Villa and Morales Commentary

However, many would argue that most of these patients did not need a BiVAD. The authors fall into the common misconception that the use of a BiVAD is equal to the need of a BiVAD.

While late implantation of right ventricular support after left VAD is clearly a risk factor for poor outcomes, "prophylactic" use of BiVAD therapy has not been shown to improve outcomes after controlling for preoperative patient characteristics. These data, in conjunction with the broader outcomes in patients implanted with a left cfVAD, suggest the focus should be on earlier implantation rather broader use of BiVAD therapy. There is morbidity and mortality associated with the use of BiVAD therapy when left VAD alone will suffice in 90% to 95% of patients. Bartfay and colleagues have described the potential utility of the EXCOR in the current era; however, outcomes can only be optimized when the right device is implanted in the right patient at the right time, which regularly results in no right VAD.

## References

- Bartfay S, Dellgren G, Hallhagen S, Wåhlander H, Dahlberg P, Redfors B, et al. Durable circulatory support with a paracorporeal device as an option for pediatric and adult heart failure patients. *J Thorac Cardiovasc Surg.* 2021;161: 1453-64 e4
- Miera O, Morales DLS, Thul J, Amodeo A, Menon AK, Humpl T. Improvement of survival in low-weight children on the Berlin Heart EXCOR ventricular assist device support. Eur J Cardiothorac Surg. 2019;55:913-9.
- VanderPluym CJ, Cantor RS, Machado D, Boyle G, May L, Griffiths E, et al.
  Utilization and outcomes of children treated with direct thrombin inhibitors on
  paracorporeal ventricular assist device support. ASAIO J. November 20, 2019
  [Epub ahead of print].
- Kormos RL, Cowger J, Pagani FD, Teuteberg JJ, Goldstein DJ, Jacobs JP, et al. The Society of Thoracic Surgeons intermacs database annual report: evolving indications, outcomes, and scientific partnerships. *Ann Thorac Surg.* 2019;107: 341-53.
- Takeda K, Naka Y, Yang JA, Uriel N, Colombo PC, Jorde UP, et al. Outcome of unplanned right ventricular assist device support for severe right heart failure after implantable left ventricular assist device insertion. J Heart Lung Transplant. 2014; 33:141-8.
- Zafar F, Jefferies JL, Tjossem CJ, Bryant R III, Jaquiss RD, Wearden PD, et al. Biventricular Berlin Heart EXCOR pediatric use across the United States. *Ann Thorac Surg.* 2015;99:1328-34.
- Kanwar MK, Lohmueller LC, Kormos RL, Teuteberg JJ, Rogers JG, Lindenfeld J, et al. A Bayesian model to predict survival after left ventricular assist device implantation. JACC Heart Fail. 2018;6:771-9.

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## Commentary: The pneumatic para-trouper

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Advanced congestive heart failure has reached epidemic proportions in the United States, with the number of end-stage patients exceeding the number of available organs for transplantation by an order of magnitude. <sup>1,2</sup> Mechanical support devices have been introduced and refined to offer bridging and long-term therapy for the failing left ventricle, with implantable continuous-flow devices now offering



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## CENTRAL MESSAGE

The EXCOR pneumatic paracorporeal ventricular assist device offers good clinical outcomes as a bridge to transplantation in adult and pediatric patients.

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2-year outcomes that rival heart transplantation.<sup>3</sup> However, pediatric patients and adults with right ventricular failure are often not candidates for this life-saving therapy and require in-hospital extracorporeal support, which is associated with significant morbidity, mortality, and cost. In the current issue of the *Journal*, Bartfay and colleagues<sup>4</sup> report their experience with the EXCOR pneumatic paracorporeal

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Commentary Timek

device (BerlinHeart, Berlin, Germany) implanted in 50 adult and pediatric patients as a bridge to recovery or transplantation. The authors used a comprehensive perioperative, in-hospital, and outpatient strategy to achieve laudable results in these difficult patients.

The use of the EXCOR device has been well described in the pediatric population, both in multicenter studies and individual reports. The pediatric portion of the report, although with impressive results, is perhaps not as interesting as the adult outcomes, since the device has not been used widely in adults across Europe and is not approved for adult use in North America. Most of the adult patients were INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) profile I, and 97% required biventricular support. It is noteworthy that overall patient survival was 82% and 75% at 1 and 5 years, respectively. Four patients died while on support, with very few patients dying after transplantation. These results speak to the medical infrastructure and care philosophy that the authors have established to support patients on the device. Intraoperatively, patients were weaned from cardiopulmonary bypass to short-term biventricular support using devicecompatible cannulas and later switched to the EXCOR device in the intensive care unit when extubated and neurologically intact. This is a clever approach that is mindful of expensive resources. With training of visiting nurses and family members, 13 of 29 patients were discharged from the hospital with the longest period of home support of more than 8 months. This tactic reduced necessity for prolonged hospitalization, which can take a physical and psychological toll on the patients. The authors did not list adult patients for transplant a priori until 3 months postdevice implantation to permit nutritional, physical, and psychological rehabilitation. Post-transplant survival was excellent, supporting this approach and emphasizing good stewardship of scarce resources. The EXCOR device offered acceptable durability, with 2 mechanical failures and 4 cases of pump thrombosis. The most frequent device-related complication were cannula-site infections, which were treated medically. The SynCardia Total Artificial Heart (SynCardia Systems, Inc, Tucson, Ariz) and implantation of intracorporeal continuous-flow devices offer alternative options for biventricular support. However, published experience of durable implantable biventricular support revealed 33% operative mortality, 1-year survival of 61%, and right ventricular assist device thrombosis rate of 37%. Furthermore, discharge to home was 61% in patients with simultaneous implants but only 27% in those receiving staged biventricular support. In this context, EXCOR device appears to be viable option for adult patients requiring biventricular support.

The current study illustrates that biventricular support with the EXOR device as a bridge to transplantation can be quite good in the setting of a thoughtful and innovative treatment plan. For these very complex patients, it indeed "takes a village" to achieve good results, and extrapolation of the presented outcomes should be viewed in that context.

## References

- Jackson SL, Tong X, King RJ, Loustalot F, Hong Y, Ritchey MD. National burden of heart failure events in the United States, 2006 to 2014. Circ Heart Fail. 2018;11: e004873.
- Miller LW. Is left ventricular assist device therapy underutilized in the treatment of heart failure? Circulation. 2011;123:1552-8.
- Ammirati E, Oliva FG, Colombo T, Russo CF, Cipriani MG, Garascia A, et al. Mid-term survival after continuous-flow left ventricular assist device versus heart transplantation. *Heart Vessels*. 2016;31:722-3.
- Bartfay SE, Dellgre G, Hallhagen S, Wahlander H, Dahlberg P, Redforts B, et al. Durable circulatory support with a paracorporeal device as an option for pediatric and adult heart failure patients. *J Thorac Cardiovasc Surg.* 2021;161: 1453-64 e4
- Maynes EJ, O'Malley TJ, Luc JGY, Weber MP, Horan DP, Choi JH, et al. Comparison of SynCardia total artificial heart and HeartWare HVAD biventricular support for management of biventricular heart failure: a systematic review and meta-analysis. Ann Cardiothorac Surg. 2020;9:69-80.
- Shah P, Ha R, Singh R, Cotts W, Adler E, Kiernan M, et al. Multicenter experience with durable biventricular assist devices. *J Heart Lung Transp*. 2018; 37:1093-101.