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Destination Unknown: The Ventricular Assist Device and the Advance of Technology

Dan D. Matlock, MD, MPH^{1,2}

¹University of Colorado Denver School of Medicine, Aurora CO

²Colorado Cardiovascular Outcomes Research Group, Denver, CO

Keywords

LVAD; Quality-of-life; Destination Therapy; Technologies

Left Ventricular Assist Devices (LVADs) are a true feat of modern bioengineering. These devices suck blood from the left ventricle and force it into the aorta at a pressure high enough to sustain life. First approved by the FDA in 1994, these devices have enjoyed a recent surge in use due to advances in the technology. Initially, LVADs were pulsatile, with a pumping mechanism that attempted to mimic the pulse pressure of the native heart. Today, these pulsatile devices have largely been replaced by the continuous flow LVADs which are smaller and have fewer moving parts.(1) LVADs are implanted either to bridge patients to transplant (or to candidacy for transplant) or as “Destination Therapy” (DT). To many, DT LVADs provide an attractive solution to fill the void between the large number of patients needing a transplant and the small number of patients receiving them.(2)

The results of the early randomized trials of the pulsatile LVADs were not impressive. Even though they were associated with a 48% relative risk reduction in all cause mortality compared to patients on maximal medical management, the two-year survival statistics were dismal at 23% in the pulsatile LVAD arm and 8% in the medical-therapy arm with 25% of the patients in the LVAD arm dying of severe sepsis.(3) A more recent trial comparing continuous flow LVADs to pulsatile LVADs demonstrated a 58% vs. 24% two-year survival favoring the continuous flow devices.(4) Additionally, the continuous flow devices had fewer complications and significant improvements in functional capacity and quality-of-life. (4) As a result, there has been a rapid growth over the past few years in the overall use of LVADs with 712 being implanted in 2009 and 614 in the first half of 2010; 97% of these were the new continuous flow devices.(1)

Why Should Geriatricians Care?

In this issue of the Journal of the American Geriatric Society, Vitale et al. use a case study to propose a call for guidance in the use of LVADs among older adults.(5) They write about a 70 year-old gentleman who received an LVAD for destination therapy and then ultimately did poorly. The authors hypothesize that his poor outcome could have been predicted pre-

Corresponding Author and Reprint Requests: Dan D. Matlock, MD, MPH; Division of General Internal Medicine; University of Colorado Denver School of Medicine; Academic Office 1, 12631 E. 17th Ave. Campus Box B-180; Aurora, CO 80045; Fax: 303-724-2270; Phone: 303-724-2242; daniel.matlock@ucdenver.edu.

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operatively using clues such as falls and gait disturbance from his prior stroke. Indeed, a fall that disconnected his LVAD's external power supply for six minutes left him with an ultimately fatal anoxic brain injury. The authors noted that people who have received an LVADs ranged from 19 to 88; somewhere in this country, 88 year-olds are receiving LVADs! Patients like the one the authors describe will likely become more common as the main reason that a patient becomes ineligible for a heart transplant is advanced age.(1) The authors were correct in saying, "we can expect a continued increase in the numbers of older adults considered for this therapy."

The authors are likely correct in saying that a consideration of geriatric syndromes could better predict who will benefit from the LVAD. There is a nuance however in that some geriatric syndromes may be partially reversible with the LVAD. Take frailty for example: imagine a gentleman with end-stage heart failure and frailty from significant cardiac cachexia. He might have trouble dressing, bathing, walking, and toileting because his heart cannot supply enough blood to meet the demands of the body. Presumably, increased cardiac output (ie, from an LVAD) could improve his functioning and actually reverse the frailty. Both pulsatile and continuous flow devices were associated with significant improvements in exercise capacity and walk distances, common aspects of the frailty syndrome(3;4) Thus, using geriatric syndromes to improve patient selection for the LVAD will require paying careful attention to measures which distinguish LVAD resistant geriatric syndromes from LVAD responsive geriatric syndromes. That said, the author's argument that geriatric syndromes should be considered when selecting patients for LVADs is well made and is an important research area to which geriatricians can and should contribute.

The Importance of Considering the Patient/Caregiver Perspective

In their paper, Vitale et al used the framework of risks, benefits, and burdens to discuss the LVADs. This is the proper framework to consider as these are exactly the issues that patients and families should think about when confronted with this decision to receive an LVAD. A decision like this which involves significant trade-offs is ripe for a formal shared decision making process. This could take the form of trained decision coaches (ie. a heart failure nurse or a palliative care team) who sit with the patient and the family and discuss the risks, benefits, and burdens. In addition, the shared decision making could be augmented with a formal decision aid - a tool which could help patients and families absorb the necessary information at their own pace. In other decisions, both decision coaches and decision aids have been shown to help patients improve their knowledge, clarify their values, and reduce their decisional conflict.(6;7) Some programs are utilizing palliative care referrals at the time of the LVAD implantation to help the patients and families clarify their goals of care and make an informed decision as well as preparing the patients and families should things not go well.(8)

The Importance of Considering Society's Perspective

LVADs cost nearly a quarter of a million dollars.(9) Some may look at the data for LVADs and still be unimpressed as a 58% two year survival is still pretty low for such an aggressive and expensive therapy. However, the technology will continue to improve. Already, third generation LVADs with only one moving part are being studied in randomized trials (clinicaltrials.gov number, NCT01166347). Fourth generation, wireless devices are currently under development which will likely have a much lower rate of infection by not having a wire that needs to be connected to a power source in the outside world.(10) Who knows what the fifth and sixth generation devices will bring? In other industries, innovations often improve efficiencies and lower costs. In health care, innovations often improve quality and/or quantity of life, but at an increased cost. LVADs are a perfect example of this.

The number of people in the U.S. over the age of 65 will increase from 40 million in the year 2010 to 87 million in 2050.⁽¹¹⁾ This “silver tsunami” will place a significant strain on the health care system.⁽¹²⁾ New technologies are increasingly expensive and decreasingly beneficial; a phenomenon Alain Enthoven has called “Flat of the curve medicine.”⁽¹³⁾ The RAND Corporation developed the Future Elderly Model to study the effects of technology, disability, obesity, and chronic disease on future medical spending and concluded that society’s greatest spending risk was “not from demographic and health trends, but rather from medical technologies.”⁽¹⁴⁾ Because of reimbursement, increasing numbers of primary care physicians are no longer accepting Medicare. Perhaps more concerning, few trainees are pursuing fields in primary care despite a clear association between primary care physicians and quality.^(15;16) Is it right to spend scarce health care dollars on LVADs while Medicare beneficiaries increasingly struggle to find primary care physicians who will even see them? This is not an easy question, this author has a Medicare patient with an LVAD who is hiking (granted, he is 33 years-old). As a clinician, it would be difficult to deny this therapy to a patient based on cost alone and these cost decisions should certainly not be done at the bedside. However, the recent economic troubles combined with the calls that Medicare is running out of money are prima facie evidence that the long overdue debate about distributive justice cannot be ignored much longer. LVADs are yet another example of why the United States needs an explicit process of considering the benefits and costs of a therapy to transparently decide what is truly “reasonable and necessary.”

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