

References

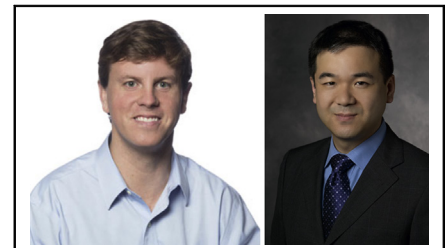
- Hernandez NB, Kirk R, Sutcliffe D, Davies R, Jaquiss R, Gao A, et al. Utilization and outcomes in biventricular assist device support in pediatrics. *J Thorac Cardiovasc Surg.* 2020;160:1301-8.e2.
- Zafar F, Jefferies JL, Tjossem CJ, Bryant R III, Jaquiss RD, Wearden PD, et al. Biventricular Berlin Heart EXCOR pediatric use across the United States. *Ann Thorac Surg.* 2015;99:1328-34.
- Schibilsky D, Haller C, Lange B, Schibilsky B, Haerberle H, Seizer P, et al. Extracorporeal life support prior to left ventricular assist device implantation leads to improvement of the patients INTERMACS levels and outcome. *PLoS One.* 2017;12:e0174262.
- Lorts A, Eghtesady P, Mehegan M, Adachi I, Villa C, Davies R, et al. Outcomes of children supported with devices labeled as “temporary” or short term: a report from the pediatric interagency registry for mechanical circulatory support. *J Heart Lung Transplant.* 2018;37:54-60.

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Commentary: To BiVAD or not to BiVAD...that is the question?

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CENTRAL MESSAGE

Poor outcomes traditionally associated with BiVAD use may be more related to patient selection and timing of implant rather than the device strategy.

It is well established that pediatric patients with advanced heart failure who receive a biventricular assist device (BiVAD) have worse unadjusted outcomes compared with patients who receive a left ventricular assist device (LVAD) alone.¹⁻³ This has led to a long-standing controversy over the optimal role of BiVAD use. Some argue that BiVADS should be strenuously avoided in virtually all cases because the risk is inherent to the right ventricular assist device (VAD) itself, whereas others argue that the poor outcomes are related to patient selection and timing of implant. As with any good controversy, debate thrives largely because of a lack of data to resolve the controversy persuasively.

In this issue of the *Journal*, Hernandez and colleagues⁴ take an important step forward in filling this data gap in pediatric VAD recipients. Analyzing INTERACS (Interagency Registry for Mechanically Assisted Circulatory Support) data from 363 children implanted with VADs since 2012, the authors show that (1) BiVAD use is on the decline in pediatric patients; (2) patients with LVAD and BiVAD differ substantially in their characteristics at implant, and (3) the difference in adjusted outcomes appears much

smaller—and possibly negligible—once the difference in patients characteristics is adjusted for using a propensity score (PS)-matching analysis.⁴ These findings are consistent with a similar study performed in adult patients with VAD that used Cox proportional hazards modeling rather than PS matching to adjust for patient differences.³

Use of PS matching to adjust for patient differences has a number of important limitations in this setting that could explain the nonsignificant difference in LVAD versus BiVAD survival. However, a PS-matched approach is still one of the best methods available to answer this important question, given the large number of potential confounders and small sample size available. As the authors note, this also creates problem for generalizability to sicker and healthier patients, where, if adequate controls existed, one might actually observe LVADs to perform better in healthier patients whereas BiVADs perform better in sickest patients. Another limitation is that many of the factors clinicians use to decide to place a right VAD were unavailable for PS development, specifically the degree of central venous pressure elevation, right ventricular (RV) dysfunction, tricuspid regurgitation, and duration of RV failure.

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Given these limitations, what can we take away from the present analysis by Hernandez and colleagues? First, similar to adult BiVAD trends, the use of pediatric BiVAD support continues to decrease over time and this is likely related to a number of factors, including the movement toward earlier implantation of LVAD support along with greater proficiency in managing pre- and postoperative RV failure (ie, afterload reduction with pulmonary vasodilators, RV inotropic support, and judicious fluid management). Second, differences in patient characteristics likely account for a significant portion of the differences in outcome, although it is difficult to exclude the possibility that LVADs may perform better than BIVADs in low-risk patients and/or BIVADs may perform better than LVADs in high-risk patients because no suitable controls were available. Thus, simple answers and blanket recommendations regarding BIVAD use are unhelpful and probably unsafe. Instead, as noted by the authors, the choice of BiVAD versus LVAD support should be dictated by the risks for severe and persistent RV failure after VAD placement.

Continued multicenter learning opportunities are crucial to furthering our understanding of what factors predict severe and persistent RV failure. Through refinements in patient selection, surgical implant strategies, and medical management practices, the pediatric community can move closer to answering the elusive question in pediatric heart failure of “to BiVAD or not to BiVAD?”

References

1. Almond CS, Morales DL, Blackstone EH, Turrentine MW, Imamura M, Massicotte MP, et al. Berlin Heart EXCOR pediatric ventricular assist device for bridge to heart transplantation in US children. *Circulation*. 2013;127:1702-11.
2. 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.
3. Cleveland JC Jr, Naftel DC, Reece TB, Murray M, Antaki J, Pagani FD, et al. Survival after biventricular assist device implantation: an analysis of the Interagency Registry for Mechanically Assisted Circulatory Support database. *J Heart Lung Transplant*. 2011;30:862-9.
4. Hernandez NB, Kirk R, Sutcliffe D, Davies R, Jaquiss R, Gao A, et al. Utilization and outcomes in biventricular assist device support in pediatrics. *J Thorac Cardiovasc Surg*. 2020;160:1301-8.e2.

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Commentary: Two sides of the same coin: Competing biventricular assist device outcomes from Pediatric Interagency Registry for Mechanical Circulatory Support data

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CENTRAL MESSAGE

The typical argument for poorer outcome with BiVAD (vs LVAD) is a difference in the patient's characteristics. Hernandez et al attempted to shed a light on this classic subject using the Pedimacs data.

The last decade has witnessed a substantial stride in the field of pediatric ventricular assist devices (VADs). Among various improvements achieved over time, less frequent use of biventricular assist device (BiVAD) would represent