Kirklin Commentary





Commentary: Adult support with a pulsatile VAD: Reawakening of a bygone era?

James K. Kirklin, MD

Bartfay and colleagues¹ in Gothenburg, Sweden, present an analysis of the Berlin Heart EXCOR pulsatile extracorporeal mechanical circulatory support (MCS) device in a combined pediatric and adult population. Of course, the US experience with this device is extensive in infants and children with single or biventricular failure.² The Berlin Heart radically changed the landscape of pediatric MCS with its introduction in the United States in 2000 and eventual Food and Drug Administration approval in 2011, becoming the only reliable source of longer term support for infants and small children and bridging thousands of young patients to heart transplantation.

The unique and important aspect of the report by Bartfay and colleagues¹ is the analyzed application of this device in adults. The authors emphasize two major indications for the Berlin EXCOR in their practice in Sweden: complex congenital heart disease (CHD) and planned biventricular assist device (BVAD) support.

In patients with CHD, the potential for atrial cannulation is an advantage of the Berlin Heart when the available sites for ventricular cannulation (in particular, with a systemic morphologic right ventricle) are considered by the surgeon to be at high risk of inflow obstruction with a standard continuous flow (CF) device. However, good outcomes have been reported with support of a systemic right ventricle using CF pumps.³ A US Interagency Registry for Mechanically Assisted Circulatory Support analysis of CF devices in adults with CHD revealed survival with the

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CENTRAL MESSAGE

Adult biventricular mechanical circulatory support with pulsatile devices may improve outcomes.

device of ~70% at 1 year, 10% less than that for non-CHD patients. ⁴ Thus, in unusual circumstances, the surgical armamentarium for adults with complex CHD could incorporate this device for isolated systemic ventricular support.

Planned BVAD support as a bridge to recovery or a transplantation strategy in adults appears to be the major area of opportunity for the Berlin EXCOR. This configuration is frequently used by congenital heart surgeons for infants and small children. Of the current options for biventricular support in the United States, the reported 1-year survival for BVADs (with a CF pump on the left side; <60%)⁵ and total artificial heart $(\sim 50\%)^6$ has lagged considerably behind isolated left ventricular support. Although not risk adjusted compared with US centers, the Kaplan-Meier 1-year survival of nearly 80% for biventricular support with 2 paracorporeal Berlin Heart pulsatile pumps, as reported by the authors, is impressive.

With the potential advantages (although not without debate) of pulsatile flow, the simplicity of implantation, and the potential for hospital discharge in Sweden, this pump has performed well in the adult biventricular configuration, albeit with the known susceptibility to embolic strokes. The major caveat in assessing the Swedish experience is the relatively short wait times for transplantation, which is currently not the case in the United States. For this to be a truly viable option in the United States, the pump could be used in an "off-label" application, with an elevated priority for organ allocation assigned on the basis of BVAD support without hospital discharge (as in the US pediatric application).

Thus, for all that pediatric surgeons have learned from their adult colleagues in the application of CF pumps in pediatric patients, perhaps this is an opportunity for those experienced with the pediatric Berlin EXCOR to return the favor

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and share their knowledge with adult MCS surgeons, adding an important BVAD option for the adult MCS team.

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Commentary: Rejuvenation of a trusted tool

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Axial and centrifugal continuous-flow (cf) ventricular assist devices (VADs) rapidly supplanted pulsatile VADs as the devices of choice for adults in the mid-to-late 2000s. Although the field has largely consolidated toward the use of cfVADs in large patients requiring left ventricular support alone, the anatomic challenges of cfVAD implantation in children (generally <20 kg), certain adults with congenital heart disease, and patients requiring biventricular support require a more individualized approach.

In the current issue of the *Journal*, Bartfay and colleagues¹ describe the use of the EXCOR (Berlin Heart, Inc, The Woodlands, Tex) in these populations. The overall outcomes are good and underscore the fact that the EXCOR performs quite well in appropriately selected



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Patient selection remains fundamental to outcomes even as the VAD armamentarium expands and evolves.

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patients. These data are especially notable when considering the current study also depicts feasibility and utility of discharge on the EXCOR with the mobile driving unit. The study is consistent with overall outcomes within the field showing improved outcomes in the current era as patient selection and anticoagulation evolve and centers garner more experience. However, a more in-depth examination of the use of the device by the authors in a biventricular assist device (BiVAD) configuration is warranted. The current results are notably better than the larger experience within the field, where BiVAD support has a 6-month survival of ~65%. This difference in outcome is likely a function of patient characteristics as well as a very liberal approach to the use of BiVAD support based on preoperative right ventricular function.

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