EDITORIAL COMMENT

Chronic Counterpulsation Devices for Heart Failure*

Carmelo A. Milano, MD

The C-Pulse System (Sunshine Heart, Inc., Eden Prairie, Minnesota) is a novel implanted counterpulsation heart assist pump that is positioned around the ascending aorta. It is non-blood contacting and may be turned off intermittently or weaned off in cases of ventricular recovery. In this issue of JACC: Heart Failure, Abraham et al. (1) describe a safety assessment study in which 20 heart failure patients received the device. The most encouraging outcome was that none of the 20 patients experienced a stroke.

Importantly, patients were pre-screened and those with ascending aortic disease were excluded. Unfortunately, 1 patient experienced a procedure- and device-related death from a mediastinal infection. Furthermore, disappointingly 40% of patients experienced drive line exit site infection. Patients who survived with the device to a 12-month follow-up time point did experience a modest increase in 6-min walk distances, although clinical improvement of heart failure was not the primary focus of this pilot study.

While the results from Abraham et al. (1) could be discounted as unexciting, the chronic counterpulsation strategy in theory addresses several of the limitations currently being encountered with the more popular rotary flow implantable left ventricular assist device (LVAD) systems. First, the low stroke rate would compare favorably to the combined ischemic and hemorrhagic stroke rate for rotary flow LVADs, which is approximately 10% per patient year of support. This is perhaps one of the most important and limiting adverse events seen with rotary flow LVADs. Furthermore, newer designs of these LVADs will not guarantee a reduction in this stroke rate, not to mention other thromboembolic and bleeding adverse events. Secondly, chronic counterpulsation may be considerably less expensive relative to implanted rotary flow LVADs. Lastly, most LVAD implants are highly invasive procedures, which require a full sternotomy and can be quite debilitating for chronic heart failure patients. Chronic counterpulsation devices may be implanted through less invasive surgical approaches. Therefore, the therapy introduced by Abraham et al. (1) offers several important theoretical advantages compared with LVAD.

Abraham et al. (1) is not designed to demonstrate device-related heart failure improvement. Clearly, a larger study will be necessary to gauge the degree of clinical improvement achieved with such devices. However, chronic intra-aortic balloon support is already practiced extensively in patients who are being bridged to cardiac transplantation. Castleberry et al. (2) reported on a cohort of over 1,000 patients in the United Network for Organ Sharing Database who were supported with intra-aortic balloon pump as a bridging strategy before cardiac transplantation. These patients experienced relatively similar short-term post-transplant outcomes relative to patients who were bridged with more complex LVAD devices. Therefore, the concept of intra-aortic balloon support for heart failure, particularly as a bridge to transplant, is not novel. These newer devices, however, would enable better functional status for patients and hopefully enable discharge from hospital units.

Finally, it is worth mentioning that the C-Pulse System is just 1 of several types of chronic

*Editorials published in JACC: Heart Failure reflect the views of the authors and do not necessarily represent the views of JACC: Heart Failure or the American College of Cardiology.

From the Heart Transplant and LVAD Program, Duke University Medical Center, Durham, North Carolina. Dr. Milano has received consulting fees (<$10,000) from Thoratec Corporation and HeartWare, Inc.
counterpulsation technologies that are being developed. For example, Lu et al. (3) described a blood contacting device placed in the descending aorta for chronic counterpulsation. The para-aortic balloon pump features a smaller pneumatic driveline that may be less prone to exit site infections, as well as a small portable driver (Figure 1). This device and insertion tools are being designed for a less invasive implant procedure. Initial animal implants have revealed robust hemodynamic support and the implant location in the descending aorta should guard against stroke. Clinical trial design will be critical in elucidating the potential benefits and limitations to these chronic counterpulsation technologies for chronic heart failure.

REPRINT REQUESTS AND CORRESPONDENCE: Dr. Carmelo A. Milano, Heart Transplant and LVAD Program, Duke University Medical Center, Box 3043, Durham, North Carolina 27710. E-mail: carmelo.milano@duke.edu.

REFERENCES


KEY WORDS balloon pump, C-Pulse, heart failure