In pursuit of the optimal hemocompatible left ventricular assist device

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

Received for publication Aug 7, 2018; accepted for publication Aug 10, 2018; available ahead of print Sept 25, 2018.

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J Thorac Cardiovasc Surg 2019;157:600-1

0022-5223/\$0.00

Published by Elsevier Inc. on behalf of The American Association for Thoracic Surgery

<https://doi.org/10.1016/j.jtcvs.2018.08.024>

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Central Message

The EVAHEART (Evaheart Inc, Houston, Tex) LVAD has a more favorable hemocompatibility profile than the HeartMate 3 (Abbott, Chicago, Ill) in a circulatory mock loop system.

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Left ventricular assist device (LVAD) implantation is a firmly established treatment modality for advanced heart failure; however, major complications such as nonsurgical bleeding, driveline infections, pump thrombosis, and stroke limit wider application to patients with less severe heart failure. Of note, more than 60% of patients who receive a continuous flow LVAD experience such severe adverse events within the first year.¹

The HeartMate 3 LVAD (Abbott Inc, Chicago, Ill) was developed with novel design features, including centrifugal flow, a magnetically levitated rotor with no mechanical bearings, wide blood flow passages, and an artificial pulse mode. The pulse mode was designed to reduce thrombotic events and mimic physiologic flow. The 2-year results of the Momentum 3 trial² demonstrated superiority of the HeartMate 3 over the HeartMate II axial-flow pump on survival free of disabling stroke, reoperation from device malfunction, and thrombosis, but it is disappointing that no difference in the incidence of gastrointestinal bleeding, stroke, and driveline infections was noted.

In comparison, the EVAHEART (Evaheart Inc, Houston, Tex) LVAD was designed with a hydrodynamically levitated bearing, large blood flow gaps, lower operational revolutions per minute range, and a pulsed flow feature created by a significant flow difference between systole and diastole. A better hemocompatible profile of the EVAHEART has been attributed to decreased shear resulting from enhanced clearance between the impeller and the pump housing, better pulsatility, and the mechanical seal system with a recirculating purge system (Cool-Seal), which may contribute to a low hemolysis rate. In this cool-seal system, the seal temperature is maintained at less than 40°C to prevent heat denaturation of blood proteins.³

In this issue of the *Journal*, Zayat and colleagues,⁴ using a circulatory mock-loop, present an in vitro comparison of

hemocompatibility between the EVAHEART and the HeartMate 3 centrifugal LVADs. They demonstrate less hemolysis, lower coagulation activation, and better preservation of the von Willebrand factor functional activity with the EVAHEART compared with the HeartMate 3. Clinical studies to date in Japan have demonstrated that the EVAHEART LVAD has lived up to its promise of having very low nonsurgical bleeding rates, possibly related to the better hemocompatible profile. In the first 96 patients who received the EVAHEART, no gastrointestinal bleeding was noted and the Japanese Registry for Mechanically Assisted Circulatory Support reports a 3-year postoperative bleeding rate of only 6.2%.^{5,6} In contrast, the rate of bleeding events in patients with the HeartMate 3 reached 15%.⁷

However, caution should be exercised in generalizing these results because in vitro studies are unable to recreate native cardiovascular anatomy containing metabolically active endothelial cells and organs. The plastic tubing used to create the mock loops can activate multiple hematologic pathways, and the nonpulsatile rigid tubes by themselves instead of the pump alone can cause Von Willebrand factor degradation and shear injury to blood components.⁸⁻¹⁰ Thus, for wider acceptance of the EVAHEART LVAD, well-designed clinical trials might have to be undertaken to clarify its role in LVAD armamentarium.

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