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REPLY: Upgrade Ambulatory Extra-Aortic Counterpulsation to Full-Support LVAD

We very much appreciate the letter from Dr. Zeriouh and colleagues, referencing our early experience with ambulatory extra-aortic counterpulsation in patients with moderate to severe chronic heart failure (1). We agree with their conclusions regarding the advantages of the C-Pulse device, compared to left ventricular assist devices (LVADs). As noted in our paper and in the letter from Zeriouh et al., the C-Pulse device is an extravascular partial-support device that eliminates: 1) the risk of device thrombosis, significantly reducing the risk of thromboembolism; and 2) the need for systemic anticoagulation, significantly reducing the risk of bleeding, in contrast to full- and partial-support LVADs. The C-Pulse device is intended for patients with advanced but not end-stage heart failure, where the need for a full-support LVAD is less and the intolerance for thromboembolism and bleeding is greater.

Dr. Zeriouh and colleagues point out that some patients undergoing partial circulatory support may develop the need for replacement of the partial support device (e.g., C-Pulse device) with a full-support LVAD. As evidenced by our data, the majority of C-Pulse treated patients improve substantially with therapy and do not require "upgrade" to an LVAD. Few (2 of 20 in our cohort) progress to a need for a full-support LVAD, and when this occurs, explant of the C-Pulse system and implantation of an LVAD can be successfully accomplished, as demonstrated in our experience, as well as in the experience of Dr. Zeriouh and colleagues. Such instances can likely be minimized through improved patient selection, as additional experience with the C-Pulse system is gained.

Dr. Zeriouh and colleagues raise questions about the impact of C-Pulse cuff action on aortic wall integrity. Published histopathology on a patient from our cohort, who completed a successful bridge to heart transplant after 21 months of C-Pulse therapy, revealed the following findings in tissue samples obtained proximal to and under the C-Pulse cuff at the location of the ascending aorta: 1) macroscopically, the aortic samples appeared grossly normal with no intimal disruption, tear, or dissection; 2) microscopically, the intima and media of the ascending aortic wall within the C-Pulse cuff remained intact, with no evidence of disruption compared to wall structure proximal to the cuff, no cystic medial necrosis, and no change in thickness; and 3) no significant inflammation was noted except mild neutrophilic infiltration in the adventitial surface. Fibrinoid degeneration on the adventitia was noted on both ascending aorta samples (2). These findings have been confirmed by pathology samples from 3 additional patients in our cohort (unpublished observations, Dr. Walter Pae [December 2010], Dr. Sanjeev Aggarwal [April 2011], Dr. Benjamin Sun [November 2011]).

Finally, we agree that if a patient has intractable arrhythmias, which impair the delivery of the C-Pulse therapy, they may not be an appropriate candidate for C-Pulse therapy. However, most cases of arrhythmia can be successfully treated to allow synchronization of the C-Pulse system with the native cardiac rhythm.

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