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VENTRICULAR ASSIST DEVICES AS DESTINATION THERAPY: PSYCHOSOCIAL AND ETHICAL IMPLICATIONS

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Abstract

One of the candidate evaluation challenges is determining when and how psychosocial domains influence short- and long-term destination therapy ventricular assist device (DT-VAD) outcomes. There are very few DT-VAD studies and no validated instruments to identify psychosocial risk factors. General practice is to borrow from the transplant literature, which may not be applicable to this unique device application. We question the relevance of using transplant psychosocial evaluation for patients who are candidates for DT-VAD only, particularly because these patients require a certain level of cognitive, psychological, and behavioral functioning to ensure proper long-term self-care with the VAD. We may be missing important psychological characteristics in our pre-evaluations by “borrowing” from the transplant literature, thereby underplaying significant factors that are especially relevant for DT-VAD candidates. Conversely, we may be screening out candidates who may benefit greatly from DT-VAD by using transplant criteria as part of the screening process. We use a case study to illustrate some of the challenges of weighing psychosocial risk factors in the DT-VAD population and to emphasize the need for developing distinct psychosocial assessment criteria for DT-VAD patients.

Introduction

Heart transplant provides the best quality of life for end-stage heart failure, but it is not an option for many patients seeking treatment due to limited availability of donor organs and medical and surgical contraindications.¹ Psychosocial risk factors and ethical considerations may preclude transplant eligibility if patients are unable to properly care for themselves and the transplanted organ. For these patients, ventricular assist device (VAD) placement as destination therapy (DT) is an alternative to transplant that can extend patients’ lives, improve functional capacity, and relieve symptoms of heart failure. However, the long-term benefits of DT-VAD therapy depend to a large extent on patient selection and identification of contraindications, including psychosocial risk factors.²

Patient selection for DT-VAD on the basis of psychosocial considerations (or exclusion from device placement, regardless of its intended purpose, on the basis of psychosocial contraindications) is an unusually complex process, involving high degrees of uncertainty as to whether and how to weigh psychosocial factors in patient selection processes.² Patient selection for DT-VAD candidates inherently involves careful strategizing and planning; multidisciplinary committees must delicately balance multifaceted risks and benefits, a process that may involve developing multivariable projections based on an astute sense of timing and risk profiling. One common strategy is to offer DT-VAD and then reconsider transplantation if reversible conditions—such as pulmonary hypertension, lifestyle factors, or obesity—improve with the LVAD therapy.^{3,4} Otherwise, psychosocial contraindications for DT-VAD placement are rooted in intuition and program practices, with little evidence to guide decision making.

Here, we use an actual, de-identified case to highlight nuances and complexities of psychosocial contraindications for DT-VAD placement.

Case

Mr. Smith is a born-and-raised Texan whose independent lifestyle gives new meaning to the “lone” in “Lone Star State.” Alone is the way he has spent his entire 60 years, raising himself as the youngest child of a single mother lost in alcohol and schizophrenia. Growing up, he spent time in the Army and became an electrician. Neither married nor social, he lived a life of routine—work, home to his dog, smoke a few cigarettes, and back to work.

One day, Mr. Smith started feeling dizzy and couldn’t catch his breath or walk without pain in his chest. After 10 days of thinking it would pass, he dialed 911. The paramedics took him to the community hospital, where he was told he was having a heart attack. This is the last thing he remembered for six weeks. During this time, he was transferred to a large urban hospital in cardiogenic shock with ischemic cardiomyopathy, congestive heart failure, and acute renal failure. He was managed on high-dose pressors, intra-aortic balloon pump support, and mechanical ventilation. Eventually, he stabilized in the intensive care unit with aggressive medical management, and his mental status improved. His sister, 15 years older and never emotionally close to him, suddenly became his surrogate decision maker as the heart transplantation evaluation began.

Since he was not a candidate for heart transplant due to severe peripheral artery disease, he was presented with information about DT-VAD. He deferred heavily to his sister and his physicians

and made his own decision reflexively, opting to defer to clinical judgment. Two weeks after DT-VAD placement, he developed a severe thrombus in his right lower extremity, which required an above-the-knee amputation performed with the consent of his sister. He had a prolonged recovery that required skilled nursing care and intensive physical therapy. After eight months in a nursing facility, he was discharged home with a wheelchair. Once again, he was alone, driving himself to clinic appointments and the grocery store and buying a puppy to keep him company. Mobility became difficult, and he was unable to take Coumadin consistently because of constrained mobility, moderate depression, and two episodes of delirium.

He was rehospitalized on numerous occasions. One hospitalization involved acute kidney injury related to vasculopathy, hypertension, and hyperlipidemia, likely stemming from resumption of cigarette use that began shortly after his VAD placement. He recovered and was discharged. Four months later, he called his VAD coordinator lethargic and confused after not taking his medications for the previous three days. When emergency medical services (EMS) arrived, his home was found to be in a deplorable condition, and Adult Protective Services was consulted. During this admission, he was also found to have a severe thrombus that required emergency pump replacement using surrogate consent.

Ironically, although Mr. Smith valued independence and self-reliance, he learned to form a dependent relationship on the VAD team, seeing them as his “life-line.”

Commentary

While some could argue that Mr. Smith never should have received a VAD as DT on the basis of psychosocial contraindications, it is difficult to base that argument on anything other than intuition, post-hoc rationalization, or subjective assessments. His sister was used as the primary source of information about psychosocial considerations because Mr. Smith was not in a position to provide full details and elaboration on his home life, although he was able to provide his agreement (or “assent”) to VAD placement. The ethical dilemmas surrounding the consequences of device implantation must be evaluated based on the values of the recipient as well as the caregivers.⁵ His sister’s knowledge, however, was quite limited due to her lack of familiarity with her brother and his current living situation. Mr. Smith had a social support system—at least one that could provide short-term oversight and assistance with maintenance—and the full extent of his independent living only became clear after device placement and pump replacement (and a check-in from EMS). His house became deplorable only after his mobility became limited and his caregiver had returned to her hometown. Thus, many of the psychosocial factors that made his life difficult after VAD placement either were not known before device placement or did not manifest until his circumstances changed after his device was placed. Even if the multidisciplinary team members were clairvoyant and able to draw out the psychosocial complexities of his home life in the limited amount of time with which they had to work, it would be difficult for them to determine which psychosocial factors should serve as contraindications to DT-VAD placement because of the lack of a solid evidence base to guide decision making.

There is considerable variability across transplant centers regarding psychosocial contraindications to DT-VAD placement, likely because there is no evidence base to support standardized, universal guidelines to inform patient selection decisions. There

are no validated instruments available to conduct psychosocial assessments for DT-VAD-only candidates because there are no consistent data to ground such an instrument. While several psychosocial instruments for transplant evaluation are emerging, including the *Psychosocial Assessment of Candidates for Transplantation* (PACT), the modified PACT,⁶ and the Stanford Integrated *Psychosocial Assessment for Transplantation* (SIPAT), (Figure 1),⁷ none of these transplant-specific instruments have been validated for DT-VAD.⁶ The reason for this lag may be because up until 2002, the VAD was used only as a bridge to transplantation.⁹ Until then, social workers and psychiatrists used the same psychosocial screening process for VAD candidates and transplant candidates, with the logic being that VAD candidates would progress to transplant and could therefore be evaluated using the same criteria as transplant candidates.⁸ This logic cannot be extended to DT-VAD-only candidates.

Aside from a lack of standardized instruments, there are only a handful of studies to guide selection decisions that have examined psychosocial factors and links to post-VAD placement comorbidity and mortality, and these studies have been unable to identify a single psychosocial predictor related to VAD outcomes. This suggests that psychosocial risk factors are multifaceted and may emerge as interrelated rather than discrete factors affecting survival outcomes.

There are some elements of transplant candidacy that will likely be found, once the destination VAD psychosocial studies have been contributed to the discipline’s body of knowledge, to parallel the transplant evaluation. The strongest predictor of transplant outcomes, psychosocial support (i.e. family, spouse, and committed friends) will likely also be a strong predictor of VAD outcomes. Indeed, the level of care required for the VAD patient following discharge is at least as intense as for the transplant patient. Lifestyle factors such as adequate housing, willingness to build and maintain personal health through diet, fitness, and follow-up appointments will likely remain relevant. Substance abuse may be less problematic, but it will be challenging to learn its extent. Similarly, the impact of psychiatric and behavioral disorders may or may not predict DT-VAD outcomes, including quality of life. Intuitively it seems likely that, for example, untreated major depressive disorder would predict a poor outcome. Maltby et al (2014) identified device understanding as a significant predictor of outcomes.⁶ Based on the early findings of a large ongoing study in Houston, Texas, factors that seem to be very relevant to DT-VAD outcomes are identifying symptoms of mental health disorders that are likely to affect ability for self-care, such as depression, anxiety, and cognitive impairment. It may also be very important to evaluate the effect of caregivers on patients’ ability and willingness to care for themselves or engage in assisted care.

Where evidence is weak or nonexistent, it can be ethically problematic to employ selection criteria for DT-VAD that is based on intuition, assumption, or eligibility for significantly different treatments like transplant. We question the relevance of using transplant psychosocial evaluation for patients who are candidates for DT-VAD only, particularly because these patients require a certain level of cognitive, psychological, and behavioral functioning to ensure proper long-term self-care with the VAD. We may be missing important psychological characteristics in our pre-evaluations by “borrowing” from the transplant literature, thus minimizing significant factors that are especially relevant for DT-VAD candidates. Conversely, we may be screening out candidates who may benefit greatly from DT-VAD by using transplant criteria

PSYCHOSOCIAL DOMAINS MEASURED BY THE SIPAT

(A) PATIENT'S READINESS LEVEL and ILLNESS MANAGEMENT (5 items)

- Item 1: Knowledge and understanding of medical illness process (that caused specific organ failure)
- Item 2: Knowledge and understanding of the process of transplantation
- Item 3: Willingness/desire for treatment (transplant)
- Item 4: History of treatment adherence/compliance (pertinent to medical issues)
- Item 5: Lifestyle factors (including diet, exercise, fluid restrictions, and habits according to organ system)

(B) SOCIAL SUPPORT SYSTEM LEVEL OF READINESS (3 items)

- Item 6: Availability of social support system
- Item 7: Functionality of social support system
- Item 8: Appropriateness of physical living space and environment

(C) PSYCHOLOGICAL STABILITY AND PSYCHOPATHOLOGY (5 items)

- Item 9: Presence of psychopathology (other than personality disorders and organic psychopathology)
- Item 10: History of organic psychopathology or neurocognitive impairment (i.e., illness or medication-induced psychopathology)
- Item 11: Influence of personality traits vs. disorder
- Item 12: Effect of truthfulness vs. deceptive behavior
- Item 13: Overall risk for psychopathology

(D) LIFESTYLE AND EFFECT OF SUBSTANCE USE (5 items)

- Item 14: Alcohol use, abuse, and dependence
- Item 15: Alcohol abuse - risk for recidivism
- Item 16: Illicit substance, abuse and dependence
- Item 17: Illicit substance abuse - risk for recidivism
- Item 18: Nicotine use, abuse, and dependence

The Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT): A New Tool for the Psychosocial Evaluation of Pre-Transplant Candidates. Maldonado, José R. et al. *Psychosomatics*, Volume 53, Issue 2, 123 - 132

as part of the screening process. Some transplant centers “soften” transplant evaluation criteria for DT-VAD-only candidates, but it is difficult to determine which criteria can be softened and to what extent this can occur in the absence of more knowledge about psychosocial predictors.

Conclusion

Life for VAD patients as a bridge until transplant is likely different from patients who know the device is their last treatment option. Even so, it is difficult to know how their lives are different, which factors account for this difference, which psychosocial factors should be assessed before device placement, and to what extent these factors should be considered. In short, our understanding of psychosocial considerations and contraindications for VAD placement is still evolving.

Until psychosocial contraindications are developed and refined according to evidence-based practices, there will be inconsistent patient selection processes that will lead to significant variation in quality of life and satisfaction with outcomes. This ambiguity is well reflected in Mr. Smith's comment that, “Well, [life on a VAD is] not that bad, but it's not that good, either. You look at it either way. It's either good, bad, or in between.”

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