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Commentary: To vent or not, that is the question

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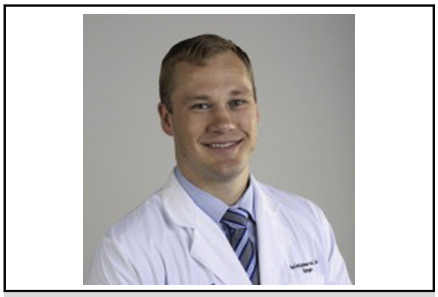

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CENTRAL MESSAGE

A proposed randomized trial would address the benefits of left ventricular venting using a percutaneous ventricular assist device in ECMO patients.

In December 2021 issue of *JTCVS Open*, Ibrahim and colleagues[1] outline the rational and design for their ongoing clinical trial at the University of Pennsylvania in "A Prospective Randomized Trial of Early LV Venting Using Impella CP for Recovery in Patients With Cardiogenic Shock Managed With VA ECMO (REVERSE Trial)." The authors are to be commended on such a difficult undertaking to answer a critical question in the field of mechanical circulatory support.

Venoarterial extracorporeal membrane oxygenation (VA ECMO) has become widely adopted for managing acute decompensated cardiogenic shock as it provides adequate blood flow and oxygenation to limit end organ malperfusion syndromes. Nevertheless, this lifesaving therapy is not without complications. Failure of myocardial recovery remains a critical problem in patients on VA ECMO. Left ventricular (LV) distention can occur during VA ECMO due to poor contractility in the ill heart, aortic regurgitation, antegrade LV filling, and most notably, increased afterload secondary to ECMO flow into the aorta. LV distention can lead to multiple complications: it results in increased wall stress and myocardial oxygen demands, and elevations in LV end-diastolic pressure can cause pulmonary edema and subsequent hypoxemia. These sequala contribute to the consistently high mortality rates of VA ECMO for cardiogenic shock.

Medical and surgical therapy can be used to combat the untoward effects of LV distention. Inotropy, diuresis, and volume removal via dialysis can help offload the failing ventricle but are often insufficient. Transvenous atrial septostomy, intra-aortic balloon pumps, percutaneous ventricular assist devices, and surgical vents are invasive means of offloading the LV. Several retrospective studies have shown the safety and efficacy of LV venting via the Impella (Abiomed, Danvers, Mass) percutaneous micro-axial ventricular assist device.[2-6]

In this current manuscript, Ibrahim and colleagues[1] outline a single-institution (multicenter) randomized controlled trial to assess the safety and efficacy of early (within 24 hours of ECMO initiation) LV venting using Impella. The study design is sound and aims to answer a highly relevant clinical question. The primary end point is survival free from inotropes, mechanical circulatory support, or transplantation at 45 days. This will be the first prospective, randomized trial to address this critical issue.

Although the authors are optimistic, there are undoubtedly challenges ahead. Statistical modeling suggests they will need 48 months to recruit; however, one cannot help but assume accruing patients for this trial will be challenging, as the authors admit. Fortunately, the Penn Medicine system is high volume for cardiogenic shock and mechanical circulatory support. The authors also mention the possibility of including additional institutions. Another significant limitation acknowledged by the authors is the opportunity for crossover, whereby a patient randomized to the VA ECMO alone arm requires insertion of an Impella at a later time frame. The authors' preliminary data show only a 1 in 17 crossover rate, and they intend to perform

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both intention-to-treat and as-treated analyses to address the crossover.

Despite these challenges, the authors are dedicated to completion of this study, and we eagerly await the results to aid in the care of these critically ill patients. We would like to congratulate Ibrahim and colleagues on this well-designed study.

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