In this issue of Circulation, 2 studies examine the value (cost-effectiveness) of 2 rapidly changing technologies: ventricular assist devices (VADs) as a bridge to transplantation for patients with heart failure and left atrial appendage (LAA) occlusion as an alternative to anticoagulation for atrial fibrillation. Both heart failure and atrial fibrillation impose an important economic and health burden on Western societies that is only going to worsen as their populations age. In addition, the high cost of treating these conditions in the United States is increasingly paid by Medicare, resulting in greater taxes and premiums for all.

Articles see p 2414 and p 2424

Heart failure is already the most common reason for hospitalization in the US Medicare program, and its prevalence in the United States is estimated to grow by 43% to 8 million people by 2030.1 The cost of this care, resulting solely from the aging of the US population, is expected to increase from $30 billion to $70 billion during the next 20 years. As the number of patients with heart failure grows, so will the number of individuals with end-stage heart failure. Given that the rate of cardiac transplantation has not increased,2 many patients, providers, and payers will consider the use of VADs as a potential therapy for those not responding to other therapies. Older-generation VADs were shown to improve survival in patients with severe heart failure (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure [REMATCH]).3 More recently, continuous-flow devices have been found to provide even better outcome and have been used routinely for several years.4 Unfortunately, the devices are expensive, with an acquisition cost near $150,000.5

The use of VADs both for destination therapy and as a bridge to transplantation has increased, resulting in estimated VAD costs in the United States climbing from $143 million to $479 million in 2009.6 Atrial fibrillation is the most common arrhythmia requiring treatment and is projected to affect 15.9 million Americans by 2050 if the growing age-adjusted rate continues.7 Although anticoagulation with warfarin or newer agents has decreased the incidence of stroke, it has also raised the risk of bleeding. Because left atrial thrombi often originate in the LAA, there is interest in occluding the appendage as a way of avoiding anticoagulation. The Embolic Protection in Patients With Atrial Fibrillation (PROTECT AF) study was a randomized trial that found LAA occlusion to be noninferior to warfarin for the combined end point of cardiovascular death, stroke, and systemic embolism.8 The cost of implanting the LAA occlusive device has been estimated to be nearly $13,000.9

Given the high cost of VADs and appendage occlusion devices relative to medical therapy, it is important to determine the value (benefit per cost) as they are currently used. The most rigorous method for evaluating value of medical care is a formal cost-effectiveness analysis. These analyses can be done either as part of a clinical trial in which both cost and outcome are determined during the course of the trial or through modeling when relevant data are available from prior work.

Both of the cost-effectiveness studies in this issue6,10 used models that suggest that the increased benefit of a device (VAD or LAA occlusion) is worth the cost. Alba and colleagues10 found that over a 20-year time horizon, using a VAD as a bridge to transplantation increases life expectancy by 1.19 years in high-risk patients at a cost of $100,841, resulting in a cost-effectiveness ratio near $85,000 per life-year gained compared with not using a VAD as a bridge. VADs in lower-risk patients had worse value with a cost-effectiveness ratio near $120,000 per life-year gained. In the model by Singh et al.,9 LAA occlusion was estimated to increase lifetime survival compared with warfarin by 0.13 years (in part as a result of less bleeding) at a cost near $42,000 per quality-adjusted life-year (QALY) gained. Although life-years are easier to measure, adjustment for quality of life is important if the disease or the treatment has a significant impact on health status.

As with clinical trials, when evaluating economic modeling studies, it is often helpful to compare results and assumptions with prior similar studies. Initial cost-effectiveness analyses of pulsatile VADs using data from the REMATCH trial found them to be a poor value, costing more than $800,000 per QALY when used as destination therapy.11 The newer continuous-flow devices have better outcomes and better value, with an estimated cost of $200,000 per QALY gained ($170,000 per life-year gained) as destination therapy compared with medical therapy.11 Reviews of prior studies of VADs used as a bridge to transplantation estimated their cost-effectiveness to range from $50,000 to more than $130,000 per life-year gained.12 However, the quality of many of these studies was considered poor.

There are fewer economic data on LAA occlusion devices, although previous studies have compared the cost-effectiveness of anticoagulants with warfarin.13 One recent study found that compared with warfarin, dabigatran costs approximately $51,000 per QALY if used at low doses and $45,000 per QALY if used at high doses.14

Most cost-effectiveness analyses are aimed at policy makers, and it is unclear how clinicians should use the results of...
these studies. Although clinicians have a duty to provide effective care to all the patients they are treating, one can argue that this duty extends to their future patients as well. Given a limited healthcare budget, these patients (present and future) will likely want their providers to be thoughtful stewards of medical resources.

Clinical decisions are often informed by practice guidelines that synthesize the available evidence of benefit. Until recently, clinical practice guidelines rarely incorporated cost into their recommendations. Similarly, legislation often has not allowed the consideration of cost in coverage decisions, requiring that a new technology be covered if it is "reasonable and necessary." However, the American College of Cardiology and American Heart Association are increasingly considering cost and value in their guidelines, appropriate use criteria, and performance measures. It will be an important service to providers and policy makers if future clinical guidelines summarize data on the strength of evidence for both benefit and value (benefit per cost).

However, to determine value, one must declare a threshold that indicates a good or poor value. Although there is no simple method to do this, one can use an expensive but widely accepted technology (such as dialysis) as a benchmark. If other technologies cost less (per life-year gained) than this benchmark, then the technology is considered an acceptable value. Traditionally, the cost-effectiveness of dialysis has been in the range of $50000 to $80000 per QALY; although a recent evaluation suggested that this ratio may now be as high $125000 per QALY.

The willingness of a society to pay for a therapy will obviously depend on the society’s wealth. The World Health Organization has suggested that an intervention that has a ratio of dollars per QALY below the gross domestic product (GDP) per capita ($48000 for the United States) is a good value (highly cost-effective), whereas one that costs 3 times the GDP ($150000 in the United States) is a poor value (not cost-effective). The 2 studies in this issue were from Canada, which has a GDP per capita similar to the United States. Although high compared with many non-Western countries, their GDP per capita is less than Switzerland at $83000 or Monaco at $171000. The United Kingdom ($39000 GDP per capita) has set a £30000 per QALY as a threshold of good value. Using the current exchange rate and a similar ratio per GDP per capita gives a corresponding US threshold for value of $60000 per QALY.

If one accepts the results reported by the authors in this issue of Circulation, one would conclude that a bridge to transplantation is likely in the cost-effective range (1–3 GDP per capita, or similar to the cost of dialysis), whereas the LAA occluder would be considered highly cost-effective (less than GDP per capita and the cost of dialysis). However, there are uncertainties in the model results of both studies that should make one cautious in interpretation.

Medical care of advanced heart failure has improved since the time of the REMATCH study comparing pulsatile VAD with medical therapy. More use of chronic resynchronization therapy and aldosterone antagonists, in addition to more β-blocker use, likely improved usual care. Without a new randomized trial, it may be difficult to know how much benefit a VAD offers over current medical/chronic resynchronization therapy.

In addition, the VAD model in this issue used 20 years as the baseline time horizon, but the model estimated that between 35% and 50% of patients will still be alive at this time. If their survival projections are correct, they are underestimating the benefits of VADs. However, their survival estimates may be optimistic given that they project a 40-year survival of 20% for 55-year-old patients being considered for transplantation.

The modeling of outcome is also important for the LAA occlusion analysis. The authors estimate a survival benefit with LAA occlusion despite the fact that the main clinical trials showed noninferiority (as opposed to superiority). This uncertainty is reflected in the probabilistic sensitivity analysis that each study conducted in which the different assumptions are varied simultaneously. For VADs, 10% of simulations were over $300000 per life-year gained. For LAA occlusion, there was still a <50% chance that this therapy was the cost-effective choice compared with warfarin and dabigatran.

For VADs, there was substantial uncertainty in the cost and outcome; for LAA occlusion, it was primarily the benefit that was uncertain. Despite the uncertainty, these studies are important for showing where the uncertainty lies and where more data are needed before clinical guidelines can recommend for or against a treatment on the basis of value.

When determining whether a health system should pay the cost of any particular care strategy, both value and the impact on the budget must be examined. Even if the treatment is cost-effective, can we absorb this cost with our current healthcare budgets? In the case of bridge to transplantation, the total number of potential VADs per year is small. There were 1949 heart transplants in 2011, and VADs were used in 35% of patients before transplantation, a number that was unchanged from 2010 but up from 20% from 2006. The wait list at the start of 2011 was 2867, so even if VADs were used in all patients on the waiting list, the overall financial burden would not be large. In contrast, the potential population for the LAA occlusion device is several million patients, so even though the cost of the device is substantially less than the VAD cost, the budget impact could be far greater.

Perhaps the greatest uncertainty is the rapidly changing technology. Newer generations of VADs and LAA occlusion devices are in development, and their impact on future cost and outcome is unclear. Cost, complications, and benefit are also likely to change as experience grows. Thus, although a VAD as a bridge to transplantation and an LAA occluder for atrial fibrillation may ultimately prove to be a good value, policy makers, guideline writers, and clinicians should wait for more definitive data before changing payment, recommendations, or treatment decisions.

Disclosures

None.

References

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Placing a Value on New Technologies

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