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The Ethics of Mechanical Support: The Need for New Guidelines

John W. C. Entwistle, M.D., Ph.D.¹, Robert M. Sade, M.D.², and Ralph J. Petrucci, Ed.D.³

¹Department of Cardiothoracic Surgery, Drexel University College of Medicine, 245 N. 15th St., Philadelphia, PA 19102

²Department of Surgery, Medical University of South Carolina, 25 Courtenay St., Charleston, SC 29425

³Department of Psychiatry, Drexel University College of Medicine, 245 N. 15th St., Philadelphia, PA 19102

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Introduction

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 that 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. VADs have been used in humans for nearly 50 years, but they have only recently seen widespread adoption to the point that they present today's clinicians with ethical challenges on a large scale. In many cases, these issues arise from patient non-compliance or other disruptive behaviors. Similar issues have been seen with organ transplantation, but guidelines and protocols for patient selection and organ allocation have been established, making psychosocial considerations, such as non-compliance and anti-social behavior, part of the selection process. In this way, the ethical issues surrounding organ transplantation have been mitigated, if not solved. To address the growing ethical problems generated by VAD implantation, similar guidelines are necessary.

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 of the linkage of VADs to organs for transplantation, which are a scarce resource, was widely believed to justify limiting their use to situations in which the chance of success was good.

Destination Therapy and New Ethical Issues

With the publication of the results of the REMATCH Trial in 2001, destination therapy (DT) became a clinical reality. While most VAD implantations still occurred in transplant centers, patients were not necessarily held to the same behavioral and social criteria as transplant candidates. Despite this change, new ethical concerns were relatively few for many reasons. The first generation device approved for DT provided only modest gains in survival, and pump infection and pump failure rates were relatively high, limiting the life expectancy of VAD patients. Moreover, many patients who suffered severe and life-threatening complications of VADs were not candidates for aggressive therapy and pump replacement due to their underlying condition and the relatively poor results seen with emergent pump replacement.

Serious ethical issues appeared after the approval for long-term use of new-generation VADs. Several factors are responsible for the increase in ethical challenges. Unlike donor hearts, these devices are not a scarce resource. Patients who receive a new-generation VAD have a very good chance of long-term survival, as infection and major complication rates have declined to low levels. These successes have resulted in their increased acceptance by both patients and physicians, so the numbers of implants has grown steadily. This has resulted in hospitals without transplant expertise and experience implanting VADs rather than referring the patient to an experienced center.

Several features of VADs may lead to ethical challenges that are particularly related to this technology. Properly used, a VAD can be immediately life saving when all other therapies have failed. However, an untoward event can be rapidly fatal. Similar issues are present with organ transplantation, but the scarcity of the resource has led to the development of guidelines for candidacy and a nationally managed waiting list, which have largely addressed ethical concerns.

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 over \$180,000.[1] Unlike some other technologies, such as hemodialysis, the cost of VAD implantation is largely focused on the immediate time around VAD implantation. Thus, if a hemodialysis patient fails to treat his dialysis access or catheter properly and revision or replacement is required, the cost to society is less than the VAD patient who fails to comply with proper treatment and dies shortly after major complications ensue. In the latter case, the cost per year of life saved is astronomical.

Clinicians are quick to acknowledge that there is a large gray area between BTT and DT when it comes to an individual patient. While devices are approved for specific indications and Medicare has strict criteria for reimbursement for DT therapy, a significant percentage of DT patients ultimately undergo transplantation after correction of the problem that contraindicated transplantation. Conversely, many patients implanted under the BTT indication never become transplant candidates. This lack of strict definitions of BTT and DT can lead to perceived inconsistencies of care from the patient's point of view, as it may not be readily apparent to a non-clinician why some patients are offered a transplant while other seemingly similar patients are not.

The prerequisites for patient compliance and responsiveness with the VAD treatment protocol following discharge is probably the same as the need for compliance in a patient who has undergone organ transplantation, and the ultimate outcome for non-compliance (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 survival or cost of further therapy. Improper driveline care is more likely to lead to a devastating complication

than stopping all medications for diabetes, hypertension or hyperlipidemia. The former may require device replacement at great cost and morbidity risk while the latter may be treated merely with reinstitution of medical therapy. Even with patients on dialysis, the consequences of non-compliance can usually be remedied with emergent hemodialysis at a fraction of the cost of VAD replacement.

Many of the poor outcomes following VAD implantation are directly related to patient non-compliance, giving rise to many ethical issues. If a VAD patient quits taking blood thinners and a thrombosis episode requires pump replacement, the patient can often be rescued, but when 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 we 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? 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.[2] 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 issue that complicates 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. VADs are implanted at relatively few hospitals, and most patients will have access to only one or two centers, if any. If patients feel that they are not being fairly treated, they have few options since VAD care is so specialized, and they are completely dependent upon the providers at their VAD institutions. 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 non-compliance is an issue, the physician has limited options for transferring the patient because there is usually no easily accessible center for the patient to receive adequate care for their life-saving device. On a related note, when a patient at one center demonstrates significant non-compliance, it is unrealistic to expect the providers at another center to want to take over the care of this patient, knowing that the situation may end badly if the non-compliance persists and the patient requires emergency care for a preventable problem.

Finally, unlike most other areas of medicine, the relationship between a patient and the VAD team is not unlike a marriage. 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. As in marriage, this relationship is intended to last for the duration of the patient's life, and equal participation by both parties is required for success. Like marriage, separation or divorce is not desirable because both parties lose the advantages of mutual support. Patients can always choose to leave the relationship, but at high personal cost because they may be unlikely to find another VAD center unless they are among the fortunate few who live in an area where this choice exists.

The VAD center, on the other hand, may be more like an abused spouse who is constrained from leaving the relationship out of fear — in this case, fear that ending the relationship might be construed as abandonment of the patient, even though there exists ethics policy that clearly states the conditions under which a physician can unilaterally terminate a relationship with a patient.[3] Just as in marriage, a poor match between 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. There seems to be a high rate of turnover amongst 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 a second VAD center, the second center has the freedom of choice to accept the patient or not under longstanding law and ethics policy, with an important exception. If the patient presents with a clinical emergency, the center is obligated, under EMTALA, to stabilize the patient before discharge or transfer to the primary care center or elsewhere.[4] 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.

Conclusion

As the use of VADs becomes increasingly prevalent, ethical issues are likely to arise at an increasing rate, as will social and legal ramifications. In a world where a patient may be kept alive by artificial means well beyond normal life expectancy, the medical community needs to be prepared to deal with the broad implications of this technology. We should adopt standards for the ethical use of such devices for the protection of patients, VAD centers, physicians, and countless others who are affected by this technology. To ensure success for this effort, 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 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 non-compliance.

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 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, which includes description of the services the center will provide and the expectations for patient adherence including support from the family, the implications of non-compliant behavior, the patient's options for redress, and end-of-life withdrawal of support. This agreement should be presented and discussed with every patient before VAD implantation, whenever possible, or before discharge from the hospital.

A VAD center may unilaterally sever its therapeutic relationship with a VAD patient who demonstrates persistent non-compliance. 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 definition of an acceptable transplant candidate.

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 a treatment plan developed previously, but should develop their own plan based on the 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 required by the second VAD center before discharge or transfer to the primary center, but the provision of such care does not obligate the VAD center to assume further care of the patient following discharge or transfer to the original center.

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