in one study conducted by Grady and colleagues (79). Patients reported anxiety, sadness, helpless, and depression 1-month and 1-year post-implantation (79). Compared to pre-implantation experiences, patients have reported significantly more self-care disability and more dissatisfaction with socioeconomic circumstances immediately post-implantation (78).

At present, it is unclear how idiosyncrasies associated with the nature of the device impacts psychological adjustment and well-being. For instance, it is possible that patients may perceive an intrusion into their daily lives because of the need for continuous monitoring post-surgery. VADs have been found to have a considerable effect on a patient's body and sense of self (90). Hallas and colleagues have explored psychological adjustment and well-being and found that patients concentrated on "normalizing" their experiences, either through cognitive comparisons with other individuals or comparisons with their pre-implantation self, in order to achieve "control" over their health circumstances (84). Studies such as this highlight a promising area of research.

Other limitations of the evidence available with regard to patients' perceptions of their quality of life post-implantation is that many of the studies focus on bridge-to-transplant and/or pulsatile technologies patients, although notable exceptions can be found (10,13,91). Additional limitations include: missing data, small sample sizes, few domains for study, and one-time snapshots of patient experiences (Table 1). Longitudinal studies that examine multiple domains (e.g., social interaction, somatic sensation, psychological and occupational limitations and effects) are critical and timely (15). Two reliable and validated instruments, the Minnesota Living with Heart Failure Questionnaire (MLHFQ) and the Kansas City Cardiomyopathy Questionnaire (KCCQ), can assist in this efforts (15,92,93) but, because quality of life is an inherently subjective and multidimensional concept, standardized instruments may not fully capture the nuances associated with quality of life. Mixed methods approaches, including qualitative interviews with VAD patients, are necessary to significantly advance knowledge (71,94).

Quality of life: Older adults

Of particular relevance and concern for older adults is that patients receiving the device as a destination therapy tend to rate their quality of life and psychological functioning lower than other VAD patients (16,83). Because the intended use of the device for patients older than 70 will likely be destination therapy, it could be argued that older adults are at risk for a perceived lower quality of life relative to younger cohorts. Yet, at present, data are conflicting on this point. For instance, Adamson and colleagues found that survival functional abilities, quality of life, and survival for patients 70 years of age or older were similar to the comparison group of younger patients (21,43). However, the younger cohort experienced significant improvement in functional capacity immediately post-placement, whereas older VAD patients did not experience similar results until 3-6 months after device placement (71,43). Similarly, a comparison between VAD-DT and VAD-BTT cohorts demonstrated no differences in quality of life or exercise tests at 3 or 6 months after placement of the device (77).

Results such as these underscore the limitations in measuring physiological age in risk calculations for VAD implantation (21)(Table 1). Studies are needed looking specifically at measures of frailty (e.g., short-distance gait speed, handgrip strength) and their associated impact on outcomes and quality of life with and without device implantation (95). Broadly, frailty is the "aggregation of physiological insults across many organ systems resulting in a syndrome of heightened vulnerability in the face of stress" (95) and is associated with advanced age. Measures of frailty are highly predictive of adverse outcomes for most medical and surgical populations. It remains to be seen how such measures of frailty can impact prognostic information in patient selection for VAD-DT, but conceivably such measures could aid in predicting death, incident disability, and other factors that could impact older adults' perceptions of quality of life (95).

Deactivation of the Device

Deactivation: Ethical permissibility and process

The clinician is charged with synthesizing and weighing a variety of concerns in order to resolve clinical challenges. The approach to ethical decision making is analogous to the systematic analysis used in clinical decision making (96). In the context of mechanical circulatory support, there are three practical ethical issues that are addressed in clinical decision making concerning the deactivation of a device. The first is whether it is ethically permissible to deactivate the device. The second is whether there are countervailing ethical considerations that suggest that it should not be performed in a given case. The third issue includes consideration of a respectful and compassionate implementation process. While the literature on these three distinct concepts is scarce, an ethical consensus is taking shape that suggests that VADs can be deactivated in many circumstances (Table 1).

The first question concerns whether it is ethically permissible to withdraw the VAD in general. With the exception of a few notable authors (97,98), most ethicists opine that it is permissible to deactivate the VAD. The grounds for ethical permissibility are usually based primarily on the ethical precept allowing informed refusal of life-sustaining therapies (96,99). It is also not uncommon for clinicians to object to deactivation of a VAD on grounds that deactivation may result in immediate or nearly immediate death which, from the perspective of a clinician who performs the deactivation (akin to moving a "switch"), it is psychologically burdensome. While psychological burdens should not be dismissed, it does not follow that such burdens are indicative of a moral problem.

Others argue that the VAD is constitutive in that it takes over a function that the body can no longer adequately perform and, as such, deactivating it would be akin to euthanasia. Yet, many treatments that take over the function of the underlying disease and organ dysfunction, such as the mechanical ventilation or hemodialysis, are withdrawn on a routine basis (99). A similar point has been made by some individuals who argue that the device is primarily internal, and it can

therefore be considered part of the "self." Yet a PEG or an ICD is internal, and few would consider these devices part of the "self" (100-103). A new pathology for the purpose of terminating the patient's life is not introduced; rather, upon deactivation, the patient would die of their underlying heart disease and organ dysfunction.

Regarding the second issue, countervailing ethical considerations that would be grounds for questioning the authenticity of the patient's desire to deactivate the VAD would include fluctuating capacity, questionable surrogate motives (in cases where the patient lacks decision making capacity), and inconsistency in stated preferences (Table 1). Although some have argued that depression should not interfere with informed decision making where the symptoms manifest as a rational response to one's circumstances (104-106), symptoms associated with depression should not be ignored. Thorough psychiatric evaluation can assist in determining whether there are unmet needs of the patient, informing an overall judgment about a patient's decision making capacity.

This leads to the third issue. Assuming VAD deactivation is considered ethically permissible and there are no countervailing ethical considerations that suggest that deactivation should not be performed, special emphasis should be placed on a compassionate and respectful implementation process. Services including ethics, psychiatry, palliative medicine and chaplaincy can collaborate to meet the patient's, family's and team's needs for competent, compassionate support (107). Individuals who conscientiously object to deactivation of the device should not be asked to be involved.

Deactivation: Advance care planning

The erratic, nonlinear clinical trajectory of heart failure can frustrate proactive advance care planning efforts (47)(Table 1). Heart failure patients have long-term limitations on functional capacity with intermittent exacerbations. Rescue attempts are provided during these exacerbations often followed by a return to near baseline (47). Hospice may not be well-suited for this patient population because it is difficult to predict which episode will be fatal. Death may be unexpected and sudden even where accurate predictive models are used (108-110). An additional challenge for clinicians is to identify optimal times to discuss advance care planning and VAD implantation for critically ill patients because their conditions and treatments can compromise decision making capacity (111). Because of the complexity associated with advance care planning and the high level of prognostic uncertainty for many patients, the default practice of many physicians is to forego timely and proactive advance care planning discussions with heart failure patients.

The optimal time to talk about patient preferences is in the ambulatory setting with the patient's cardiologist (Table 1). The venue is traditionally a non-emergent setting where the patient is capacitated (48). The goal of initial conversations about advance care planning is to assist patients in thinking about quality-of-life-determinants. To identify these determinants, cardiologists should discuss with patients different scenarios that can affect patients' perspectives on quality of life. If and when the patient becomes eligible for consideration of a VAD, VAD-associated factors (e.g., chronic renal failure, stroke, refractory infections) should be discussed (112, 113).

Thorough advance care discussions are typically anticipatory and iterative, wherein conversations and planning incrementally build and become more concretized and specific. A more detailed conversation can take place after VAD placement if there is a negative shift in a patient's performance status. Patients should be encouraged to make advance decisions as explicitly as possible and communicate those decisions to their surrogate decision makers, to prevent life-sustaining treatment with outcomes not acceptable to the patient (114,115).

In one study describing advance care planning for 69 VAD-DT patients, the authors found that patients' perception of decreased satisfaction in their ability to engage in life activities served as the catalyst for end-of-life discussions. Over one-third of these patients actively participated in these discussions, with the majority of them seeking to actively deactivate device support at the time of the discussions (as opposed to waiting until a loss of consciousness) (116).

Conclusion and Areas for Future Research

As VADs increasingly become mainstream therapies for advanced heart failure, large-scale trials examining VAD-specific observations are needed. For example, women with VADs are at significant risk for suffering from hemorrhagic stroke for reasons that remain unclear (3,117). Further, challenges remain for how to optimally manage right-sided heart failure with placement of an LVAD, and there is a lack of consensus concerning device speed (3).

Second, owing to the broadening of psychosocial criteria for VAD-DT, there has been an acknowledgment that some patients may receive a VAD who cannot or will not take care of themselves or the device (31). Accepting nonadherent patients has tremendous ramifications on patient survival and outcomes (31). For instance, improper drive line care may require device

replacement at a significant cost and increased morbidity risk (31). By highlighting the implications of accepting patients who cannot or will not adequately take care of themselves, Entwistle and colleagues underscored the importance of defining psychosocial exclusionary criteria for VAD-DT recipients. Studies examining isolated psychosocial factors contributive to poor outcomes in the context of VAD implantation are needed.

Perhaps more importantly, in light of the recent shift towards placement of the device as a destination therapy, future research should focus on older adults. Objective measures identifying frailty are needed to assist in predicting outcomes. Mixed methods approaches and qualitative interviews are necessary to advance our understanding of older adults' perceptions of quality of life with a VAD (71). For instance, in a recent study involving continuous-flow devices, many patients reported disruptions in sleep. The extent to which sleep disruptions influence emotional distress, anxiety, or depression remains to be seen (71,118). Investigation of these gaps in knowledge could enhance patients' quality of life and aid in psychological adjustment post-VAD implantation for older adults.

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