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ETHICAL DILEMMAS SURROUNDING THE USE OF VENTRICULAR ASSIST DEVICES IN SUPPORTING PATIENTS WITH END-STAGE ORGAN DYSFUNCTION

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Abstract

Successful practice of cardiovascular medicine requires familiarity with the complex ethical issues that accompany therapeutic innovation and diffusion. Even as technologies transition from experimental to standard care, challenges remain. Mechanical circulatory support devices, for instance, are increasingly conceptualized as conventional therapies. Despite this, or perhaps because of it, the ethical issues surrounding the use of these devices in patients with end-stage organ dysfunction are becoming increasingly apparent. In this paper, we provide an introduction to ethical considerations related to the use of ventricular assist devices (VADs) in end-stage organ failure, focusing on three stages or decision points: initiation, continued use, and deactivation. Our goal is not to exhaustively resolve these dilemmas but to illustrate how ethical considerations relate to decision making.

Introduction

The practice of cardiovascular medicine requires that physicians be familiar with the complex ethical issues surrounding therapeutic innovation and diffusion. For example, mechanical circulatory support devices are increasingly conceptualized as conventional therapies, yet the use of these devices in patients with end-stage organ failure is raising serious ethical concerns. This paper introduces some ethical considerations regarding the use of VADs in patients with end-stage organ dysfunction and focuses on three decision points: initiation, continued use, and deactivation. Our goal is to illustrate how ethical considerations relate to decision making and offer an agenda for future research.

Stage 1: Initiation of the Device

Mr. P is a 59-year-old man whose medical history includes idiopathic dilated cardiomyopathy. He is a farmer by occupation and has been married for 33 years. Mr. P suffered an acute myocardial infarction and subsequently went into cardiogenic shock. He was intubated, underwent placement of an intra-aortic balloon pump, and was administered high doses of pressors at a community hospital. Following transfer to a tertiary hospital, it is determined that Mr. P is a candidate for a VAD as a bridge to decision. He remains incapacitated and inotrope-dependent.

In discussions with the team, Mr. P's wife is equivocal. She remarks that her husband was a "loner" who valued his independence. While she acknowledges that she would like her husband to live, she laments that he often told her he never wanted to live on life support. She articulates her understanding that with implantation "he may live," and without it "he will certainly die." For this reason, she feels she has "no choice."

Commentary

Estimates from 2010 indicate there are approximately 5.8 million heart failure patients in the United States, with an incidence of 670,000 new diagnoses made each year.[1] The number of patients awaiting heart transplantation continues to significantly outpace the supply, resulting in longer transplant waiting times and increasing mortality among those on the waitlist. As a result, mechanical circulatory support devices are now used both as interim measures for patients awaiting transplantation and as permanent, end-stage therapy (destination therapy) for a larger population of patients.[2-4]

Despite the growth of VAD programs and the development of educational tools, most patients and families are not familiar with these devices. Like Mr. P's wife, they are in the uncomfortable position of having to make a decision about initiation in accordance with the patient's values (in keeping with the preferred "substituted judgment" standard for surrogate decision making), with little time and much clinical and ethical uncertainty. For this reason, ethicists are increasingly called upon to help with these kinds of cases.[5] Here, we provide some ethical considerations used in analyzing such a case. This approach to an ethical decision — the synthesis and weighing of a variety of concerns and ethical appeals — is analogous to the systematic analysis used for clinical decision making.[6]

One way to approach this case would be to consider the consequences of the available options.[7, 8] If the team were not to implant the device, the consequence to the patient would almost certainly be death. This consequence is irreversible and at first glance may seem the worst that could befall the patient. It is relevant that, unlike interventions that typically lead to complete recovery, VAD implantation may only shift end-of-life trajectories.[9] In many cases, the VAD offers patients the prospect of some improvement in functioning for a period of time. In the best-case scenario, it results in an appreciable improvement in quality of life until transplantation, with significant recovery thereafter.[3, 10-14] However, realization of this outcome rests on many contingencies and inevitably involves burdens.[9, 15]

It is important to recognize that consequences must be evaluated based on the values of the individuals affected.[7] From the fact scenario, we know that Mr. P has a strong aversion to dependency in general and to dependence on life support in particular. Some people perceive that any prolongation of life, even at a low level of functioning, is beneficial;[7] Mr. P may not be one of them. What we do not know is how Mr. P would evaluate various outcomes and trade-offs. Would the mere possibility of recovery to his baseline be worth an extended hospitalization involving dependence on many forms of life support? What activities must he be able to perform

in order to derive satisfaction from life? Conversations with Mr. P's wife and other family members may assist in providing a more comprehensive picture of Mr. P and his values. In this way, the appeal to consequences is related to the appeal to rights. While we may believe that Mr. P has a right to aid in a life-threatening situation, this right is waivable, and he also has a right to refuse unwanted medical intervention.[7, 8] In cases where the patient is unable to speak for himself, we must rely on the accounts of others to assess whether his fundamental values would support consent or refusal.[6, 7]

The appeal to consequences should also be considered from the perspective of Mr. P's wife. The caregivers of VAD recipients may experience significant burdens from VAD implantation, particularly as destination therapy.[9, 15, 16] In addition, a spouse's perspective may be entitled to consideration under the appeal to rights. In many cases, the spouse, as the person with closest formal relationship to the patient, will be the legally authorized surrogate decision maker. In ethical terms, the weight of the spouse's judgment is increased if there is evidence that the spouse and patient had a close relationship in actuality, as suggested by a 33-year marriage.

Other ethical appeals, such as the appeal to virtues like integrity and compassion, should be assessed.[8] The medical team might argue that failing to provide a therapy they perceive as conventional would amount to substandard care, violating their sense of professional integrity. This argument usually proceeds as follows: We accepted this patient and, having done so, we have a moral obligation to treat him to the greatest extent possible. This claim should be viewed with some caution. To suggest that there is a moral obligation to treat a patient to the exclusion of other considerations presumes that the patient actually wants that treatment, which is unclear from the facts in this case.

Stage 2: Continued Use of the Device

After exploring Mr. P's values with his wife and other family members, the ethicist concludes there is genuine uncertainty about whether he would consider a VAD "life support." At the same time, her conversations provide clear, consistent guidance concerning outcomes (essential to Mr. P: the ability to return to his farm, handle most activities of daily living himself, help with some farm chores, and fish) and trade-offs (unacceptable to Mr. P: intensive care lasting more than a few weeks). Taking this into account, Mr. P's wife and the team decide to proceed with implantation but to consider this a time-limited trial of therapy.

Commentary

The most complex ethical and clinical dimension of this case is the uncertainty: the patient's perspective is uncertain, the intended use of the device (bridge to transplantation or destination therapy) is uncertain, and the outcome is uncertain. The team and the patient's wife do not want to prematurely forego treatments that might help, and delay increases the risks of infection and death secondary to irreversible renal and hepatic failure.[13, 17] On the other hand, they want to avoid indefinite exposure to treatment that may become disproportionately burdensome relative to benefits.[6, 18, 19]

This type of scenario justifies a time-limited trial (TLT), in which the clinician and patient or family agree to try a specific therapy over a defined period and then determine if the patient is improving or deteriorating. The benefit of a TLT is that it is designed for cases with considerable uncertainty and profound consequences, such as this one. A wise use of a TLT is one in which, as here, the clinicians clarify the patient's goals and priorities to the greatest extent possible.[19] Objective markers of improvement or deterioration should be determined by the medical team and provided to the patient's wife (and the patient, if and when he is able to participate). The timeframe for reevaluation should be determined in large part by the patient's condition and the patient's or family's needs.[19] If clinicians use a TLT to simply "buy time" or "get the family to agree" with no parameters or defined objectives, the TLT is not serving its purpose of establishing mutual expectations and structuring dialogue. It is important to recognize that a TLT is not a binding contract and should not be used as such.[19] For example, if the patient regains capacity postimplantation and requests deactivation of the device, the TLT should not be used to postpone deactivation decision making or preclude its occurrence.

Stage 3: Deactivation of the Device

Four months postimplantation, Mr. P is regaining modest functional and cognitive abilities. However, the course has been arduous and, as he states, "painful." His health after implantation was compromised by infection, sepsis, and renal failure. He spent several months in the hospital and is now in a skilled nursing facility. He is deconditioned, walks little, and eats poorly. He needs assistance with most of his daily activities, including hygiene. At this time, transplantation is not anticipated but remains a theoretical possibility.[20] Mr. P adamantly and consistently requests deactivation of the device and other aggressive life-sustaining measures (e.g., hemodialysis). Citing his continued improvement and cognitive abilities, some members of the medical team argue that deactivation of the device would be akin to active euthanasia.

Commentary

There are three practical ethical questions that must be answered in any clinical decision involving the deactivation of mechanical circulatory support devices: (1) Is the act of deactivation of this particular device morally permissible? (2) If deactivation is morally permissible, are there countervailing ethical considerations that suggest that it could not or should not be performed in this particular case? (3) If it is ethically acceptable in this case, what should the process entail and how should it be properly implemented?

Concerning the first question, a consensus has developed within the transplant ethics community that deactivation of a VAD is appropriate. The grounds for ethical permissibility are usually framed in terms of the well-established ethical and legal consensus that competent, informed patients (or their surrogates, acting in accordance with substituted judgment) have the right to request the withdrawal of any life-sustaining intervention they perceive as unduly burdensome relative to benefits.[6, 15, 18, 21-25]

It is important to note that although an ethical consensus is taking shape, some ethicists remain opposed to device deactivation in many circumstances.[20, 26] It is also not uncommon for clinicians to object to deactivation of a VAD. Usually, the argument proceeds as follows: the VAD is a long-term, continuous, constitutive (i.e., it takes over a function that the body can no longer perform) life-sustaining intervention.[21, 23, 27] Deactivation of it may result in an immediate or nearly immediate death. However, many long-term, continuous, constitutive life-sustaining interventions (e.g., mechanical ventilation, hemodialysis, artificial nutrition and hydration) are withdrawn routinely.[23] The immediacy of the death, while psychologically troublesome, is not typically considered morally relevant. Others argue that, as (primarily) an internal device, the VAD becomes part of the "self." Yet a percutaneous endoscopic gastrostomy and an implantable cardioverter-defibrillator are internal, and few would consider

such regulative devices part of the "self." All of these devices are distinct from the body.[23, 24, 28, 29]

The argument that device deactivation is comparable to active euthanasia requires discussion. In active euthanasia, the proximate cause of the patient's death is the introduction of a new pathology for the purpose of terminating the patient's life. In cases of device deactivation, the patient dies of their underlying heart disease, in much the same manner as a patient dies of lung dysfunction when mechanical ventilation is withdrawn. A new pathology (e.g., surgical wound) is not introduced, which would be grounds for questioning the ethical legitimacy of device deactivation.[23]

As to the second question, are there countervailing ethical considerations suggesting that deactivation could not or should not be performed in this particular case? Fluctuating capacity, ICU psychosis, and inconsistency in stated preferences would certainly be grounds for questioning the authenticity of the patient's desire to deactivate the VAD, but those elements are not present in this case. Does depression affect one's ability to make informed decisions? Although some have argued that depression may be a rational response to one's circumstances and, as such, does not interfere with informed decision making,[30, 31] we would not counsel indifference to symptoms of depression. Rather, we believe a thorough psychiatric evaluation, performed at different times, can assist in determining whether the patient has unmet needs and in assessing the existence and degree of depression, informing an overall judgment concerning decisional capacity.

This leads to our third question. Assuming VAD deactivation is considered ethically permissible and there are no countervailing ethical considerations that suggest that deactivation could not or should not be performed, special emphasis should be placed on the deactivation 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.[32] Further, the integration of palliative medicine relieves members of the team who conscientiously object to the deactivation from actually having to perform it.

Implications for Future Research

This paper has highlighted major ethical dilemmas for three stages of VAD use: initiation, continued use, and deactivation. In doing so, it becomes apparent that many questions and issues remain unresolved. What we provide below is an outline of questions and issues that could serve as the basis for future research.

(1) An initial question is whether advance-care planning (ACP) can realistically be done in cases such as Mr. P's, involving an unexpected heart attack followed by a precipitous decline. We think this may be possible. Since Mr. P had cardiomyopathy, he might have been under the care of a cardiologist prior to his heart attack. To facilitate end-of-life decision making, should cardiologists discuss the possibility of VAD implantation and/or transplant prior to needing these interventions with every patient? How can the cardiologist convey these discussions and preferences in a way that could be readily understood by clinicians in an outside facility?

(2) A second and related question concerns the kinds of advance directives (ADs) that should be used to guide and document ACP. Advance directives have been proposed as a tool to facilitate ACP, yet it is easy to see how they can fail to achieve this goal in the context of mechanical circulatory support.[33, 34] For example, one of the authors of this paper met with a prospective VAD patient prior to implantation. She noticed a living will on his chart with the words "no dialysis" and "no prolonged intubation" or "other life support measures." When she asked the patient about this, he reiterated his preferences and said he conceptualized VAD placement differently than dialysis and other forms of life-sustaining treatment but was unwilling or unable to articulate a general basis for this distinction. By focusing on various realistic scenarios that can adversely affect quality of life, such as debilitative comorbid conditions and complications due to VAD-associated factors (e.g., chronic renal failure, stroke, refractory infections), the author was able to get a better sense of what the patient found unacceptable.[23, 25]

(3) Finally, what kind of data would improve ACP? To strengthen ACP conversations, we need more information regarding patients' perceptions on quality of life following VAD implantation. What literature exists in this area has generally focused on transplantation or first-generation VADs.[35-39] It would be equally important for the transplant ethics community to have a better understanding of how often patients request withdrawal of VAD support. In one institution, 21% of patients or their surrogates requested withdrawal of support.[23] These findings are similar to another smaller study.[40] Yet it is still unclear when the requests were made, what reasons were provided, and how the clinicians responded. Only as we more fully work out answers to these questions will we make serious headway towards preventing or mitigating many of the ethical challenges outlined in this paper.

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