Percutaneous temporary circulatory support devices and their use as a bridge to decision during acute decompensation of advanced heart failure

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ABSTRACT

Temporary mechanical cardiac support (TMCS) devices intend to restore systemic perfusion and prevent further end-organ damage in patients with refractory cardiogenic shock until the insult is addressed. TMCS has been associated with reductions in hospital costs and in-hospital mortality. We review the four primary TMCS modalities available: intra-aortic balloon pump, TandemHeart, veno-arterial extracorporeal membrane oxygenation, and Impella pump. All have their own implantation technique and hemodynamic profile, and their use may therefore be tailored to the specific patient's needs. The appropriate TMCS may thus help stabilize the patient, enabling the care team to make decisions about durable support or transplantation.

KEYWORDS Advanced heart failure; bridge to decision; cardiogenic shock; mechanical circulatory support

Heart failure is one of the most challenging situations of modern medicine and a common reason for hospitalizations worldwide. According to recent estimates, 2.6% of Americans and 11% of people over the age of 80 years have heart failure.¹ Despite advances in therapy, acute heart failure portends a poor prognosis with high morbidity and mortality. The most common cause of in-hospital mortality in these patients is refractory cardiogenic shock, which carries a mortality rate exceeding 50%.² Historically, a therapeutic strategy in the setting of cardiogenic shock involved the use of inotropic support, afterload reduction with vasodilators, tedious volume management with diuretic use, and revascularization in cases of ischemic disease.³ Inotropes and vasodilators help increase cardiac output, but the true impact of inotropes on end-organ perfusion may vary based on the degree of vasoconstriction. High levels of vasoconstriction, in turn, can adversely affect the heart itself.⁴ Over the last decade, utilization of temporary mechanical cardiac support (TMCS) devices has increased rapidly in the treatment approach of refractory cardiogenic shock.⁵ Interestingly enough, use of short-term TMCS has been associated with a reduction of hospital costs along with a decrease in in-hospital mortality.⁵

TMCS devices intend to restore systemic perfusion and prevent further end-organ damage until the insult that resulted in cardiogenic shock is addressed. This is accomplished by augmenting cardiac output and left ventricular (LV) unloading, decreasing filling pressures, and improving coronary perfusion.⁶ These devices provide the circulatory support that enables the care team to make decisions as to the patient's candidacy for durable support devices or transplantation.⁷ Essentially, four primary TMCS devices are available for hemodynamic support: intra-aortic balloon pump (IABP), the TandemHeart percutaneous ventricular assist device (TandemLife, Pittsburgh, PA), veno-arterial centrifugally driven extracorporeal membrane oxygenation (VA-ECMO), and Impella pumps (Abiomed, Danvers, MA).⁸ These devices each have their own implantation technique and hemodynamic profile. Therefore, their use may be tailored to the patient's specific needs. *Table 1* provides an overview of the main technical characteristics of these devices.⁹

TYPES OF TEMPORARY MECHANICAL CARDIAC SUPPORT

The IABP, used for cardiogenic shock since 1968, is one of the oldest TMCS devices and has been the mainstay for

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Received February 12, 2018; Revised April 20, 2018; Accepted April 26, 2018.

Table 1. Technical features of currently available percutaneous assist devices^a

	IABP	TandemHeart	Impella 2.5	Impella CP	ECMO
Pump mechanism	Pneumatic	Centrifugal	Axial flow	Axial flow	Centrifugal
Cannula size (French)	7–9	21 inflow, 15–17 outflow	13	14	18–21 inflow, 15–22 outflow
Hemodynamic support (L/min)	0.5	Max. 4.0	Max. 2.5	Max. 3.7–4.0	Max. 7.0
Pump speed (rpm)	0	Max. 7500	Max. 51,000	Max. 51,000	Max. 5000
Implantation time	+	++++	++	++	++
Risk of limb ischemia	+	+++	++	++	+++
Anticoagulation	+	+++	+	+	+++
Hemolysis	+	++	++	++	++
Postimplantation management complexity	+	++++	++	++	+++

^a+, ++, +++, +++++, relative qualitative grading concerning time ("implantation time"), risk ("risk of limb ischemia"), intensity ("anticoagulation," "postimplantation management complexity"), and severity ("hemolysis"). Reprinted from Van Herck et al⁹ with permission from Sage Publications Ltd. IABP indicates intra-aortic balloon pump; ECMO, extracorporeal membrane oxygenation.

hemodynamic support.¹⁰ More than 40,000 IABPs are used annually in the USA, and up to 19% of those are used in patients with cardiogenic shock.¹¹ The IABP uses the concept of counterpulsation to help with the augmentation of diastolic aortic pressures and LV afterload reduction. It provides an approximately 20% increase in cardiac output with a 10% to 20% decrease in heart rate with an overall increase in myocardial oxygen supply.⁷ However, despite the stabilization of hemodynamics, the IABP has not shown the expected improvement in mortality.³ The cost of the device itself is relatively low (estimated \$1500 to \$2000). The average cost of hospitalization requiring IABP support was around \$55,000 based on the national inpatient sample data from 2007 through 2012.¹²

As TMCS devices evolved, the Impella Recover System was developed in Europe and has been increasingly utilized in patients with acute heart failure, acute coronary syndromes, and protected percutaneous coronary intervention (PCI). The Impella system has a caged blood flow inlet placed retrograde into the LV. The pump aspirates blood from the LV, which is then injected by means of a micro-axial pump into the ascending aorta. The device may be implanted via the femoral, brachial, or axillary approach. The Impella platform consists of three commercially available pumps providing various degrees of hemodynamic support. Impella 5.0 offers a full systemic circulatory support (up to 5 L/min), direct LV unloading, and minimally invasive implantation without sternotomy.¹³ The axillary approach allows for patient mobility with profound device stability. This is crucial in patients who are awaiting transplant or left ventricular assist device (LVAD) placement and who may be dependent on this device for several weeks. There have been reports of successful use of Impella 5.0 for hemodynamic support in cardiogenic shock in order to prolong the time needed to make a decision for long-term management.^{14–16} The cost associated with this technology is considerable

(\$35,000–\$50,000 per device console), and the disposable components range from \$1000 to \$32,000.¹⁷ The index admission cost for patients being treated with a percutaneous ventricular assist device was around \$91,000 with an average length of stay of 13 days.¹⁸

Other available TMCS devices utilize extracorporeal pumps and include TandemHeart devices and VA-ECMO systems.¹³ The TandemHeart LV support pump requires a trans-septal puncture to divert blood from the left atrium to the femoral artery. This unloads the left atrium and reduces end diastolic pressures while providing a significant increase in both cardiac output and mean arterial pressure.^{13,19} This helps with increased oxygen delivery and can assist with discontinuation of inotropes. The TandemHeart has been used for circulatory support in patients with refractory cardiogenic shock in both ischemic and nonischemic cardiomyopathy.¹⁹ The TandemHeart can also be used in an emergent setting. However, trans-septal punctures are not done emergently in most centers.⁸

The ECMO system has been available for 4 decades and was initially used primarily in neonates and respiratory distress.²⁰ With the recent evolution of ECMO systems and improved implantation techniques, placement is not necessarily performed in the operating room. VA-ECMO has been used more frequently for hemodynamic support, with Guenther and colleagues observing a 30-day survival rate of 49% in patients with cardiogenic shock.²¹ VA-ECMO continues to be used more frequently in patients with accompanying pulmonary failure who fail other TMCS devices. Total procedure cost and charge for ECMO placement in the USA run around \$45,700 and \$63,884, respectively.²² The mean daily cost of a patient on ECMO runs around \$16,430.²³ The average length of stay of patients on ECMO for a cardiac condition ranged from 5.1 to 10.1 days in the USA, and the total treatment cost ranged from \$105,034 to \$335,565.²² Another study showed an average cost of surgical hemodynamic support (ECMO and extracorporeal

VAD) of \$144,257 with an average length of stay of 18 days.¹⁸

OUTCOMES

TMCS devices have had a major impact on morbidity in patients with decompensated advanced heart failure in refractory shock. However, their efficacy is inherently dependent on prompt assessment of the patient's clinical status, determining the need and candidacy for TMCS, and having a robust system for implementation of these devices. This has led to the establishment of a multidisciplinary shock team at several institutions. The shock team typically consists of interventional cardiology, an advanced heart failure specialist, cardiothoracic surgery, and critical care. Constant communication among these providers is necessary to ensure that all options are considered and that the best approach is selected. Steps should be taken to facilitate multidisciplinary rounds with contributions from each of the four core disciplines. It is important that any potential TMCS device option can be deployed 24 hours a day, 7 days a week. Early studies have shown that shock teams can help decrease time to implementation of the device; certain institutional data have shown a slight but statistically significant decrease in short- and long-term mortality rates as well.^{24,25}

Registry data have shown a wide variation in outcomes for cardiogenic shock from one institution to another with the use of TMCS devices, especially with the Impella.²⁶ This is most likely due to variation in the recognition of shock and timing of the placement of these devices. This variation in outcomes has led to initiatives to establish a standardized protocol for implementation of TMCS in patients with cardiogenic shock, especially in the setting of acute myocardial infarction. The Detroit Cardiogenic Shock Initiative (DCSI) is an example of one such initiative.

The DCSI is a collaboration among five heart hospitals in the Detroit, Michigan, area with the goal of determining whether outcomes in cardiogenic shock can be improved by using standardized protocols, such as inserting an Impella early and prior to PCI. Initial results have been encouraging, with a rapid door-to-LV unloading time averaging 82 minutes. Most (62%) of these patients were supported with Impella prior to PCI. These results showed an increase in survival rates in patients with cardiogenic shock from 51% to 84%. All survivors were discharged home with their native heart.²⁴ Preliminary findings from the DCSI showed improved clinical outcomes, lending support for early application of TMCS prior to reperfusion in the setting of hemodynamic compromise. Initial results also showed a decrease in inotropic/vasopressor support in approximately 80% of cases. The improved outcomes correlated with an increased use of Impella with protocol-driven hemodynamic monitoring guiding escalation and weaning, resulting in reduced exposure to high-dose inotropes. The DCSI experience has led to the concept of "door-to-support time" as a new metric for potential improvement in

outcomes in patients with acute myocardial infarction and cardiogenic shock.²⁶

Historically, deployment of TMCS was reserved for patients with significant hemodynamic compromise, but there was an inherent bias in the utilization of TMCS only in patients who were considered reasonable candidates for a bridge-to-transplant or destination LVAD or for an orthotopic heart transplant.⁵ Decisions as to whether a patient would be a reasonable candidate for transplant, durable circulatory support, or palliative care can be complex, and a meaningful amount of time is needed.¹⁶ TMCS can assist with hemodynamic stabilization and, in turn, help the multidisciplinary team make these critical decisions. In a recently published multicenter retrospective study, Hall et al showed that the Impella 5.0 may provide a reasonable bridge to destination strategy for patients with advanced heart failure and acute hemodynamic instability.¹⁶ Use of the Impella 5.0 in these patients showed statistically significant improvements in the cardiac index, systolic blood pressure, cardiac output, and pulmonary capillary wedge pressure. As many as 66% of patients survived to the next therapy, which is better than the 50% survival rate in INTERMACS I. Gaudard et al, in a 40-patient retrospective study, showed that the use of Impella 5.0 allowed faster weaning of inotropes along with a better than predicted 28-day mortality.¹⁴ Consistent with previous reports, both of these studies made the case for earlier implantation of the Impella 5.0, before end-organ failure, as the key to successful outcomes.

Over the past decade, the use of durable LVADs has increased exponentially. However, LVAD implantation in INTERMACS I patients has decreased due to the high risk of early postimplantation failure.¹⁶ TMCS devices have provided the physician with an alternative approach. By stabilizing and improving the hemodynamic profile, patients who were not initially candidates for durable LVAD may thus be reconsidered. In a single-center study, Lima et al showed a 75% survival to next therapy and improved hemodynamics with the Impella 5.0.¹⁵ However, a study by Shah and colleagues showed mortality rates similar to those of INTERMACS I in patients undergoing TMCS device implant prior to durable LVAD despite improved hemodynamics.²⁷ Hence, an improved hemodynamic profile in the setting of TMCS devices should be assessed cautiously when considering durable LVAD placement, because these patients may have a high residual risk.²⁷

In summary, the increased use of TMCS has led to a paradigm shift in care delivery for refractory cardiogenic shock. TMCS can provide the needed hemodynamic support in a short time to prevent or to curtail end-organ injury. Its early deployment by a multidisciplinary shock team may improve outcomes in patients with refractory cardiogenic shock. Care teams must recognize that escalating doses of inotropes and vasopressors in the setting of severe refractory cardiogenic shock may eventually be deleterious to the heart due to increases in myocardial oxygen demand. TMCS can

help stabilize these patients so that decisions can be made for the next level of care, whether a bridge to LVAD, transplant, or transition to palliative care.

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