Continuous flow left ventricular assist devices: Dare to compare

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Disclosures: Author has nothing to disclose with regard to commercial support.

Received for publication Sept 24, 2015; accepted for publication Sept 24, 2015; available ahead of print Oct 27, 2015.

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0022-5223/\$36.00

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<http://dx.doi.org/10.1016/j.jtcvs.2015.09.104>

Stulak and colleagues¹ report on a unique effort by a consortium of 5 experienced centers that focuses on a comparison of outcomes for patients undergoing implantation of 1 of 2 approved durable continuous flow left ventricular assists devices (CFLVADs). Data were prospectively collected and collated in the Network Registry. A total of 734 CFLVAD recipients spanning 10.3 years (76% HeartMate II [Thoratec Corp, Pleasanton, Calif], 24% HVAD [HeartWare Inc, Framingham, Mass]) were included in this retrospective, comparative analysis. HVAD recipients were younger, smaller, less ill, and had better preoperative renal function and hemodynamic characteristics. The HVAD cohort had a disproportionate number of bridge-to-transplant patients.

The main findings of this study include a nearly identical and laudable early survival (HeartMate II, 92.6% and HVAD, 92.5%) that approximated 60% at 3 years for both devices. HeartMate II recipients had a longer median length of stay (20 vs 16 days; $P < .001$) and neither device was an independent predictor of gastrointestinal bleeding or infectious complication.

The clear benefits of these CFLVADs on survival and quality-of-life metrics have been clouded by the high adverse event burden rates and, in particular, by the incidence of cerebrovascular accidents in HVAD recipients and of pump thrombosis in HeartMate II recipients. In regard to the former, the authors found a higher risk of stroke in HVAD recipients, a finding seen in the randomized A Clinical Trial to Evaluate the HeartWare Ventricular Assist System (ENDURANCE) trial² (28.7% vs 12.1% at 2 years; $P < .001$) as well as in a single center series³ (44% vs 10% at 1 year; $P = .04$).

The issue of HeartMate II pump thrombosis was highlighted simultaneously by Starling and colleagues,⁴ who described a nearly 4-fold increase in the incidence of early HeartMate II pump thrombosis and by a review of the Inter-agency Registry for Mechanically Assisted Circulatory Support registry⁵ demonstrating an increase in the incidence of HeartMate II pump exchange or death due to thrombus. Stulak and colleagues¹ failed to duplicate these results and mirrored the findings of the ENDURANCE study documenting a higher rate of pump thrombosis for the HVAD cohort and a subsequent reduction by inflow sintering.

HeartMate II (Thoratec Corp, Pleasanton, Calif) and HVAD (HeartWare Inc, Framingham, Mass) left ventricular assist devices.

Central Message

Comparative effectiveness studies of CFLVADs are critical to advance knowledge and improve the care of patients with advanced heart failure.

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One may be tempted to criticize the findings of this comparative effectiveness study by citing lack of randomization, inclusion of trial patients, and differing populations, but substantial merit can be derived by publication of prospective registries that evaluate competing devices. Such registries reflect a more accurate real-world experience, can provide data granularity (eg, specific infectious organism), and outline protocols and practice patterns (eg, attitude toward surgical management of moderate tricuspid regurgitation) that are simply not available in national registries.

Our field has a scarcity of comparative effectiveness studies; only the HeartMate II destination therapy trial,⁶

TABLE 1. Comparison of HeartMate II (Thoratec Corp, Pleasanton, Calif) and HVAD (HeartWare Inc, Framingham, Mass) continuous flow left ventricular assist devices

Parameter	HeartMate II	HVAD
Mechanism	Continuous flow, axial	Continuous flow, centrifugal
Operating range (typical range), rpm	6000-15,000 (8000-11,000)	2400-3200 (2400-2800)
Inflow sintering	Complete	Partial (ring)
Placement	Subdiaphragmatic	Intrapericardial
Antithrombotic prescription	Aspirin/warfarin	Aspirin/warfarin
Bridge to transplant approval	Yes, 2008	Yes, 2012
Destination therapy approval	Yes, 2010	No
No. of implants worldwide	>21,000	>9000

the yet-unpublished ENDURANCE trial results, and a single institution study,³ have compared competing technologies. It would be useful to compare devices side by side (Table 1). Furthermore, as health care reform focuses on containing growth, medical device companies will face the pressure already existing for the pharmaceutical industry to provide clinical proof of efficacy, safety, and/or cost benefit when compared to available alternatives.⁷ As a field we must embrace the forces that are shaping health care delivery and support studies that provide evidence of value to desperately ill patients. We must dare to compare!

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