The Ethics of Mechanical Support: The Need for New Guidelines

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Each generation of physicians has been faced with new therapies or technologies that have dramatically changed the way medicine is practiced. Usually, mainstream adoption of such medical advances has been an uncomplicated process. Occasionally, these advances require a thorough reexamination of the way in which we approach medical care because they represent such a change in patient management that our conventional assumptions no longer apply. New-generation ventricular assist devices (VADs) represent such a technology. Although VADs have been used clinically for nearly 50 years, they have only recently been adopted so widely that they present today’s clinicians with ethical challenges on a large scale. In some cases, these ethical issues arise from patient noncompliance or other disruptive behaviors. Similar issues have arisen in organ transplantation, but the scarcity of donor organs has led to the adoption of allocation guidelines that have largely mitigated these issues.

In the 1990s, VADs were used primarily in patients awaiting transplantation who needed interim support until a suitable organ could be identified. For the most part, they were implanted only in transplant centers as a bridge to transplantation (BTT), and VAD candidates were judged by the same criteria used to evaluate patients for transplantation. Thus, if patients were not candidates for transplantation, they were not candidates for VAD insertion. The decision to exclude certain candidates from VAD therapy was made easier because organs for transplantation are a scarce resource, and this scarcity was widely believed to justify selective allocation of resources. Guidelines and protocols for patient selection and organ allocation were established, making psychosocial considerations, such as noncompliance and antisocial behavior, part of the selection process. In this way, many of the potential ethical issues surrounding organ transplantation have been avoided. To address the growing ethical problems generated by VAD implantation, similar guidelines are necessary.

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Destination Therapy and New Ethical Issues

With the publication of the results of the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial in 2001 [1], destination therapy (DT) became a clinical reality. Although most VAD implantations still occurred in transplant centers, destination therapy allowed the VAD teams to relax the strict behavioral and social criteria used to assess transplant candidates. Candidates were still thoroughly vetted, but VADs were sometimes seen as reasonable when rejection for transplantation was due to psychosocial issues of moderate severity. Despite this change, new ethical concerns in VAD patients were relatively few, because the first-generation device approved for DT provided only modest gains in survival, and pump infection and pump failure rates were relatively high, limiting longevity expectations of VAD patients. Moreover, many patients who suffered severe and life-threatening complications of VADs were not candidates for aggressive therapy and pump replacement owing to their underlying conditions and the relatively poor results seen with emergent pump replacement. Issues regarding end-of-life decisions arose and have been addressed in the literature [2].

In our experience, serious ethical issues appeared more frequently after the approval for long-term use of new-generation VADs, and this is related to several factors. Unlike donor hearts, these devices are not a scarce resource, and restrictions on VAD candidacy based on psychosocial issues of mild to moderate significance alone are less well established. Patients who receive a new-generation VAD have a very good chance of long-term survival, as infection and major complication rates have declined significantly [3]. These successes have resulted in increased acceptance of VADs by both patients and physicians, so the number of implants has grown steadily. Additionally, the number of new VAD centers has grown, including some hospitals without transplant expertise and experience that can now implant VADs rather than referring the patient to an experienced center.

Properly used, a VAD can be immediately life saving when all other therapies have failed. However, several features of VADs may lead to ethical challenges that are uniquely related to this technology. To the public, VADs are a relative unknown. We believe that many patients facing imminent death opt for VAD therapy without full realization of the effects that this technology will have on...
their daily lives, despite attempts at education by the VAD team. Moreover, VADs are a costly technology. While costs and reimbursement vary between VAD brands and hospitals, the average Medicare payment to hospitals for an implantable VAD in 2009 was more than $180,000 [4]. Complications such as infection can increase the cost of implantation by twofold or more [5]. The cost of unsuccessful VAD therapy is particularly high when compared with that of therapies, such as hemodialysis, that are less dependent upon new technology. An early death of a noncompliant hemodialysis patient is less costly to society than is the VAD patient who fails to comply with proper treatment and dies of preventable major complications months after implantation. In the latter case, time of survival is short and the cost of the device implantation so high that the cost per year of life saved is very large.

The intended use of the VAD has ethical implications as well. There is a large gray area between BTT and DT, sometimes referred to “bridge to decision” for patients whose suitability for transplantation is uncertain. In our experience, approximately 40% of VAD patients fall somewhere in this gray area, and similar numbers are seen in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) with 42% undergoing implantation as a “bridge to candidacy” [6]. Because bridge to decision does not qualify for Medicare reimbursement, patients are labeled as either BTT or DT with the understanding that the implanting decision may not be final. At 18 months after implantation, 17% of DT patients have undergone transplantation after correction of the problem that contraindicated transplantation [7]. Conversely, some patients implanted under the BTT indication never become transplant candidates. Even though there are strict criteria for BTT and DT, the reality that it is difficult to accurately predict an individual patient’s clinical course can lead to perceived inconsistencies of care from the patient’s point of view, as it may not be readily apparent to a nonclinician why some patients are offered a transplant while other, seemingly similar, patients are not.

The prerequisites for patient compliance with the VAD treatment protocol after discharge is similar to that of a patient who has undergone organ transplantation, and the ultimate outcome for noncompliance (major complication or death) is similar in both scenarios. There are few areas in medicine in which rigorous compliance has as much immediate impact upon the patient’s survival or the cost of further therapy. Improper driveline care for a short period is more likely to lead to a devastating complication than is stopping medications for hypertension or hyperlipidemia. The former may require device replacement at great cost and morbidity risk whereas the latter may require only reinstitution of medical therapy. Even for patients on dialysis, the consequences of noncompliance can usually be remedied with emergent hemodialysis at a fraction of the cost of VAD replacement.

Many of the poor outcomes in patients discharged on a VAD are directly related to patient noncompliance, giving rise to many ethical issues. If a VAD patient stops taking blood thinners and a thrombosis episode requires pump replacement, the patient can often be rescued. If it happens a second, third, or fourth time, how will we know when no more effort and cost should be expended on a patient who has shown insufficient personal responsibility? Are we obligated to replace pumps indefinitely? Can the patient, third-party payer, or society afford that financial burden? If a patient has been ignoring driveline care and a low-grade driveline infection to the point that the entire VAD becomes infected, are we obligated to replace the pump and treat the patient with long-term antibiotics even though we know that the chance of long-term success is low and that the cost of this heroic therapy is very high? If a DT patient who is a marginal transplant candidate suffers a complication of the device that can only be remedied with transplantation, should that patient be listed and transplanted? Currently, patients and their families expect that we will do everything to keep them alive regardless of the cost and effort because the technology to do so exists, the so-called “technological imperative” [8]. This belief may remove some of the incentive for the patient to be a full partner in the medical care process. By formally placing some responsibility for good outcome on the patient and having the backing of our professional societies in doing so, we may be able to reduce the impact of ethical issues surrounding VAD implantation.

A further problem that clouds the ethical landscape is limitation of patients’ choices of physicians, and conversely, lack of alternative centers for physicians to refer their patients when there is a poor physician-patient relationship. The VADs are implanted at relatively few hospitals, with only 99 centers in 35 states approved by Medicare for DT [9]. Most centers are located in large metropolitan areas, and patients in rural areas may be hundreds of miles from the nearest center [10]. If patients feel that they are not being fairly treated, they have few options as VAD care is so specialized, and they are completely dependent upon the providers at their VAD institution. Not only must they utilize that center for VAD care, they are often committed to that hospital for all of their inpatient needs. When patient noncompliance is an issue, the physician has limited options for transferring the care of the patient because there is often no easily accessible alternative for the VAD patient to receive adequate care. Conversely, when a patient at one center demonstrates significant noncompliance, it is unrealistic to expect the providers at an alternative center to want to take over the care of this patient, knowing that the situation may end badly if the noncompliance persists.

Finally, unlike most other areas of medicine, there is a strong interdependence between a patient and the VAD team. 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. For all practical purposes, this relationship lasts for the duration of the patient’s life, and equal participation by both parties is required for success. Patients can always choose to sever ties with the VAD center, but at high personal cost if another center is not available for any of several reasons.

The VAD team physicians, conversely, may feel constrained from leaving the relationship out of fear that
ending the relationship might be construed as abandonment of the patient. Even though existing ethics policy clearly states the conditions under which a physician can unilaterally terminate a relationship with a patient [11], the VAD situation is relatively unusual in that the patient may not be able to find an alternative and is dependent upon the expertise of a VAD center for survival. Poor interpersonal chemistry between a patient and VAD team can lead to conflict and stress. Unfairly, perhaps, much of this stress is shouldered not by the VAD physicians but by the VAD coordinators and other staff who have to deal with the patients and their families at a more intimate level. In our experience, there seems to be a high rate of turnover among VAD coordinators, and the stress of this relationship is at least partly to blame. It takes much time and effort to adequately train a VAD coordinator and other support staff, so it seems prudent to take this into account when establishing the ground rules for the care of the VAD patient.

If a VAD patient chooses to leave the primary care center and to seek care at an alternative VAD center, the second center has the freedom of choice to accept the patient or not under long-standing law and ethics policy, with an important exception. If the patient presents with a clinical emergency, the center is obligated, under the Emergency Medical Treatment and Active Labor Act, to stabilize the patient before discharge or transfer to the primary care center or elsewhere [12]. However, once the emergency has been stabilized, the issue of which center is responsible for the care of the patient’s long-term VAD needs may be problematic, especially in the patient who has demonstrated repeated episodes of noncompliance. Thus, even if a center has successfully separated itself from a VAD patient, it is still obligated to provide emergency care to stabilize the patient, nullifying the ability of the VAD center to effectively terminate this relationship.

Conclusions
As the use of VADs becomes increasingly prevalent, ethical issues are likely to arise at an increasing rate, as will their social and legal ramifications. In a world where patients may be kept alive by artificial means well beyond the life expectancy associated with their disease processes if untreated, the medical community needs to be prepared to deal with the broad implications of such technologies. Standards for the ethical use of VADs are needed for the protection of patients, VAD centers, physicians, and countless others who are affected by this technology. While credentialing of a VAD center requires that mechanisms are in place to mitigate the ethical issues that may arise, credentialing bodies such as the Joint Commission have offered little guidance for accomplishing this goal. To ensure success in establishing standards that will be broadly if not universally observed, input from all involved parties is needed—cardiac surgeons, heart failure cardiologists, nurses, patients, healthcare policy experts, legal experts, mental health professionals, and ethical and religious representatives—and it will take the weight of our national and international professional societies behind such guidelines to make them authoritative. A set of minimum standards can be adopted by which all VAD patients, treating physicians, and VAD centers can expect fair treatment. Equally importantly, medical professionals can be assured that, by making our patients equal partners in their care, there might be less need to fear medicolegal action for poor outcomes related to patient noncompliance.

These considerations lead us to propose a set of recommendations that could be a first step toward developing a uniform VAD usage policy that will limit ethical dilemmas arising from this technology.

Recommendations
A VAD center should develop and implement a written policy regarding the use of VADs. The policy should contain a detailed description of patient selection criteria, as determined by the center, as well as a statement of center and patient obligations. Those obligations should be made explicit in a mutual agreement form that includes description of the services the center will provide, the expectations for patient adherence, including family support and the implications of noncompliant behavior, the patient’s options for redress, and the conditions under which support could be withdrawn. This agreement should be presented and discussed with every patient before VAD implantation, whenever possible, or before discharge from the hospital.

A VAD center, at its discretion, can use the same or similar psychosocial criteria for VAD implantation as it does for transplantation. If a patient presents with a major VAD complication and does not meet the center’s criteria for VAD implantation or transplantation, then the center should not be obligated to provide emergency device exchange. In this situation, the center would be obligated only to provide emergency support and stabilization with conventional therapies such as pharmacologic or balloon pump support.

A VAD center may unilaterally sever its therapeutic relationship with a VAD patient who demonstrates persistent noncompliance. In doing so, it should give the patient adequate notice of its intent, generally about a month in advance, and provide emergency services during that month. The center may offer to help the patient find another center that is willing to treat the patient.

A VAD center should not offer transplantation to a VAD patient who is at risk of death or disability due to a complication of an implanted VAD if the patient does not meet the center’s transplant selection criteria.

A VAD center that receives a request from another medical center or physician to assume the care of a VAD patient in transfer is free to accept or refuse the transfer of care. If the center accepts the patient, physicians are not obligated to follow the treatment plan developed at the other center, but should develop their own plan based on their center’s VAD policy and their own clinical judgment.
A patient may seek care at a second VAD center, but that center is not obligated to accept the patient. In an emergency, stabilization procedures are legally required by the second VAD center before discharge or transfer to the primary center. Emergency care can be limited to conventional therapies if the patient does not meet the center’s criteria for VAD implantation. The provision of emergency care by a VAD center does not obligate the VAD center to assume further care of the patient following discharge or transfer to the primary center.

References