Editorial

Insanity of Left Ventricular Assist Therapy
Doing the Same Thing and Expecting Different Results

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If you can measure that of which you speak and can express it by a number, you know something of your subject; but if you cannot measure it, your knowledge is meager and unsatisfactory.

—Lord Kelvin

The success or failure of left ventricular assist device (LVAD) therapy can be measured in several ways. The landmark clinical trials, REMATCH¹ and INTrEPID,² defined success in terms of mortality and morbidity, compared with standard medical therapy. Indeed, these are the primary benchmarks used by the US Food and Drug Agency when evaluating a device for market approval. On a grander scale, success may be measured in terms of the popularity or use of the therapy. In this respect, LVAD therapy would be deemed as an abject failure. Thirty years ago, the Office of Technology Assessment projected the annual need to be on the order of 100,000 in the United States and 200,000 worldwide³; yet the current rate of LVAD implantation has yet to achieve 5% of this target.

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For many of these intervening years, it was believed that the barriers to widespread growth of this therapy were the technology itself: the unsatisfactory safety and efficacy of the devices. Now that current LVADs are sufficiently small, quiet, and durable and serious complications of infection and thromboembolic events have been mitigated, we must look to a different metric of success.⁴ This is precisely what Oppenheimer & Co did in a recent survey of cardiac surgeons.⁵ When asked “what are the greatest factors driving wider adoption of LVADs for destination therapy?,” the overwhelming response was: “portability and device wear profile.” The response was not “small size,” “easier implant strategy,” or “cost,” which were at the bottom of the list. But why? The external hardware and accoutrements are nothing but incidental accessories. They cannot affect outcomes. Could they?

Why Not Ask the Patients Themselves?
The patient’s response to this question is reported in the article by Brouwers et al⁶ in this issue of Circulation: Heart Failure. And the response is unanimous: quality of life. Their survey, which encompasses 16 quantitative studies of patient-reported outcomes from 1999 to the present, is also a reminder that patients have been making this plea for as long as they have been asked the question. In other words, it should not come as a surprise that anxiety, depression, uselessness, and other psychosocial pathological conditions are at variance with the well-intended goal of LVAD therapy.

Several months before the 1982 historic implantation of the first “permanent” artificial heart into Dr Barney Clark, Dr Robert Jarvik was quoted by Scientific American, “If the artificial heart is ever to achieve its objective, it must be more than a pump. It must also be more than functional, reliable and dependable. It must be forgettable.”⁷

Even 9 years before, in 1973, the Artificial Heart Assessment Panel, commissioned by the National Heart and Lung Institute, warned of the psychiatric and social implications of this technology.⁸

An obvious question, therefore, is “What can/should we do now that we have not already done over the past 4 decades?” Brouwers and colleagues⁶ provide several insightful and important clinical guidelines that are important to both outcomes and decision making, defined in a holistic sense. What they do not mention are remedies that may be contributed from the engineering community, of which I am a member. Those of us who develop this technology are also beholden to the tenet, primum non nocere, perhaps not by oath, but certainly in spirit. We may not be qualified to rule on best practices of medicine, but it is our obligation as “part of the problem” to also be part of the solution. This includes an obligation to ensure the responsible use of the technology.

To wit, this engineer respectfully suggests that the patients, their caregivers, and members of their support system become more completely engaged in decision making involving their care. This evolution is already occurring, described eloquently in the book Complications by Atul Gawande, MD:

A decade or so ago, doctors made all the decisions; patients did what they were told. Doctors did not consult patients about their desires and priorities and routinely withheld information — sometimes crucial information, such as what drugs they were on, what treatments they were being given, their diagnosis; patients were even forbidden to look at their own medical records: it wasn’t their property. ... They were regarded as ... too fragile and simple minded to handle the truth, let alone make decisions.⁹

Having entered an era of increased patient involvement, we should provide them tools to make rational choices, based on their true desires and priorities, despite the duress of being...
critically ill. For example, the use of online social networks, and decision support software, may provide patients with group support, and the opportunity to consider more deeply the costs and benefits of LVAD therapy (over and above the 30- to 60-minute consultation with the cardiac surgeon that is typical of many [most] centers). Such tools would both spare those patients who would ultimately grow to regret accepting LVAD therapy, and hopefully, provide patients who are most likely to benefit with confidence that an implanted mechanical device may in fact be preferable to the certain demise of standard care.

The previous remarks are not meant to shirk responsibility to further improve the LVADs themselves. Indeed, developers of the next generation of LVAD systems must focus greater attention on ergonomics of peripherals, reduced power requirements, robust feedback-control, and reduced invasiveness, to both diminish the encumbrance and approximate the efficacy of cardiac transplantation.

In summary, Brouwers et al is a clarion call to the LVAD community to direct its full attention to quality of life. They speak to the clinical community to increase clinical emphasis on patient-reported outcomes “to optimize the care of an increasingly growing population of LVAD patients.” To this call may be appended an appeal to the bioengineering community to continue the pursuit of the truly “forgettable” LVAD.

Disclosures

WorldHeart, Inc was a scientific collaborator.

References


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