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Intervention in Cardiogenic Shock

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ABSTRACT

Cardiogenic shock is characterized by hypotension along with signs of hypoperfusion. It has been defined by various societies and clinical trials in different manner. Acute myocardial infarction is the most common cause of cardiogenic shock. Despite early percutaneous coronary intervention, shock secondary to acute coronary syndrome carries mortality rates reaching up to 40–50%. Mechanical circulatory support has been designed to potentially improve outcomes in such patients, but data remains scarce on mortality benefits and long-term outcomes.

Keywords: Mechanical circulatory support, Cardiogenic shock, Impella, Left ventricle assisted device

INTRODUCTION

Cardiogenic shock is characterized by hypotension along with signs of hypoperfusion. It has been defined by various societies and clinical trials in different manner. Recent European society of cardiology (ESC) 2017 guidelines for the management of acute myocardial infarction (MI) defined cardiogenic shock as "persistent hypotension (Systolic blood pressure [SBP] <90 mm Hg) despite adequate filling status, with signs of hypoperfusion."[1] The SHOCK (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock) trial defined cardiogenic shock as clinical criteria of hypotension (SBP <90 mmHg for ≥30 min, or requirement of support to maintain SBP ≥90 mm Hg) and end-organ hypoperfusion (cool extremities, or urine output <30 mL/h or heart rate ≥60/min) along with hemodynamic criteria (cardiac index ≤2.2 L $min^{-1}m^{-2}$ and pulmonary capillary wedge pressure (PCWP) ≥15 mmHg).[2]

Acute MI is the most common cause of cardiogenic shock. Despite early percutaneous coronary intervention (PCI) shock secondary to acute coronary syndrome carries mortality rates reaching up to 40–50%.[3] Other common causes include arrhythmias, valvular heart disease, myocarditis, and cardiomyopathies. For increasing blood pressure, pharmacological treatment including inotropes and vasopressors can be administered, but they have their own limitations, like increased myocardial oxygen consumption, peripheral hypoperfusion, and tachy-arrythmias at high doses, with limited randomized clinical trial (RCT) data showing any prognostic benefit.[4] The introduction of intra-aortic balloon pump (IABP) in 1967 heralded a new era of mechanical circulatory support (MCS) for the treatment of cardiogenic shock.

A recently published SCAI consensus statement[5] has classified cardiogenic shock into five stages, starting with stage "A" – At risk of developing CS, with no overt signs and symptoms; stage "B" – Beginning, characterized by hypotension without hypoperfusion; stage "C" – Classic, hypotension with hypoperfusion requiring interventions; stage "D" – Deteriorating, with no response to

initial interventions, and requires further escalation, and lastly, stage "E" – Extremis, circulatory collapse with ongoing cardio-pulmonary resuscitation (CPR). They have further defined clinical, bio-chemical and hemodynamic parameters in each stage. While stage A and B patients can be taken for PCI directly, stages C-E patients need additional supportive measures, for hemodynamic and/or respiratory support, before proceeding to catheterization lab.

MCS IN CARDIOGENIC SHOCK

MCS is mainly used as a Bridge to recovery, a temporary method to assist during PCI and till recovery from cardiogenic shock. They can be classified based on pump location (extra-corporeal, para-corporeal, or intracorporeal), pump mechanism (pulsatile flow, continuous flow with axial design, or continuous flow with centrifugal design), and ventricle supported (Left ventricle assist device [LVAD], right ventricle assist device, or bi-ventricular assist device). While studies have shown the benefits of MCS in such patients, the optimum timing of intervention remains controversial, with recent studies indicating that early initiation of MCS is warranted and delays lead to higher chances of mortality.[6,7]

The commonly used MCS in cardiogenic shock (summarized in Table 1) include-

IABP

IABP was the first MCS device designed and used, and it is also the most used device. It is deployed using common femoral artery access, and placed in the descending aorta, 2 cm below the left subclavian artery. It consists of a 7.5–8 F double lumen catheter with a polyethylene balloon at its distal end, which is inflated with helium gas during diastole (middle of T wave on surface electrocardiogram (ECG), or immediately after dicrotic notch on aortic pressure tracing) and deflated during systole (peak of R wave on ECG). It improves coronary perfusion during diastole and decreases left ventricle (LV) afterload. It leads to a small improvement in cardiac output (0.5–1 L/min), improved SBP and Coronary blood flow, decreased LV pre-load, LV end diastolic pressure (LVEDP) and PCWP, reduced LV wall stress and myocardial oxygen demand, and improved reperfusion post-thrombolysis.[8] It provides only partial support, and requires some level of LV function and electrical stability for optimum function. Contra-indications for IABP include aortic aneurysm or dissection, moderate or severe aortic regurgitation, severe peripheral arterial disease, uncontrolled sepsis and bleeding diathesis and complications include stroke, cardiac tamponade, and limb ischemia.

Initial observation studies showed some encouraging results, but large RCTs have failed to demonstrate any

Table 1 : Summary of temporary mechanical circulatory support devices.

MCS device	Type of device	Support given	Method of placement	Hemodynamic support	Contraindications
Intra-aortic balloon pump	Extra-corporeal, counter-pulsation pneumatic pump	Partial support (0.5–1 L/min)	Percutaneous (7–9 F cannula in femoral artery), or surgical	LV preload↓ Afterload ↓↓ Stroke volume↑ PCWP↓ Coronary perfusion↑	1. Aortic Regurgitation 2. Severe PAD 3. Aortic aneurysm 4. Severe thrombocytopenia
Impella	Intra-corporeal, continuous flow, micro-axial pump	Impella2.5 - Partial support (1–3 L/min), Impella CP- Full support (3.5–4 L/min) Impella5.0-Full support (5 L/min)	Percutaneous for Impella 2.5 and CP (13–14 F femoral artery), Surgical for Impella 5.0 (22 F)	LV preload↓ Afterload - Stroke volume↓↓ PCWP↓ Coronary perfusion?	1. Aortic Regurgitation 2. Aortic Stenosis 3. Severe PAD 4. VSD 5. LV thrombus
VA-ECMO	Para-corporeal, continuous flow, centrifugal pump	Full support (5–6 L/min)	Percutaneous or surgical (Inflow - 18–21 F femoral vein and outflow - 15–22 F femoral artery)	LV preload↓↓ Afterload↑↑ Stroke volume ↓↓ PCWP ↓↓ Coronary perfusion?	1. Aortic Regurgitation 2. Aortic Stenosis 3. Severe PAD 4. VSD 5. LV thrombus
Tandem Heart	Para-corporeal, continuous flow, centrifugal pump	Partial support (2-4 L/min)	Percutaneous (21 F femoral vein-inflow, 15–17-femoral artery-outflow)	LV preload ↓↓ Afterload ↑↑ Stroke volume ↓↓ PCWP ↓↓ Coronary perfusion?	1. Predominant RV failure 2. VSD 3. LV thrombus

MCS: Mechanical circulatory support, VA-ECMO: Veno-arterial extra-corporeal membrane oxygenation, LV: Left ventricle, VSD: Ventricular septal defect

survival benefit. The IABP-SHOCK trial showed that IABP did cause unloading of LV, but no significant improvement in hemodynamics.[9] IABP-SHOCKII trial randomized 600 patients with acute MI and cardiogenic shock to IABP versus no IABP along with early PCI and routine care in both groups. The primary end-point of 30-day all cause mortality, among the two groups showed no significant difference (39.7% mortality in IABP group and 41.3% in control group (P = 0.69).[10] Based on these data, the ESC guidelines has given a Class III recommendation for routine use of IABP in acute ST elevation myocardial infarction (STEMI) patients with cardiogenic shock and a Class IIa recommendation if cardiogenic shock is due to mechanical complications.[1]

Impella

Impella is a continuous-flow, micro-axial rotatory pump which is placed percutaneously across the aortic valve, and pumps blood from LV into the ascending aorta at a rate of 2.5 L/min for Impella 2.5 and 4.3 L/min for Impella CP. Impella 2.5 and Impella CP can be placed percutaneously using a 12–14 F femoral access retrogradely across the aortic valve, while Impella 5.0 and Impella 5.5 require surgical placement. It acts by unloading of LV, improves coronary perfusion pressure and coronary flow and decreases the afterload and myocardial oxygen consumption. Complications of Impella include bleeding, vascular injury, trauma to aortic valve and stroke. Key contra-indications to use of Impella include severe peripheral arterial disease, LV thrombus, mechanical aortic valve, critical aortic stenosis, and severe right ventricular failure.

The Impella-EUROSHOCK registry is a single-arm observational study which enrolled 120 patients with acute MI complicated by cardiogenic shock and showed a high 30-day mortality of 64.2%, with decreased lactate levels, implying improved perfusion.[11] A few small non-randomized studies compared Impella with extra-corporeal membrane oxygenation (ECMO) and IABP and demonstrated better survival with Impella.[12,13] ISAR-SHOCK trial was a small RCT which enrolled 25 patients with acute MI and Cardiogenic Shock to Impella 2.5 versus IABP showed similar 30-day mortality of 46% in both groups, but better hemodynamics with the use of Impella.[14] Another small RCT was the IMPRESS trial which was a randomized, open-label trial and enrolled 48 patients with acute MI and Cardiogenic Shock to Impella CP or IABP and showed similar mortality (46% Impella and 50% IABP, P = 0.9) in both the groups.[15] Another study compared pre-PCI versus post-PCI placement of Impella and showed improved survival when Impella was placed before starting PCI (50%) versus when placed after PCI (23.1%).[16]

Despite limited RCT data backing its use, Impella is commonly used MCS in the setting of acute MI complicated by cardiogenic shock.

Veno-arterial ECMO (VA-ECMO)

VA-ECMO is a modified heart-lung machine and provides full cardio-pulmonary support. It consists of a continuous flow, centrifugal pump for propulsion of blood, and a membrane oxygenator for exchange of gases. A venous cannula is used to drain de-oxygenated blood from patient, and it is passed through membrane oxygenator for gaseous exchange, and oxygenated blood is infused back into the patient through arterial cannula, and it provides flow of 4–6 L/min. It requires 14–19 F arterial, and 17–21 F venous cannulas. It decreases LV pre-load, but increases the afterload, and myocardial oxygen demand. Its complications include bleeding, hemolysis, limb ischemia, air embolism, stroke, infections, renal failure, pulmonary edema and Harlequin syndrome and contra-indications include poor life-expectancy and terminal illness due to futility.

Many observational studies have been done to study the VA-ECMO in acute MI patients with cardiogenic shock patients and have shown variable survival rates, ranging from 47% to 60.9%.[17] An observational study done in 2019 studied a retrospective cohort of National Inpatient Sample database from 2000 to 2014, 2692 of approx. 9 million patients with acute MI had ECMO done, which comprised 0.5% of all admissions of acute MI with cardiogenic shock. The survival rate was 40.8% and 57.9% patients received concomitant IABP or percutaneous LVAD, signifying the trend towards increasing use of multiple MCS devices in a single patient. 11.7% patients were given long-term therapy with a durable LVAD or heart transplant, in this cohort in-hospital mortality was 35.9% as compared to 62.9% mortality in those who did not receive the same.[18] There are no RCTs till date to study ECMO in acute MI patients complicated by cardiogenic shock. EURO-SHOCK and ECLS-SHOCK are two studies undergoing currently in this patient population.

Due to lack of RCT data, ESC guidelines have given a Class IIb recommendation for the use of short-term MCS devices (Percutaneous cardiac support devices, ECLS, and ECMO) in patients with refractory shock.

TandemHeart

It is a para-corporeal percutaneous ventricular assist device which acts by pumping blood from left atrium to femoral artery, bypassing the LV entirely. It uses a centrifugal flow, continuous pump, and delivers partial support (2–4 L/min) and a 21 F trans-septal cannula for draining LA. It decreases LV pre-load, filling pressure and myocardial oxygen demand, while increasing the afterload. The TandemHeart works in parallel circulation to the native heart. Complications include thrombo-embolism, stroke, limb ischemia, femoral AV

fistula, bleeding, and contraindications are ventricular septal defect and aortic regurgitation.

Small observational studies have shown improved hemodynamic support with the use of TandemHeart. A study by Kar *et al*. enrolled 80 patients with severe refractory cardiogenic shock of ischemic etiology and showed significant improvement in cardiac index, SBP, mixed venous oxygen saturation and urine output.[19] The mortality at 30 days and 6 months was 40.2% and 45.3%, respectively. Two small RCTs compared TandemHeart with IABP and found better hemodynamic support with TandemHeart but no difference in 30 day mortality between the two groups.[20,21]

COMBINATION OF MCS DEVICES

Some studies have shown the use of multiple MCS devices in a single patient. The rationale behind the use of a combination of devices is that VA-ECMO while reducing the LV pre-load leads to an increase in the afterload due to retrograde flow into aorta, and requires unloading of LV. This can be achieved using an Impella or IABP used simultaneously. A study compared 255 patients with LV unloading (VA-ECMO with Impella) with 255 patients without LV unloading (VA-ECMO alone) showed lower 30-day mortality with LV unloading, although there were higher complications in unloading group.[22]

CONCLUSION

Despite the availability of advanced technology in patient monitoring and management and early revascularization, ACS complicated by cardiogenic shock is still associated with unacceptably high mortality rates. MCS has been designed to potentially improve outcomes in such patients, but data remains scarce on mortality benefits and long-term term outcomes. In addition, these devices are limited by requirement of expertise for proper deployment, high cost and their own set of complications. Larger RCTs are required to definitively prove survival benefit, indications, choice of device, timing of initiation, and post-operative management.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Conflicts of interest

There are no conflicts of interest.

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