

FOCUS ISSUE: TECHNOLOGY AND HEART FAILURE THERAPEUTICS 2024 SHARK TANK

LETTERS

RESEARCH LETTER

Pulsatile Ventricular Assist Platform

A Novel Surgically Implanted Ventricular Assist Device



Temporary mechanical circulatory support (MCS) in cardiac surgery is expanding. It has been proven to reduce perioperative mortality in postinfarction septal rupture and to stabilize hemodynamics until surgical correction can be safely performed. Furthermore, it has been found to enhance survival and long-term outcomes by preventing postcardiotomy cardiogenic shock and facilitating weaning in patients dependent on cardiopulmonary bypass. MCS is more beneficial when implanted prophylactically before circulatory collapse. However, it has also been demonstrated to improve survival rates in cases of cardiac arrest.¹⁻⁵

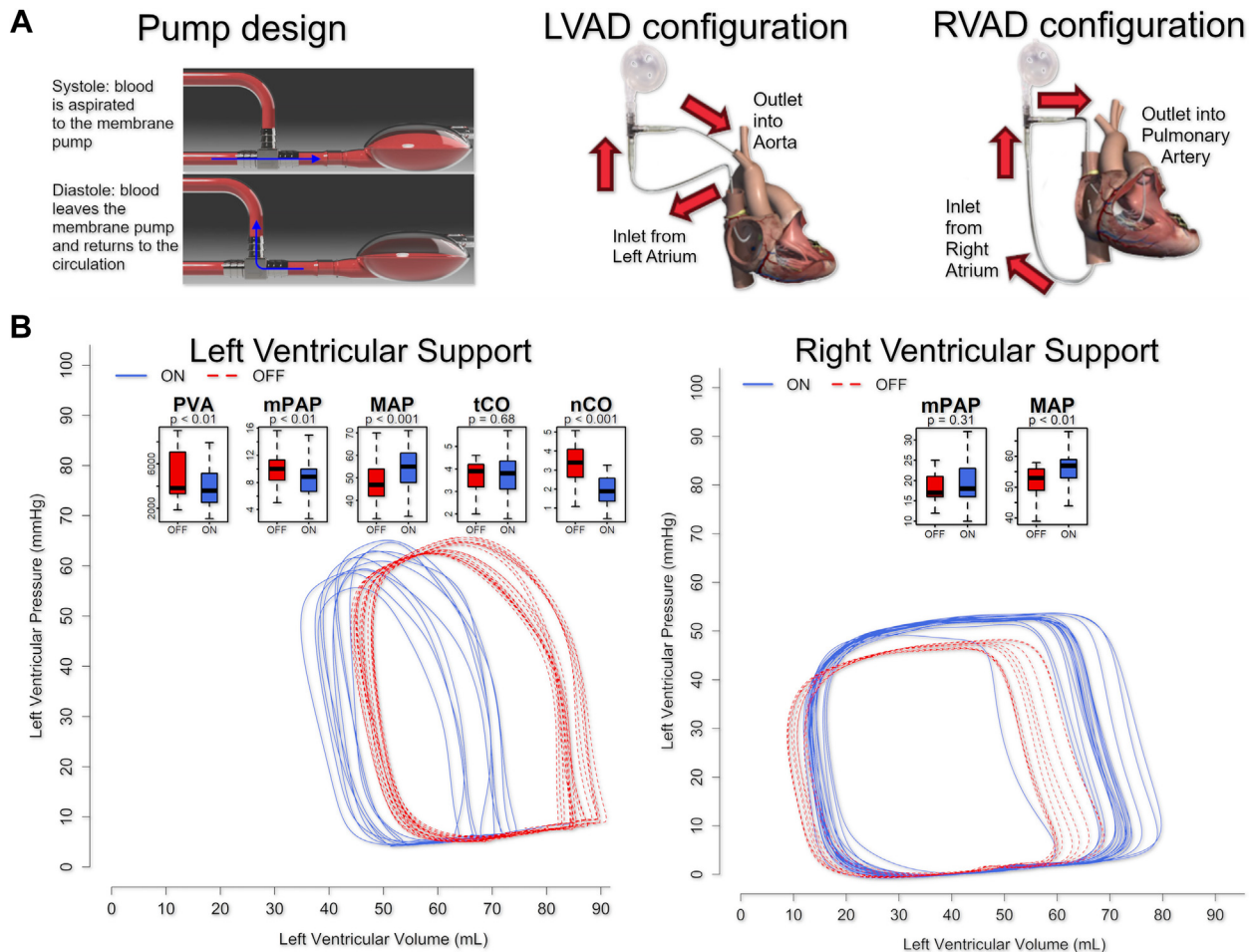
In the operative setting, MCS devices are considered adequate if they: 1) reduce intracardiac pressures and volumes; 2) increase myocardial oxygen supply and end-organ perfusion; 3) minimize myocardial oxygen consumption; and 4) decongest the venous circulation downstream. Pressure-volume (PV) analysis allows real-time evaluation of these subtle changes and is the gold standard for evaluating hemodynamic interventions.³⁻⁵

Modern MCS devices currently depend on continuous flow, but recent evidence suggests that pulsatile flow may be more physiological and effective.^{1,4} Therefore, developing new pulsatile ventricular assist devices (VADs) may improve the efficacy of MCS therapy and potentially enhance clinical outcomes.

We have developed a novel MCS prototype that operates on pulsatile synchronized flow and can be connected to any intra-aortic balloon pump (IABP) console. The pulsatile ventricular assist platform (pVAP) is capable of assisting either the right or the left ventricle (LV). It consists of a T-shaped splitter with a flow-driven 2-way valve on its lumen. One opening of the splitter is connected to a membrane

pump, while the other 2 openings serve as the inlet and outlet for the blood. The operator places specific cannulas on the desired heart chambers or blood vessels and connects them to the inlet and outlet of the splitter. The membrane pump, which is connected to the IABP console, is divided into a blood chamber and a helium chamber by a thin, flexible membrane (**Figure 1A**). The 2-way valve directs the flow by occluding the outlet during systole and the inlet in diastole. During systole, helium aspiration creates negative pressure on the blood chamber, which fills with blood from the circulation. In diastole, the reverse occurs, expelling up to 55 mL of blood back into circulation. The frequency with which aspiration/ejection cycles occur can be autonomously set at the IABP console or synchronized with the native heart rate using the electrocardiogram or the arterial blood pressure waveform.

Thirteen healthy pigs weighing between 69 and 100 kg were anesthetized, sedated, and anticoagulated (activated coagulation time >190 seconds). A pulmonary artery catheter was inserted to continuously monitor the pigs. A conductance catheter was placed in the LV (CDLeycom). The pVAP was implanted through sternotomy as a right ventricular assist device (RVAD) in 7 animals and as a left ventricular assist device (LVAD) in 6 other animals. The RVAD configuration utilized 14- to 19-F cannulas to collect blood from the vena cava or right ventricle (n = 3) and eject it into the pulmonary artery. In the LVAD configuration, 20- to 28-F cannulas collected blood from the left atrium and ejected it into the ascending aorta. The console operated asynchronously with the native heart. The flow of the pump outlet was measured using a flowmeter (em-tech GmbH). Blood pressure was measured in the ascending aorta and the pulmonary trunk. Measurements were taken with the device both off and on. The experiments were conducted in compliance with institutional and national requirements for the care and use of laboratory animals, and received approval from the animal care and use committee. This preliminary analysis compared all available hemodynamic data between on and off states for both LVAD and RVAD configurations using Mann-Whitney U

FIGURE 1 Design and Hemodynamics

(A) Design and operation of the new prototype. Blood is directed from and to the circulation using an extra-corporeal chamber as a temporary receptacle. The surgical setup is shown on the right side. (B) The prototype unloads the left ventricle, shifting the pressure-volume loops to the left and downward. This coincides with a reduction in myocardial oxygen consumption and an optimization in systemic and pulmonary pressures. When used in the right side, the prototype increases left ventricular preload and shifts the left ventricular pressure-volume loops in the opposite direction. This coincides with improvements in systemic and pulmonary pressures as well. DPAP = diastolic pulmonary artery pressure; MAP = mean arterial pressure; mPAP = mean pulmonary artery pressure; nCO = native cardiac output; PVA = pressure-volume area; RVAD = Right Ventricular Assist Device; SPAP = systolic pulmonary artery pressure; tCO = total cardiac output.

tests with an alpha level of 5% in the R Statistical Package v4.3.2 (R Foundation for Statistical Computing).

The pump generated a flow of 2.2 ± 0.3 L/min when operating as an LVAD (in vivo) and 2.7 L/min when operating as an RVAD (in vitro). As an LVAD, the pVAP unloaded the LV, resulting in a leftward and downward shift of the PV loops (Figure 1B). The PV area and the mean pulmonary artery pressure exhibited significantly lower values, whereas the mean arterial pressure increased significantly. The PV area is a proxy for myocardial oxygen consumption.

The total cardiac output (CO) did not show any significant difference with the VAD on vs off. However, the native CO exhibited significantly lower values with the LVAD on. This indicates a down-regulation of the LV function with reductions in output and metabolic demands, along with stabilization of total CO and increased systemic pressures. As an RVAD, the pVAP increased the LV preload, causing the LV PV loops to shift rightward and upward. The mean arterial pressure was higher, and the mean pulmonary artery pressure trended towards higher levels (Figure 1B).

In summary, the first experiments with the pVAP demonstrated it is effective in improving hemodynamics intraoperatively. Its ease of use and customizable features have the potential to make it a flexible solution for high-risk cardiovascular procedures.

Marcelo B. Bastos, MD, MHSc^a

*Oren Malchin, MBA^c

Sara Knigge, PhD^b

Günes Dogan, MD^b

Ezin Deniz, MD^b

Jan D. Schmitto, MD, PhD^b

*PulseCath BV

Nieuwe Stationsstraat 20

6811 KS, Arnhem, the Netherlands

E-mail: oren@pulsecath.com

From the ^aThoraxcenter, Erasmus University Medical Center, Rotterdam, the Netherlands; ^bHannover Medical School, Hannover, Germany; and ^cPulseCath BV, Arnhem, the Netherlands.

PulseCath BV funded the study and provided the equipment. Dr Malchin is the CEO of PulseCath BV. Dr Bastos has received personal fees from PulseCath BV. All other authors have reported that they have no relationships relevant to the

contents of this paper to disclose. The authors would like to express their gratitude to the entire team at Medimplant GmbH for their valuable contribution.

This work was presented at the 2024 CRF THT Shark Tank; March 4-6, 2024, Boston, Massachusetts.

Editor's Note: To view the authors' full presentation at TCTMD Shark Tank, please visit <https://www.jacc.org/journal/basic-translational/tht-2024-shark-tank>.

The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the [Author Center](#).

REFERENCES

1. Salter BS, Gross CR, Weiner MM, et al. Temporary mechanical circulatory support devices: practical considerations for all stakeholders. *Nat Rev Cardiol*. 2023;20(4):263-277.
2. Kamga P, Kaira H, Paxton JH. Short-term mechanical circulatory support devices: uses and outcomes. *Curr Emerg Hosp Med Rep*. 2024;12(11):1-10.
3. Bastos MB, Burkhoff D, Maly J, et al. Invasive LV pressure-volume analysis: overview and practical clinical implications. *Eur Heart J*. 2020;41(12):1286-1297. <https://doi.org/10.1093/eurheartj/ehz552>
4. Bastos MB, McConkey H, Malkin O, et al. Effect of next generation pulsatile mechanical circulatory support on cardiac mechanics: the PULSE trial. *Cardiovasc Revasc Med*. 2022;42:133-142.
5. Burkhoff D, Naidu SS. The science behind percutaneous hemodynamic support: a review and comparison of support strategies. *Catheter Cardiovasc Interv*. 2012;80(5):816-829.