Revisiting Surrogate Consent for Ventricular Assist Device Placement

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When patients lack decision-making capacity, their surrogate decision makers (designated by an advance directive or by legally established hierarchies) make decisions on behalf of patients in keeping with patient values, goals, and preferences, an ethical concept known as “substituted judgment” [1]. Existing ethical recommendations advocate using only the patient and discourage using surrogate decision makers when initiating ventricular assist device (VAD) placement as destination therapy (DT) [2–4]. For example, in a 2006 Annals of Thoracic Surgery article, Dudzinski [5] wrote that, “patients who lack capacity to voluntarily consent should not be offered DT because they are unable to weigh benefits and burdens.” The justifications provided in these recommendations are that VAD-DT placement is a noncurative, highly preference-sensitive decision involving tradeoffs and lifestyle changes that, ideally, only patients and clinicians should weigh (ie, “first person” consent) [3, 4]. The following case highlights the limitations of existing ethical recommendations and the complexities involved in using surrogate consent for device placement. We offer ethically justified strategies for responding to these challenges.

Mr K, a 50-year-old patient with ischemic cardiomyopathy and end-stage heart failure (New York Heart Association class IIIb), was admitted to our hospital in cardiogenic shock and renal failure. He had not been previously admitted to our hospital or been seen in our outpatient clinics. Upon admission, he was intubated, on high-dose pressor support, and continuous hemodialysis. He underwent placement of an intraaortic balloon pump, resulting in minimal improvement in his clinical status. The patient lacked decision-making capacity.

Using a surrogate consent process, the heart failure team discussed with Mr K’s wife percutaneous VAD support with a TandemHeart (Cardiac Assist Inc, Pittsburgh, PA), with the goal of long-term VAD support with a HeartMate II LVAD (Thoratec, Pleasanton, CA) as bridge-to-decision. According to her, VAD support had never been discussed with her or her husband, and she was uncertain about his wishes. She remarked that her husband said he “never wanted to live on life support.” However, she acknowledged that these statements were made in the context of seeing someone “in a vegetative state.” Given the possibility of a meaningful quality of life, she concluded that her husband would want device placement.

Mr K was successfully bridged from a TandemHeart to a HeartMate II LVAD but was not considered a transplant candidate. He regained decision-making capacity a few days after LVAD placement. Mr K was discharged to an acute rehabilitation facility 15 days after LVAD placement and continued to functionally improve. Two weeks after discharge to this facility, Mr K requested device deactivation, saying he found life with an LVAD to be unacceptable. The device was deactivated 5 days later, after consultations with psychiatry, ethics, palliative care, social work, and chaplaincy, and after two patient care conferences with Mr K, his wife, and the team.

The recommendation that only first-person consent be used for VAD-DT placement assumes that the intended use of the device as DT is certain at the time of placement, an assumption no longer clinically accurate (illustrated by reports indicating that 33% of VADs are implanted as bridge-to-decision) [5]. Further, in our experience, many heart failure programs do not adhere to this recommendation for first-person consent and instead use surrogate decision making for VAD placement when patients lack decision-making capacity, regardless of initial intended use, as is done with many other life-saving interventions. Yet, as suggested by our case report, decision making for VAD placement of any type may be unusually complex in ways that have not been fully appreciated, causing us to reflect on and ultimately question the appropriateness of using surrogate consent for VAD placement in future cases.

Complexities Involved in Using Surrogate Consent for VAD placement

Surrogate decision making for VAD placement is challenging for several reasons. First, most patients are unfamiliar with VADs and likely never discussed this technology with their families [6]. Thus, a surrogate’s ability to accurately represent a patient’s wishes and goals for VAD placement may be constrained. Surrogates are widely (if not universally) used to make decisions about life-sustaining technologies for patients who lack decision-making capacity. This is because a surrogate’s interpretations of a patient’s preferences are arguably better than using alternative decision makers.
Nonetheless, surrogates are imperfect in their prediction of patients’ preferences [7, 8]. For other types of end-of-life decisions involving technologies that are presumably more familiar to patients and surrogates, such as ventilators and dialysis, surrogates predict patients’ treatment preferences with only 68% accuracy [7]. Because surrogates and patients are likely more familiar with ventilators and dialysis than they are VADs, we project similar—if not decreased—predictive abilities by surrogate decision makers for VAD placement.

Second, decisions about VAD placement may need to be made urgently, as is the case for some other life-sustaining therapies. As with Mr K, patients and their values may not be known to the tertiary facility that implants the device, and advance care planning documentation is typically available in only 5% of admissions [9]. Understandably, most surrogates may choose VAD placement even when, as in the case of Mr K, there is evidence suggesting that the patient may not want it.

An ethically supportable “rule of thumb” is that, in the face of clinical uncertainty, one should act to save life, with the knowledge that decisions can be reversed and life-saving interventions can be discontinued later [10]. When decisions need to be made quickly, a surrogate may not have the opportunity to reflect fully on the patient’s wishes or, alternatively, may choose to intervene, regardless of the patient’s preferences, until the patient regains decision-making capacity and is able to make his or her own decisions about continued interventions [10].

Third, unlike many other surgical interventions, VADs may be placed “permanently” but with accompanying disease-related and iatrogenic morbidity and loss of functional status in some cases [11]. After regaining decision-making capacity, patients may find their resulting quality of life unacceptable due to declining functional ability, worsening or new comorbidities, the burdensomeness of device maintenance, or limitations on daily activities [5, 12]. In these instances, patients may wish their surrogates’ decisions to be reversed. Even with first-person consent and a high-quality informed consent process, patients can change their minds after placement.

As our case and the discussion above suggests, the recommendation that only first-person consent be used for VAD-DT placement is clinically impractical, but using surrogate consent for VAD placement is problematic because decision-making for VAD placement can be unusually complex. In recognition of this tension, we recommend that heart failure programs use surrogate consent for VAD placement when patients lack decision-making capacity, regardless of its intended use, but with several ethical safeguards. We believe these ethical safeguards can minimize the likelihood of surrogates incorrectly evaluating patient preferences.

**Ethical Safeguards**

Heart failure programs should recognize the possibility (and ethical and legal permissibility) of deactivating devices if or when patients regain decision-making capacity and decide that their resulting quality of life is unsatisfactory. Regardless of the initial intended purpose (DT or bridge-to-transplant) and the consenter authorization (patient or surrogate) for VAD placement, continued use is justified only when its short-term goal (prolonging life) and long-term goal (preserving for the patient some interactive capacity and an acceptable quality of life) are being achieved [11]. If the resulting quality of life is unacceptable to the patient, indefinite VAD support is difficult to ethically or legally justify.

Patients with heart failure should be referred early to a center offering advanced therapies to help establish options in advance of the need to make decisions. The patient’s sentiments, goals, and options should be revisited at least annually and documented carefully [2]. This kind of advance care planning could minimize ethical problems that occur in cases like Mr K’s where VAD placement had never been discussed with the patient or his family, and the facility offering VAD placement did not know the patient or his goals.

When the need for mechanical support approaches, consent discussions should be postponed until the patient regains decision-making capacity and is able to provide first-person consent (if clinically feasible). The likelihood of deactivation requests will probably be minimized when first-person consent is provided because preference-sensitive tradeoffs and burdens would be directly weighed by the patient. Even if first-person consent is not possible in a timely manner and surrogate consent is needed, patients who lack decision-making capacity should be included in the consent process as much as possible.

If first-person consent is not possible and surrogate consent is needed, we suggest using an independent patient advocate to help surrogates explore the trade-offs, benefits, and limitations of post-VAD placement in relationship to the patient’s previous activities of daily living and lifestyle. In this way, we are encouraging a process similar to the Centers for Medicare and Medicaid’s mandated role of an Independent Donor Advocate, with the goal of enhancing informed and voluntary decision making [13].

In anticipation of patients requesting device deactivation, VAD centers should create guidelines, including resources and clinical services to be consulted, reasons for consulting each service, and the timing of the consultations. These guidelines should recommend discussion of a time-limited trial. A well-defined, time-limited trial of continued interventions may be appropriate to allow sufficient time to discuss therapeutic alternatives and outcomes (in keeping with shared decision making) and to address reversible, unmet needs that may affect deactivation decisions. The primary ethical justification for time-limited trials is to respect patient wishes for device deactivation while preventing impetuous decisions based on reversible, unmet needs or misunderstandings. The precise time frame should be determined by consensus-building efforts between and among multidisciplinary health care professionals and patients and surrogates based on explicit clinical outcomes or goals [14].
Finally, heart failure programs should enhance informed consent processes as much as possible to minimize the likelihood of surrogates incorrectly evaluating patient preferences. Toward the goal of enhancing informed consent processes, the American Heart Association’s recently published Scientific Statement emphasizes the need for development of decision aids for advanced heart failure patients [2]. Decision aids present outcomes, risks, benefits, and medical uncertainties in a clear, comprehensive, scientifically valid, and unbiased manner to help people make value-based treatment decisions. Decision aids may be presented in booklets or be in an electronic format on web sites, computer programs, or videos [15]. Reviews have concluded that decision aids increase knowledge, decrease decisional conflict, increase accurate risk perceptions, and increase matches between values and choices [16]. Surrogate decision aids would require a modified emphasis and include strategies to delineate surrogates’ and patients’ values and preferences and minimize surrogates’ conflicts of interests that could impact decisions. Such decision aids could be valuable tools for independent patient advocates.

In conclusion, The Annals of Thoracic Surgery has published 2 articles that provide helpful ethical recommendations on mechanical support, one by Dudzinski (2006) [3] and the other by Entwistle and colleagues (2011) [6]. When Dudzinski advocated that only first-person consent be used for VAD-DT placement, she encouraged revisiting surrogate consent once “transplant teams acquire more experience and as the device improves” [3]. Seven years later, we revisit surrogate consent and conclude that using surrogate consent for VAD placement can be challenging because of device-related features, yet ethically supportable with appropriate safeguards.

We build on the suggestions of Entwistle and colleagues [6] that “features of VADs may [have led] to ethical challenges that are uniquely related to this technology,” by acknowledging that decisions about initiating VAD placement are challenging and, in some cases, perhaps more complex than decisions about initiating other life-sustaining interventions. Because of this, we call for an enhanced surrogate consent process for VAD placement when patients lack decision-making capacity. This enhanced surrogate consent process incorporates several ethical safeguards to minimize the likelihood of surrogates incorrectly evaluating patient preferences. When these specific safeguards are in place, we believe surrogate consent can be ethically supportable for VAD placement, regardless of its intended use.

References