Reducing the cost of left ventricular assist devices: Why it matters and can it be done?

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Central Message

Improving the cost-effectiveness of LVADs must focus on reducing readmissions and ambulatory costs. Unfortunately, these are ambitious goals that are easier said than done.

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Feature Editor's Note—The burdening costs of heart failure care continue to rapidly escalate as the prevalence of heart failure increases with the aging of the US population. Durable left ventricular assist device (LVAD) therapy, unconstrained by supply or restrictive patient criteria as in heart transplantation, has now become the prevailing surgical treatment (exceeding that of heart transplantation) for patients experiencing symptoms from advanced heart failure that are refractory to guideline-directed medical therapies. LVAD therapy is impactful and associated with important improvements in survival, functional status, and quality of life. For these reasons and because of the limitations of heart transplantation, the number of patients receiving durable LVAD therapy as permanent therapy (ie, destination therapy) continues to grow. However, the costs of durable LVAD therapy are sobering and the need for LVAD therapy has raised considerable debate on the ethics of how best to provide this care.¹ In this issue of the Journal, Shih and Dimick examine the cost-effectiveness of LVAD therapy in adults, citing the recent study by Baras Shreibati and colleagues.² Their critique of the study by Baras Shreibati and colleagues² is a compelling synopsis of the stark costs of LVAD therapy through analyses of cost per quality-adjusted life years and incremental cost-effectiveness ratios, and how these metrics of durable LVAD therapy compare with other treatments. As emphasized by Shih and Dimick, the ability to immediately improve on the relative cost value of LVAD therapy will likely be difficult. Although care in the United States, at least in the foreseeable future, is not withheld on the basis of thresholds of cost metrics such as cost per quality-adjusted life years or incremental cost-effectiveness ratios, these types of cost-effectiveness analyses challenge physicians, industry, and payors to improve the economics of the therapy and drive important

advances in technology and provide us all with an important societal perspective.

Francis D. Pagani, MD, PhD

Heart failure is a growing public health problem in the United States, currently affecting greater than 6 million Americans with a cost upwards of \$26 billion annually on heart failure therapies to the US health care system.³ As the overall US population ages, the burden of heart failure will only grow. Left ventricular assist device (LVAD) therapy has emerged as a promising advanced heart failure therapy to prolong survival and increase quality of life for people with end-stage heart failure. Randomized control trials have demonstrated the viability of LVAD therapy as destination therapy with superior long-term survival and quality of life when compared with medical management.⁴ However, LVAD therapy is costly and ever changing.

In the recent article by Baras Shreibati and colleagues,² the authors perform a Markov model analysis to assess costs of destination LVAD therapy in noninotrope-dependent ambulatory patients compared with medical management.² Using cost and efficacy data from previously published studies to input into their Markov model, they estimate that LVAD increased life-years (6.28 vs 5.67) and quality-adjusted life years (QALYs) (4.41 vs 2.67) when compared with medical management, but at a cost of increased readmissions (13.03 vs 6.35) and costs (\$726,200 vs \$361,800) over the patient's lifetime. Furthermore,

readmissions for LVAD were costlier than readmissions for medical management of heart failure (\$19,465 vs \$12,377, $P < .001$), although monthly outpatient care costs were similar (\$2974 vs \$3364, $P = .54$). When viewed in the lens of life-years or QALYs gained, the incremental cost-effectiveness ratios (ICERs) for LVAD therapy over medical management (calculated by dividing the difference in costs between 2 interventions by the difference in health effects) were \$597,400 per life-year gained and \$209,400 per QALY gained.

These numbers may seem nebulous, but are easier to interpret in the context of ICERs for other medical and surgical treatments. Cost-effectiveness ratios became en vogue in the 1970s when first looking at the decision to mandate Medicare coverage of patients in end-stage renal disease. The cost-effectiveness ratio for dialysis at the time was approximately \$50,000. Since then, ratios less than \$50,000 per QALY in general were considered attractive, whereas greater than \$100,000 per QALY was considered unattractive.⁵

In the context of other heart failure therapies, the ICER is approximately \$3700 to \$10,400 per QALY gained for addition of an angiotensin-converting enzyme inhibitor versus placebo and \$12,800 to \$29,500 per life-year gained for addition of carvedilol versus placebo.⁶ For invasive procedures, the ICER was \$30,000 to \$60,000 per life-year or QALY gained for ICDs in primary prevention for patients with heart failure.⁶ For coronary revascularization, cost-effectiveness analyses have estimated ICERs of ranging from less than \$10,000 to \$30,000 per QALY or life-year gained for coronary artery bypass grafting over percutaneous coronary intervention for the ASCERT, FREEDOM, and SYNTAX trials.⁷⁻⁹ Transcatheter aortic valve replacement was determined to have an ICER of \$50,212 per life-year gained and \$61,889 per QALY gained when compared with medical therapy for patients with severe aortic stenosis with prohibitive surgical risk in the PARTNER B trial.¹⁰

ICERs for LVAD therapy also have been explored in a sicker cohort of patients with heart failure who were inotrope-dependent.¹¹ LVAD destination therapy was estimated at \$202,000 per QALY gained, similar to noninotrope-dependent ambulatory patients. Immediate heart transplant had an ICER of \$94,800 per QALY gained, whereas LVAD therapy as a bridge to heart transplantation with a median wait time of 5.6 months had an ICER of \$226,300 when compared with inotrope-dependent medical therapy.

From the perspective of large payors in our health care system, LVADs, although clinically effective in improving survival and quality of life, are not cost-effective when compared with other medical and surgical interventions. Despite its high cost, LVAD therapy use continues to increase. The most recent INTERMACS report includes

more than 22,000 implants of Food and Drug Administration–approved mechanical circulatory support devices from 2006 to 2016, not including devices still in investigational trials.¹² From 2015 to 2016, approximately half of all LVADs were being implanted in patients with a strategy of destination therapy. In the current health care climate, explicit rationing of expensive advanced therapies such as LVADs does not occur. In fact, the Patient-Centered Outcomes Research Institute established by the Affordable Care Act has been prohibited from establishing strict cost-per-QALY thresholds. Decisions to initiate LVAD therapy are based purely on clinical assessment of the risks and benefits. Furthermore, we should work toward expanding access to LVAD therapy to uninsured and underinsured populations, otherwise disparities in health outcomes for patients with heart failure may worsen.

The high cost of LVAD therapy clearly must be overcome for LVAD therapy to further proliferate widely. Baras Shreibati and colleagues² address this in their Markov modeling. Using sensitivity analyses, they estimate costs could dramatically decrease if readmissions and outpatient costs decrease. Scenario analyses were performed by varying parameters in their Markov model, and they found that the ICER was most sensitive to total readmission rate, outpatient costs, and readmission costs. Baras Shreibati and colleagues² calculated that if LVAD outpatient costs could be halved and readmission rates were halved to 1 readmission per patient-year, the ICER for LVAD decreased to a more palatable \$86,900 per QALY gained.

Decreasing readmission rates and outpatient costs in the real world is much more difficult than in a computer simulation though. Readmissions can be an especially difficult issue to tackle. For LVAD therapy, readmissions may be due to a complication of device therapy such as gastrointestinal bleeding, stroke, device infection, or thrombosis, but they may also be due to other causes unrelated to the LVAD. Although not as well studied in the population with LVAD, readmissions for heart failure can be frequent, unpredictable, and highly variable.¹³ Some data suggest a large driver of readmissions may be due to lower social and economic conditions. Social factors such as living alone, unmet functional needs, limited education, and lack of self-management skills have been identified as most predictive of readmission.¹⁴ The importance of these issues is magnified when considering the patient with an LVAD, potentially in need of home nursing, postsurgical care, complicated medication regimens, physical therapy, and other intensive adjuncts. These issues must be addressed in addition to the technical aspects of LVAD therapy to effectively decrease the readmissions. In addition, many interventions to reduce readmissions often require more outpatient coordination of care. Thus, lowering readmission rates in patients receiving LVAD therapy more than likely would increase monthly outpatient costs, not decrease them.

An additional way that readmissions may decrease is with research and technology improvements in LVAD therapy. Newer iterations of LVADs may have less pump thrombosis episodes or decrease driveline infections, resulting in less readmissions and reoperations. However, although the addition of new technology may decrease long-term ongoing outpatient or readmission costs, these are often negated by increased upfront costs of the technology.

Baras Shreibarti and colleagues² have shown that LVAD therapy, although it improves survival and quality of life, comes at a great cost with an unpalatable ICER. Although this can be reduced greatly to acceptable levels by decreasing readmissions and outpatient costs, this in practice may be difficult to achieve.

Conflict of Interest Statement

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