Percutaneous Mechanical Support in Cardiogenic Shock: A Review

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Supplementary Issue: Heart Failure: An Exploration of Recent Advances in Research and Treatment (A)

ABSTRACT: Cardiogenic shock (CS) is a life-threatening condition associated with significant morbidity and mortality. Pharmacological therapy is often the first line of treatment but mechanical support can provide substantial hemodynamic improvement in refractory CS. Percutaneous mechanical support devices are placed in a minimally invasive manner and provide life-saving assistance to the failing myocardium. We review the percutaneous devices currently available, the evidence behind their use, and the new advances in percutaneous technology being evaluated for the treatment of CS.

KEYWORDS: cardiogenic shock, percutaneous mechanical support, heart-assist device

SUPPLEMENT: Heart Failure: An Exploration of Recent Advances in Research and Treatment (A)

CITATION: Gilani et al. Percutaneous Mechanical Support in Cardiogenic Shock: A Review. *Clinical Medicine Insights: Cardiology* 2015:9(S2) 23–28 doi: 10.4137/CMC.S19707.

RECEIVED: November 13, 2014. **RESUBMITTED:** April 09, 2015. **ACCEPTED FOR PUBLICATION:** April 28, 2015.

ACADEMIC EDITOR: Thomas E. Vanhecke, Editor in Chief

TYPE: Review

FUNDING: Authors disclose no funding sources.

COMPETING INTERESTS: Authors disclose no potential conflicts of interest.

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Introduction

Cardiogenic shock (CS) is a serious complication of acute myocardial infarction, with the mortality rate being as high as 50%.[1] CS is defined by systemic hypoperfusion with systolic blood pressure <80 mmHg in the setting of marked decrease in cardiac index (<1.8 L/mm/m^2) with elevated left ventricular filling pressures (pulmonary wedge pressure >18 mmHg).[2] The low output state during CS can lead to multiorgan failure, which is associated with significant morbidity and mortality.

The pathophysiology of CS relates primarily to left ventricular pump failure, which results in decreased systemic and coronary perfusion.[3] Systemic hypoperfusion results in catecholamine release and activation of systemic inflammatory and coagulation cascades.[4] The interplay of these mechanisms then leads to further myocardial ischemia and dysfunction. Although pharmacologic agents such as inotropes and vasoconstrictors are the initial treatment modalities to improve perfusion, they do not break this vicious cycle.[1] Mechanical circulatory support can interrupt this downward spiral by improving hemodynamics and providing time for myocardial recovery.[4] Percutaneous mechanical support can augment cardiac output and therefore serve as a bridge to recovery. The goal of this review is to provide an overview of the percutaneous mechanical support devices currently available for patients with CS.

Intra-Aortic Balloon Pump (IABP)

IABPs were first introduced in humans in the 1960s and are the most commonly used form of mechanical hemodynamic support in CS.[5,6] The balloon is advanced from the common femoral artery into the aorta, with the proximal tip placed before the left subclavian artery (Fig. 1).[7] Inflation of the balloon occurs in diastole, augmenting diastolic pressure to increase coronary blood flow. Deflation occurs in systole, decreasing afterload and promoting left ventricular blood outflow. The net effect is decreased myocardial oxygen consumption, increased cardiac output, and lower peak left ventricular wall stress.[8] The hemodynamic benefit with IABP is increased cardiac output of 0.5–1 L/min.[9] Major complications associated with IABP are low (0.5%), and include limp, bowel, and renal ischemia.[7] The mortality rate with IABP is less than 0.05%.[10] IABP should be used cautiously in peripheral arterial disease and is contraindicated in patients with severe aortic regurgitation and aortic dissection.[7]

However, there is conflicting evidence regarding the benefit of IABP in CS, and randomized trials have been difficult to perform in this patient population.[11] The data from the Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) Trial Registry demonstrated lower in-hospital mortality for patients with CS after myocardial infarction if treated with IABP.[12] Results from the cohort study Global Utilization of Streptokinase and TPA

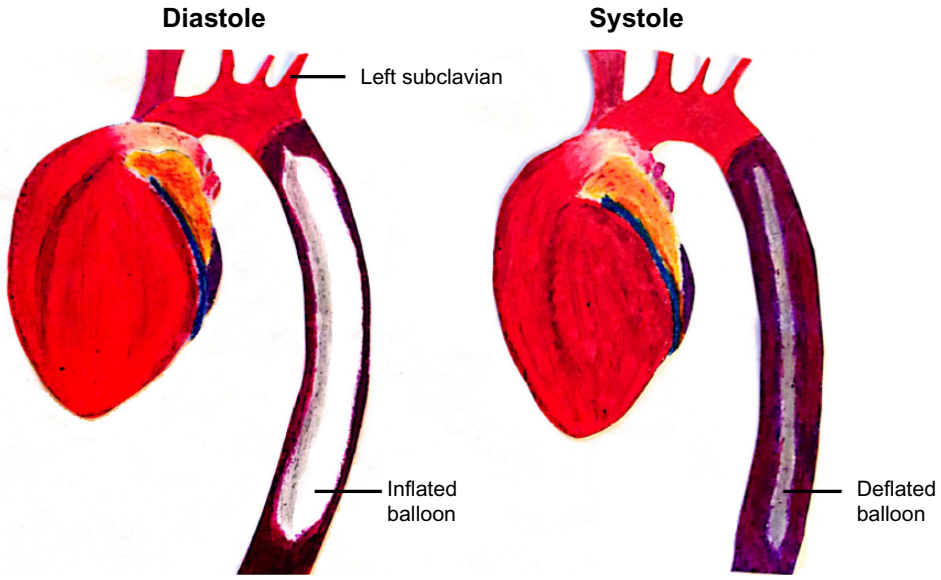

Figure 1. Illustration of intra-aortic balloon pump located distal to left subclavian artery (Pictorial reprinted with permission from artist Ridha Gilani).

for Occluded Coronary Arteries (GUSTO-1) showed that early use of IABP had lower mortality at 30 days and 1 year.[13] More recently, the Intra-aortic Balloon Support for Myocardial Infarction with Cardiogenic Shock (IABP-SHOCK II) trial evaluated 600 patients in CS after myocardial infarction, and randomized them to IABP versus no IABP.[14] This study found no significant difference in all-cause mortality between the two groups at 30 days. Therefore, the 2013 American College of Cardiology/American Heart Association (ACC/AHA) STEMI and European Society of Cardiology (ESC) STEMI guidelines give IABP therapy in CS class IIa and IIb recommendations, respectively.[11,15]

Percutaneous Left Ventricular Assist Devices – Impella® and Tandem Heart®

The Impella (Abiomed Inc.) is an axial flow pump on a pigtail catheter that crosses the aortic valve to unload the left ventricle by delivering nonpulsatile blood flow to the ascending aorta (Fig. 2).[16] Currently, there are three Impella systems available for femoral introduction. The larger Impella 5.0 system provides up to 5 L/min and requires femoral cutdown for placement due its 21 Fr motor pump.[17] The Impella 2.5 device is introduced from a femoral percutaneous approach and can deliver an output of 2.5 L/min through a 12 Fr motor pump. The Impella CP uses the same delivery platform as the Impella 2.5 but is able to provide 4 L/min through a 14 Fr motor pump.

The contraindications to the placement of the device include moderate aortic stenosis or insufficiency, ventricular septal defect, left ventricular thrombus, and significant peripheral vascular disease.[18] Although aortic stenosis is considered an exclusion criterion in clinical trials with Impella, a small series showed that implantation was feasible in patients with severe AS and left ventricular impairment.[19,20] A balloon-assist technique can be used to facilitate device implantation if unassisted attempts fail.[20] The most commonly reported complications of Impella placement include limb ischemia, vascular injury, and bleeding requiring blood transfusion.[21] Hemolysis has been reported in 5%–10% of patients during the first 24 hours.[22] Proper positioning of the inlet cannula reduces risk of hemolysis and aortic valve injury.[4] One small study evaluated the safety profile of Impella in comparison to IABP and found similar vascular and bleeding risk, with blood transfusions occurring in 38.4% and 32.2% of patients in the Impella and IABP groups, respectively.[23]

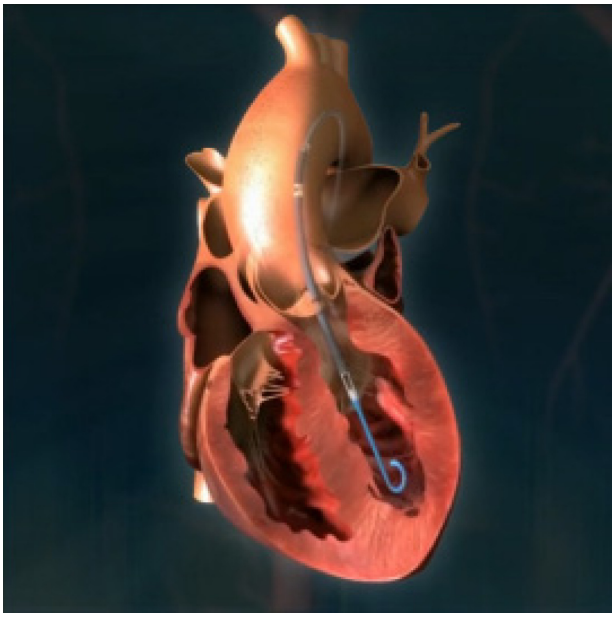

Figure 2. The Impella with the inflow area in the left ventricle and the outflow area in the ascending aorta (Reprinted with permission from Abiomed).

The hemodynamic benefits of Impella have been evaluated in small, randomized controlled trials and observational studies. The Impella LP 2.5 versus IABP in Cardiogenic Shock (ISAR-SHOCK) trial randomized 26 patients with CS due to acute myocardial infarction to treatment with Impella or IABP.[24] The Impella resulted in greater increase in cardiac index (CI) at 30 minutes when compared to IABP (Impella CI 1.71 L/min/m^2 at baseline to 2.20 L/min/m^2 at 30 minutes vs IABP CI 1.73 L/min/m^2 at baseline to 1.81 L/min/m^2) but this difference was not statistically significant and there was absolutely no difference in mortality rates at 30 days. A retrospective review by Lemaire et al evaluated the use of Impella in 47 patients, where the indication for placement included cardiogenic shock in 15 and postcardiotomy cardiogenic shock in 32. Successful Impella wean and ventricular function recovery occurred in 72% of patients.[25] The 30-day mortality in this high-risk population was 25%, which is significantly lower than the 50% morality often seen in patients with cardiogenic shock.[1,25] The USella Registry compared the outcomes of CS in acute myocardial infarction patients supported with Impella 2.5 before percutaneous coronary intervention (pre-PCI) versus those that received the device after percutaneous coronary intervention (post-PCI). The study found better survival to discharge in the pre-PCI group in the setting of refractory CS (65.1% vs 40.7%, $P = 0.003$).[26] A recent meta-analysis involving 2,843 patients from 13 trials compared the safety and efficacy of IABP, percutaneous left ventricular assist device (LVAD), and medical therapy (MT) in patients undergoing high-risk PCI. Mechanical hemodynamic support showed no survival benefit over medical therapy even in cardiogenic shock (IABP vs MT, $P = 0.230$; LVAD vs MT; $P = 0.535$), but was associated with an increase in moderate to severe bleeding.[27]

Impella technology is becoming increasingly important in the management of CS because it improves hemodynamics.[28] The Impella CP combines the added benefit of percutaneous deliverability and higher cardiac output. Although no direct hemodynamic comparison has been described between the Impella CP and 2.5 L, a recent case series showed that the Impella CP device was safe with low incidence of vascular complications.[29] Further prospective randomized and adequately powered studies are necessary to evaluate the usefulness of Impella CP in CS refractory to pharmacotheraphy.

The TandemHeart® device (CardiacAssist Inc.) is an external centrifugal pump, with a 21 Fr inflow cannula placed transeptally into the left atrium and an outflow cannula placed into the femoral artery (Fig. 3).[28] Oxygenated blood is pumped into the femoral artery and can provide 3.5–4.5 L/min of cardiac output.[4] The insertion time on average can exceed 30 minutes in nonemergent situations.[30]

The requirement of transeptal puncture increases the risks and complexity of device placement. The complications associated with device placement include tamponade, major bleeding, aortic insufficiency, critical limb ischemia, arrhythmias, and residual atrial septal defect, which can later require closure.[18] One case series found that access site bleeding occurred in 25% of patients.[31] Contraindications include aortic insufficiency, ventricular septal defect, and significant peripheral artery disease.[18] It can be particularly useful in cases of CS complicated by significant aortic stenosis.

Two randomized, controlled trials and a retrospective analysis have evaluated the efficacy of TandemHeart in CS. The first study randomized 41 patients with acute myocardial infarction presenting with CS to IABP or TandemHeart and showed higher cardiac index but no mortality benefit at 30 days (43% TandemHeart vs 45% IABP).[32] Complications such as severe bleeding ($n = 19$ vs $n = 8$, $P = 0.002$) and limb ischemia ($n = 7$ vs $n = 0$, $P = 0.009$) were encountered more frequently with TandemHeart. A second study randomized 30 patients presenting with CS and found similar hemodynamic improvement with TandemHeart when compared to IABP but no improvement in survival at 30 days.[33] A larger retrospective study analyzed 117 patients with CS refractory to IABP and vasopressor support treated with TandemHeart.[34] Hemodynamic improvement after implantation included an increase in cardiac index (0.52 to 3.0 L/min/m^2), systolic blood pressure, mixed venous oxygen saturation, and urine output. A decrease was seen in pulmonary capillary wedge pressure, lactic acid level, and creatinine. The mortality rate at 30 days was 40.2%.

Despite the hemodynamic improvement seen with Impella and TandemHeart in comparison to IABP, no study has shown a survival benefit. Therefore, the 2013 ACC/AHA STEMI guidelines give class IIb recommendation for alternative left ventricular assist devices for circulatory support in patients refractory CS.[15]

Extracorporeal Membrane Oxygenation (ECMO)

ECMO was first used in adults in 1972, and is able to serve the function of both the heart and lungs.[35] Deoxygenated blood taken out of the body through a drainage cannula is passed through an oxygenator and returned to the systemic circulation.[36] The oxygenator is a gas exchange device that directly oxygenates and removes carbon dioxide from the blood. Blood flow is generated by a centrifugal pump, where a rotating impeller spins blood outwards at high flow rates with minimal trauma to blood components.[7] When combined with an oxygenator, the TandemHeart can also serve as the external centrifugal pump for ECMO (Fig. 4). If blood is removed from a central vein and returned into the venous system, the process is referred to as veno-venous ECMO (VV-ECMO).[37] When blood is drained from the venous system and returned into the arterial system, the process is known as veno-arterial ECMO (VA-ECMO).[37] VV-ECMO provides respiratory support, while VA-ECMO is used for cardiorespiratory support, including CS. Complications associated with VA-ECMO include severe bleeding, hemorrhagic stroke, embolic phenomenon, nosocomial infections, and multiorgan dysfunction.[38,39] Advances in extracorporeal technology,

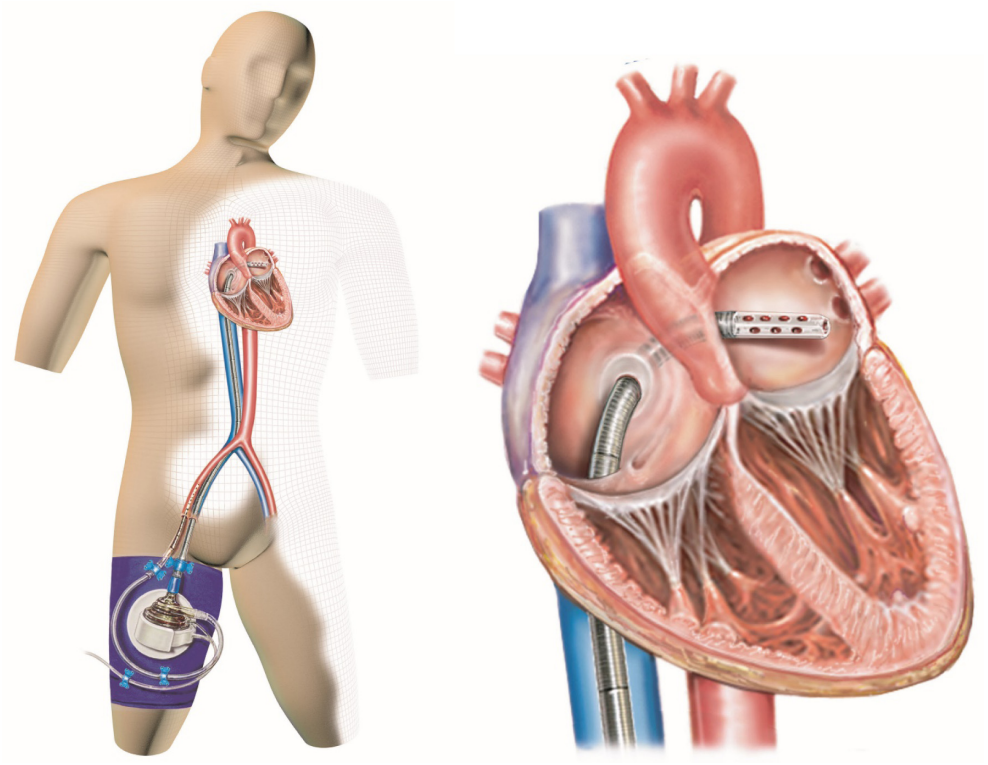

Figure 3. TandemHeart external centrifugal pump placed transeptally into the left atrium and the outflow cannula placed into the femoral artery (Reprinted with permission from CardiacAssist).

including the advent of new pumps and oxygenators, have decreased these risks significantly.[40]

The benefit of ECMO in CS patients has been evaluated in small nonrandomized studies. The survival rate associated with ECMO in these studies ranged from 31%–64%.[38,41–43] The Extracorporeal Life Support Organization (ELSO) registry data collected from 223 ECMO centers reported 4,042 adults treated for CS, with a survival rate of 40% at discharge.[44]

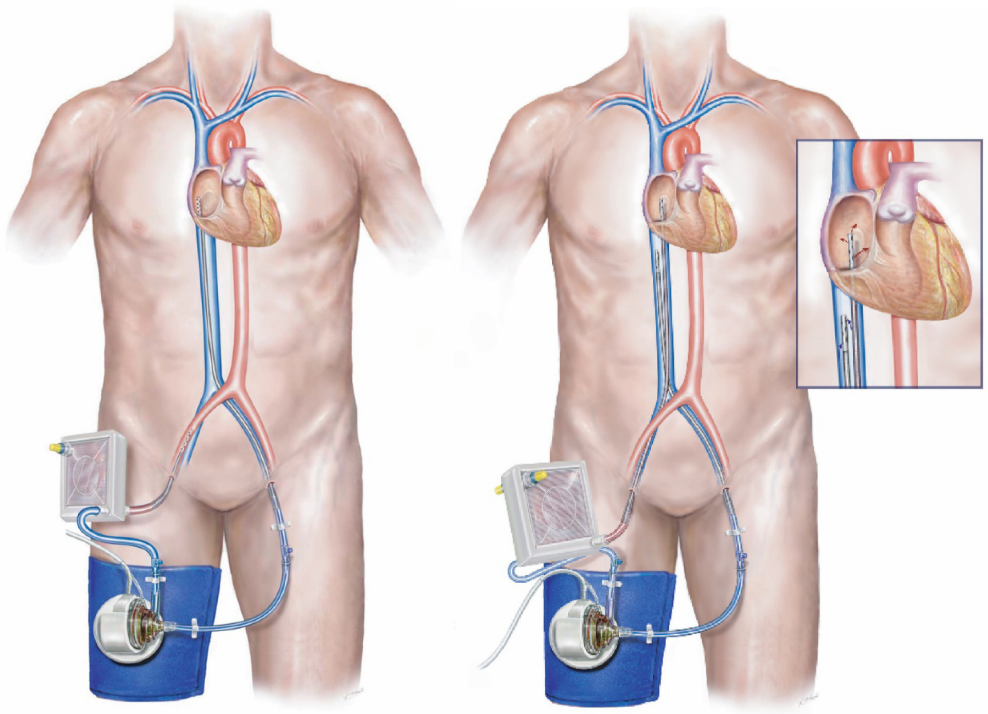

Figure 4. TandemHeart device in VA-ECMO (left) and VV-ECMO configuration (right) (Reprinted with permission from CardiacAssist).

One cohort study from a single institution prospectively compared the outcomes of Impella and TandemHeart versus ECMO for postinfarction or decompensated cardiomyopathy-related CS.[45] No difference was seen between the two groups with respect to hospital mortality, wean from mechanical support, bridge to long-term destination therapy and transplant, or limb complications.

The timing of when to initiate ECMO is controversial, as there are no consensus recommendations from the ACC/AHA.[7,15] ESC STEMI guidelines note that ECMO can be used in CS as destination therapy or a bridge to transplant, but the evidence for benefit is limited.[11] Randomized, controlled trials are ultimately necessary to determine the true benefit of ECMO in CS.[46]

Advancement in Percutaneous Ventricular Assist Devices

Newer percutaneous ventricular assist devices are in development for CS with the goal to provide hemodynamic support while simultaneously limiting complications by using smaller delivery systems. Thoratec Corporation's HeartMate PHP™ is a catheter-based axial flow pump that can provide up to 5 L/min.[47] Inserted percutaneously through the femoral artery, the 12 Fr catheter contains a distal collapsible, covered nitinol cannula with an impeller that expands to 24 Fr. A clinical trial for the evaluation of the HeartMate PHP in CS is currently under way. The Reitan Catheter Pump (RCP) is another transcatheter pump undergoing evaluation for CS. The RCP is a 14 Fr collapsible propeller inside a protective cage that is positioned in the descending part of the thoracic aorta via the femoral artery.[48] An initial small, prospective, nonrandomized study of 14 patients showed 30% improvement in cardiac index at 24 hours (1.85 to 2.45 L/min/m^2; $P = 0.08$), 22% reduction in serum creatinine at 24 hours (174 to 142 umol/L $P = 0.0002$), and an increase in glomerular filtration rate (GFR) from 50.2 to 61 mL/min ($P = 0.001$).[48] The Impella RP (Right Percutaneous) System (Abiomed Inc.) is a percutaneous microaxial pump that is being evaluated for right ventricular failure.[49] It aspirates blood from the inferior vena cava and expels it into the pulmonary artery at the maximum rate of up to 4.4 L/min. It may serve as a percutaneous hemodynamic support option in CS secondary to right ventricular failure.

Conclusions

Although percutaneous mechanical support devices used in CS can improve hemodynamics, studies have not shown clear mortality benefit. However, it is obvious that there are numerous logistic and ethical challenges in performing a large randomized study in CS patients, such as appropriate patient selection, device selection, timing of initial support initiation, and cost effectiveness.[4] Randomized, controlled trials comparing the various percutaneous devices currently available may shed light on appropriate patient and device selection, and further advances in technology may also lead to improved outcomes in this sick patient population.

Acknowledgment

We wish to thank D Gershon Lewental for comments that greatly improved the manuscript.

Author Contributions

Conceived and designed the review article, wrote the first draft of the manuscript: FSG. Jointly developed the structure and arguments for the paper: FSG, LG. Contributed to writing: FSG, SF, RD, LG. Agreed with manuscript results and conclusions: FSG, LG. All authors read and approved the final version.

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