

## Letters

### TO THE EDITOR

## Upgrade Ambulatory Extra-Aortic Counterpulsation to Full-Support LVAD



We read with interest the study by Abraham et al. (1) in which the Sunshine Heart C-Pulse implantable extra-aortic counterpulsator (Sunshine Heart, Inc., Eden Prairie, Minnesota) was used for the treatment of patients with advanced heart failure (New York Heart Association functional class III and IV). In recent years, significant technologic improvements in the field of mechanical circulatory support have led to the development of smaller and more reliable continuous-flow blood pumps resulting in improved morbidity and mortality (2). In addition to these full-support devices, the concept of partial support has been successfully demonstrated in “less sick” patients (i.e., not sick enough to justify the use of full-support left ventricular assist devices [LVADs]). One such partial-support system—the Synergy CircuLite Micropump (CircuLite Inc., Saddle Brook, New Jersey)—has been used successfully to treat this patient group, as described previously (3). In addition, our group showed that this pump was also capable of supporting inotropic dependent patients and those in cardiogenic shock (4). However, despite initial successes with demonstrated improvements hemodynamics and quality of life, the Synergy had to be withdrawn from the market and is currently undergoing design enhancements to resolve issues that became evident during initial clinical use.

In contrast to partial-support LVADs such as the Synergy, the C-Pulse is an extravascular device that eliminates the need for systemic anticoagulation, significantly reducing the risk of bleeding and overcomes the problem of device thrombosis. However, a limitation of all forms of circulatory support that rely on maintenance of partial left ventricular function is the possible need for replacement of the partial-support device with a full-flow LVAD; Abraham et al. (1) alluded that 2 patients (10% of cohort) had to be upgraded to a full-support LVADs during follow-up

despite progressive improvements in New York Heart Association functional class of the entire cohort. In our center, we have also faced the need to upgrade both Synergy and C-Pulse recipients to full-support LVADs. We believe that this possibility should be considered before implantation particularly in the case of patients with borderline left ventricular function and the potential need to replace the device should form part of the patient consent process. That upgrade of the Synergy device, which is always implanted without sternotomy, is technically more straightforward and is not directly comparable to a typical full-flow LVAD device exchange because the sternum is preserved and the access to the left ventricle and aorta does not require re-exploration of a previously exposed surgical field. In contrast, upgrade of the C-Pulse system (wrapped around the ascending aorta, which is also used for the outflow graft anastomosis) may be associated with technical challenges due to adhesions of the extra-aortic cuff to the adventitia, particularly when C-Pulse implant duration has been prolonged. In our institution, during such an upgrade 4 months after C-Pulse implantation in a patient with an underlying history of ischemic heart disease, we were confronted by dense adhesions, particularly between the aortic wall and the C-Pulse cuff. Additional care had to be taken during the dissection of the ascending aorta and while performing the outflow-graft-to-aorta anastomosis as the impact of C-Pulse cuff action on aortic wall integrity in the context of anastomotic surgery is not fully characterized. As this issue may prove to be problematic after longer term follow-up, it would be interesting to know about the authors’ experience of the technical aspects and severity of tissue adhesions, particularly between the extra-aortic cuff and aortic wall.

In keeping with the study of Abraham et al. (1) in which 1 patient with arrhythmias required upgrade to an LVAD, in our institution we experienced a similar problem: persistent multifocal ventricular ectopy in an amiodarone intolerant patient despite uptitrated beta-blocker therapy and cardiac resynchronization therapy defibrillator (CRT-D) pacing optimization. This limited the efficacy of C-Pulse therapy leading to recurrence of heart failure symptoms. These findings suggest that patients with intractable arrhythmias may not be ideal candidates for C-Pulse treatment and an alternative treatment strategy should be considered.

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## REFERENCES

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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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