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Editorial

Innovative Intra-Aortic Circulatory Support Pump: Novel Hemodynamics

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In the past 3 decades, interventional cardiology has evolved in a "golden era" of innovation, providing an ever-expanding portfolio of devices (and drugs) that have transformed disease management. The advent of percutaneous mechanical circulatory support (MCS) devices has shifted the paradigm for the management of hemodynamic compromise and has facilitated the performance of high-risk percutaneous coronary interventions (PCIs).

First came the intra-aortic balloon pump (IABP), which boosts aortic pressure and coronary perfusion by systolic unloading and diastolic augmentation, thereby establishing its value in unstable ischemia and decompensated heart failure. Innovation has relegated the IABP to secondary status. Left ventricular (LV) pumps (eg, Impella) that directly generate cardiac power while concomitantly unloading the ventricle have attained superior hemodynamic benefits, increasing cardiac output (CO) and, thereby, stabilizing aortic perfusion pressure while simultaneously reducing pulmonary congestion (including under conditions of severe mitral regurgitation). Importantly, Impella is highly valuable in high-risk PCI, providing a "safety net" of hemodynamic stability that facilitates more complete revascularization.[1]

ModulHeart: A novel intra-aortic MCS device

The present study[2] reports the safety and feasibility of ModulHeart (Puzzle Medical Devices Inc), a novel percutaneous intra-abdominal aortic MCS device configured by 3 in-parallel pumps constrained in an expandable nitinol anchor. Each pump is designed to rotate at a speed lower than that in comparable devices, thereby cumulatively augmenting CO with lesser blood element damage. For deployment, the 3 pumps are aligned "in series" along a catheter, with the unexpanded anchor device just behind. Delivered through a 22F femoral sheath, the pumps are advanced until the anchor device is unsheathed in the aorta distal to the renal arteries, and then the pumps are pulled back into and assembled "in parallel" within the anchor. Disassembly is achieved by advancing the pumps in series, and then resheathing the anchor, followed by the pumps.

This first-in-human feasibility and safety study in 4 patients undergoing high-risk PCI (so designated on the basis of coronary anatomy, not clinical parameters, because LV performance and renal function were intact) showed the following: (1) device implantation was successful in all and accomplished efficiently (delivery time, 8 minutes; removal, 7 minutes); (2) hemodynamic benefits were characterized by increased CO (2.4–3.1 L/min) with concomitant reduction in filling pressures, including LV end-diastolic pressure (LVEDP) (9–2 mm Hg); interestingly, aortic pressures proximal and distal to the device were unchanged; (3) marked increases in urine output during and after the pump run; and (4) neither hemolysis nor pump thrombosis.

Translating innovative creativity to efficacy and clinical applicability

The authors should be congratulated for the creative development of this novel device and early "proof of concept" study. Achieving the clinical promise of ModulHeart requires further study to elucidate a number of important considerations.

Hemodynamic mechanisms of action

The ModulHeart mimics neither a direct LV pump nor an IABP; rather, it appears to act via "hybrid" hemodynamic mechanisms. This direct intra-aortic pump is hypothesized to increase CO and decrease LVEDP by afterload reduction attributable to induction of a "negative pressure head" at the pump inlet and/or downstream "Venturi effects." Interestingly, the observed enhanced urine output is ascribed to "intra-aortic fluid entrainment" conjectured to increase renal flow and perfusion. These proposed mechanisms require careful pathophysiological consideration. Based on first principles, the device is a direct pump that generates CO at least distal to its abdominal aortic position. To what extent it reduces LV afterload and, thereby, improves CO and lowers filling pressures requires further study. Whether renal function is augmented by the mechanism described is an intriguing hypothesis.

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Performance in severe LV dysfunction and hemodynamic compromise

The present "proof of concept" study was performed in hemodynamically stable patients with intact LV ejection fraction. Whether this distally positioned intra-aortic pump can achieve sufficient hemodynamic support in patients manifesting hemodynamic compromise from a severely depressed LV ejection fraction has yet to be established. Under this pathophysiological setting, the "unloading" efficacy of this aortic pump must be carefully considered. A major attribute of LV pumps (eg, Impella) is direct unloading of the depressed, dilated LV with markedly elevated filling pressures. Therefore, in addition to directly generating CO, the LV pump concomitantly decompresses the ventricle, which exerts manifold beneficial effects, including relief of pulmonary congestion and reduced preload, which relieves ischemia by lowering this primary determinant of O_2 demand and diminishing the adverse compressive effects of elevated LVEDP on the subendocardial capillary bed (ie, the "vascular waterfall effect"). Lessons learned from extracorporeal membrane oxygenation alone in cardiogenic shock emphasize that MCS without LV unloading can exert deleterious effects because increased venous return to the "unvented" LV may exacerbate distension, thereby worsening pulmonary congestion and imposing detrimental effects on LV performance and recovery.[3] Appreciation of this problem has led to a combined extracorporeal membrane oxygenation and Impella support strategy (ECpella) to concomitantly maintain systemic circulation and unload the LV. The present observations provide cautious optimism that ModulHeart can unload the LV however, the extent of this capability needs to be established. Finally, the ModulHeart's requisite of a 22F arterial sheath must be considered in comparison to Impella (14F sheath), particularly for "single-access technique" PCI.

Continued innovation renders the MCS field increasingly bright. Future ModulHeart investigations in patients with decompensated heart failure will help establish the niche for this device.

Declaration of competing interest

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