Unsuccessful clinical outcomes: Sometimes the stepping stones toward valuable innovation

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Central Message

Modifications to implantation of the total artificial heart are necessary in the Fontan population, but an ideal strategy is yet to be accepted.

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In this issue of the *Journal*, Woods and colleagues¹ present an innovative solution for the implantation of the total artificial heart (TAH; SynCardia, Tucson, Ariz) in patients with a Fontan circulation. Although the literature is typically full of successful case reports, important breakthroughs often come from unsuccessful ventures. We therefore applaud Woods and colleagues¹ for reporting this disappointing outcome in sharing their innovative technique. With only 6 TAHs implanted in patients with Fontan circulations worldwide (personal communication, SynCardia) and only a single previous report in the literature, TAH application to the Fontan circulation is in early development.²

One recurrent issue for our field is waiting until patients are too ill before applying technology to a new, difficult patient cohort. In this case, the TAH was implanted in a very challenging, vasoplegic patient listed for combined heart-liver transplant only after a failed attempt of ventricular assist device therapy resulting in extracorporeal membrane oxygenation support. As noted by Woods and colleagues,¹ had the TAH been the initial strategy, perhaps the outcome might have been better. The TAH's hemodynamic profile may make it an ideal device for resuscitating the patient with a late failing Fontan circulation who has poor cardiac output and venous congestion. Unlike a systemic ventricular assist device or even transplantation, it can immediately provide a supraphysiologic cardiac index (>4 L/min/m²) with a central venous pressure less than 6 mm Hg. This low central venous pressure potentially allows the patient with a Fontan circulation to have reversal of protein-losing enteropathy, congestive hepatopathy, congestive renal insufficiency, and other conditions. A second point is that the atria are often quite thickened and fibrosed in patients with a chronically failing Fontan

circulation. This case demonstrated that the fibrous atrio-ventricular skeleton is not necessary to secure the TAH ventricles. The report excellently depicts and describes the technique necessary to allow expansion and bisection of the common atrium for TAH implantation. Notably, this technique is applicable to a variety of congenital heart anatomies if the integrity of the atrium is sufficiently strong. Third, the use of a fenestration may not have been necessary. Placement of a fenestration in patients with a Fontan circulation supported with a systemic ventricular assist device is becoming commonly practiced, because flow across the usually abnormal vasculature of these patients is often in question. For the TAH, however, which does not rely on passive flow to fill and has a well-known ability to pump through quite high resistances, the use of a fenestration may not be advantageous and may be disadvantageous (increased stroke risk). Finally, an issue often discussed with TAH use in patients with a Fontan circulation is the negative pressure set by the device possibly causing the atrium or other right-sided capacitance chamber to collapse; however, this will not happen. The negative pressure of about 8 to 14 mm Hg that one sets on the controller is used to evacuate air from the tubing and air chamber, not to generate actual negative pressure in the atrium. Issues of inflow chambers collapsing or of inadequate filling are thus related to compression by the device or tamponade. As more patients with a Fontan circulation reach end-stage heart

failure, it will be interesting to observe the application of TAHs in this challenging patient population. This technical innovation by Woods and colleagues¹ represents a valuable stepping stone in the development of a successful strategy for TAH support of patients with a Fontan circulation.

References

1. Woods RK, Neibler R, Kindel S, Troshynski T, Joyce LD, Hraska V. A new method for implanting a total artificial heart in the patient with a Fontan circulation. *J Thorac Cardiovasc Surg.* 2019;157:353-5.
2. Rossano JW, Goldberg DJ, Fuller S, Ravishankar C, Montenegro LM, Gaynor JW. Successful use of the total artificial heart in the failing Fontan circulation. *Ann Thorac Surg.* 2014;97:1438-40.