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Case Report

Is Combined use of Impella 2.5L and Intra-Aortic Balloon Pump for Refractory Cardiogenic Shock Superior to Either Device Alone?

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Abstract

Cardiogenic Shock (CS) is still a significant cause of in-patient mortality. None of the standard support devices, Intra-Aortic Balloon Pump (IABP) and Impella (IMP), have shown to improve mortality. There is no available data on the superiority of combined versus individual device use. We present a compilation of six cases reported separately in literature where combined IMP-IABP treatment is used for refractory CS. Overall, we noted that combined use seemed to be a safe, effective and potentially superior alternative treatment option for refractory CS. Future studies are needed to further evaluate this strategy.

Keywords: Cardiogenic shock; Mechanical circulatory support; Impella; Intra aortic balloon pump

Abbreviations

CS: Cardiogenic Shock; IMP: Impella 2.5L Device; IABP: Intra-Aortic Balloon Pump; ECMO: Extracorporeal Membrane Oxygenation; NSTEMI: Non-ST Elevation Myocardial Infarction; EF: Low Ejection Fraction; Fr: French; TTE: Transesophageal Echocardiography; STEMI: ST Elevation Myocardial Infarction; AMI: Acute Myocardial Infarction; LV: Left Ventricle; CABG; Coronary Artery Bypass Graft; CAD: Coronary Artery Disease; PCI: Percutaneous Intervention; VF: Ventricular Fibrillation; VT: Ventricular Tachycardia

Introduction

Despite emerging innovative treatments, in-hospital mortality of Cardiogenic Shock (CS) remains significantly high [1,2]. American College of Cardiology/American Heart Association 2004 and 2013 guidelines indicate that mechanical circulatory support device use for treating CS refractory to pharmacological therapy can be useful [3,4]. There are two common non-surgical mechanical devices used to treat CS. The first device is the Intra-Aortic Balloon Pump (IABP). However, despite hemodynamics improvement, clinical trials failed to show mortality benefits [5]. The second device is Impella (IMP) which also has FDA approval for treatment of severe CC [6]. Several studies have shown that IMP provides better hemodynamic benefits when compared to IABP; however, there is also no mortality benefit [7,8]. Given the lack of mortality benefit with single strategy of IABP or IMP, combined use of both devices is the next logical alternative.

We found three reported observational studies that evaluated combined use of two or more mechanical support devices (including IABP, IMP and/or ECMO) for CS treatment. We extracted details from these studies where both IABP-IMP, in particular, were used for treatment of refractory CS mainly post-cardiac surgery and found a total of 26 out of 55 patients. Among the 26 patients, 14 recovered [2,9,10]. However, with limited information about individual patients, and no current randomized clinical trials addressing combined IABP-IMP, we sought to review the available literature for individual cases where both devices used to aid in better evaluation of this strategy [11-16].

In this paper we present six individual cases on the combined use of IABP and IMP for treatment of refractory CS. We also present a comprehensive literature review on this strategy discussing the rationale behind this approach, outcomes, hemodynamic benefits of these mechanical support devices in Cardiogenic shock and highlight possible superior outcomes; which could include mortality benefits.

Case Presentation

Methods

We performed a MEDLINE, EMBASE, PUBMED and Google Scholar search of the literature from 2004-2016 using the key words Impella, IABP, Cardiogenic shock and combined use. We limited our search to the English literature. We present a summary of included cases and clinical aspects of outcomes.

Definitions

Cardiogenic shock (CS) is a state of end-organ hypoperfusion due to cardiac failure in the absence of hypovolemia characterized by14:

1. Persistent hypotension (systolic blood pressure <80-90mmHg or mean arterial pressure 30mmHg <baseline).

2. Severe reduction in cardiac index (<1.8 L/min/m^2 without support or <2.0-2.2 L/min/m^2 with support).

3. Adequate or elevated filling pressure (left ventricular end-diastolic pressure >18mmHg or right ventricular end-diastolic pressure >10-15mm Hg.

Case descriptions

Case (1) [17]: 42-year-old male was admitted with Non-ST Elevation Myocardial Infarction (NSTEMI) and low Ejection

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Table 1: Summary of Presented Cases.

Author/Year	Indication and Course	Duration of Device Use	Outcomes
Case 1: Enezate 2016	NSTEMI requiring CABG. Complicated by post operation CS. Maximum vasopressors, IABP. Followed by bedside IMP insertion under TEE guidance	IABP: 48 hours	Patient was discharged home
		IMP: 72 hours	
Case 2: Wiktor 2010	STEMI treated by PCI complicated by CS. Maximum vasopressors, IABP then IMP was inserted	IABP: 10 days	Patient was discharged home
		IMP: 6 days	
Case 3: Pavlidis 2014	Multivessel CAD treated with PCI, complicated by CS, IMP 2.5L was inserted initially then followed by IABP and inotropes.	IABP: 36 hours	Patient was discharged home
		IMP: 24 hours	
Case 4: Jung 2008	MI treated by PCI, complicated by CS, required vasopressors and IABP then followed by IMP insertion later.	IABP: 6 days	Died
		IMP: 2 days	
Case 5: Gupta 2009	Cardiac arrest (VT), complicated by CS. Vasopressors followed by IABP and IMP insertion at the same time.	IABP: 2-3 days	Patient was discharged home
		IMP: 1-2 days	
Case 6: Cubeddu 2012	MI complicated by CS and cardiac arrest (VF), resuscitated initially followed by PCI and IMP insertion. Followed later by IABP vasopressors.	IABP: 72 hours	Died
		IMP: 72 hours	

CABG: Coronary Artery Bypass Graft; CAD: Coronary Artery Disease; Imp: Impella 2.5L Device; PCI: Percutaneous Intervention; STEMI: ST Elevation Myocardial Infarct; TEE: Transesophageal Echocardiography; VF: Ventricular Fibrillation; VT: Ventricular Tachycardia. *All cases had documented severely reduced left ventricular ejection fraction (<25%) at time of impella insertion.

Fraction (EF) of 20%. Coronary angiogram showed triple vessel coronary disease. The patient underwent emergent coronary artery bypass surgery which was complicated by cardiopulmonary arrest. After successful resuscitation, the patient had CS, which was initially treated with vasopressors and IABP.

The patient continued to be hypotensive, so IMP was inserted bedside via 6 French (Fr) right femoral artery sheath and placed bedside under Transesophageal Echocardiography (TTE) guidance. Hemodynamics improved with IMP, IABP and vasopressor support. The patient was weaned off pharmacological vasopressor support and IABP after 48 hours and off IMP after 72 hours. The patient continued to clinically improve and was eventually discharged to a rehabilitation facility and then home. Pre-discharge EF improved to 55-60%.

Case (2) [12]**:** A previously healthy 67-year-old female presented with an anterolateral ST Elevation Myocardial Infarction (STEMI) complicated by CS. EF on admission was 10%. The patient remained hypotensive despite conventional pharmacotherapy for CS. IABP was placed and revascularization was performed with stents to the left descending, left circumflex and second obtuse marginal arteries.

Given the persistent shock, IMP was placed percutaneously via the left femoral artery and titrated up to maximal support and IABP support was continued. Hemodynamics improved allowing for the patient to be weaned off IMP 6 days later and off IABP after 10 days. The patient continued to improve and was discharged to rehabilitation facility then home. Follow up EF improved to 30%.

Case (3) [13]**:** A 63-year-old female patient with multiple comorbidities presented with angina. Coronary angiography demonstrated multi-vessel coronary disease. Initial EF was normal. Elective Percutaneous intervention was performed on the left anterior descending artery, which was complicated by hypotension and bradycardia. IABP and temporary pacing wire were immediately inserted. Other lesions were stented and flow restored in all vessels; however, the patient remained in refractory CS despite inotropic support and IABP. IMP was inserted via 13 Fr left femoral approach and IABP was restarted. That was followed by rapid hemodynamic improvement, which enabled weaning off inotropes within a few hours. IMP and IABP were successfully removed 24 and 36 hours later, respectively. The patient continued to improve and was transferred to a rehabilitation facility. Pre-discharge EF was normal.

Case (4) [14]**:** 70-year old male with severe CS post Acute Myocardial Infarction (AMI) despite insertion of IABP and optimal pharmacological pressure support. Intervention of left main and left anterior descending artery stenosis was conducted. EF was 22%. IMP was emergently inserted. Initial hemodynamics and microcirculation flow improved with use of both devices. However, the patient remained unstable and died on the following day.

Case (5) [15]**:** A 37-year-old female with a past medical history of asthma and a recent diagnosis of peripheral T-cell lymphoma in the left lung was admitted with dizziness, numbness and increased dyspnea. The following day she was found unresponsive due to sustained ventricular tachycardia. She was resuscitated and placed on inotropic support. EF was 15%, and hemodynamic parameters were consistent with CS. Coronary angiogram demonstrated normal coronary arteries.

Because of the continued hemodynamic instability, IMP was inserted in addition to the existing IABP. Both devices were then initiated. Over the subsequent 24 hours, the patient was weaned off inotropes. 24 hours later IMP was discontinued followed by IABP. The patient was discharged home later. Pre-discharge EF was 50%.

Case (6) [16]**:** A 48-year-old previously healthy male presented with AMI, resulting in CS with EF of 15%. Coronary angiography showed an occluded left main artery with collateral flow. Immediately after angiography, the patient developed ventricular fibrillation and asystole. He was resuscitated and started on pharmacological vasopressor support. IMP was inserted via left femoral approach resulting in immediate hemodynamic improvement.

She developed ventricular arrhythmias following left main intervention and remained in severe CS, therefore IABP was inserted through the right femoral approach. The simultaneous use of the

IABP and IMP was maintained for 72 hours. Hemodynamics initially improved and vasopressors were weaned off. Unfortunately, the hospital course was complicated by persistent multi-organ failure and sepsis resulting in death four days later.

Discussion

CS has a mortality rate of up to 60-80% [1,10]. However, hospital survivors have an excellent chance for long-term survival with good quality of life [15]. The current treatment of IMP and IABP, individually, does not improve the 30-day mortality [8,5]. Hence, an optimal strategy of mechanical support is still to be determined [2]. We investigated current combined device use in the literature, presenting six cases that can guide future work in the field.

Our report presents six cases of severe CS of different etiologies where both mechanical devices were used (Table 1), as well as provides an overview of current literature. All of the patients had severe CS refractory to pharmacological treatment and single device mechanical support, which necessitated further mechanical support by the usage of a second device. This was followed by dramatic hemodynamic and clinical improvement allowing for weaning off of pharmacological and mechanical supports in four out of six patients. There was documented improvement of EF in all four patients who were eventually discharged home. Noteworthy, weaning and recovery rates noted in all these cases exceeded the expected survival for this group of patients. The complication rates observed in the above cases were low and there were no vascular complications observed. However, there remains several important aspects that still need to be answered regarding combined device strategy including, but not limited to, cost, patient eligibility, local expertise, resources and contraindications.

Sauren et al. studied this combined strategy in an animal model 16 Their strategy resulted in enhanced systemic, cerebral, and coronary blood flow, further increase in mean arterial pressure and resulted in improvement of the Left Ventricle (LV) workload, end-diastolic pressure and myocardial oxygen supply-demand relationship when compared to either device alone [14,18]. It might also improve tissue microcirculation during CS [5]. This indicates that the best myocardial oxygen supply-demand ratio is obtained with the IABP-IMP combination support mode which enhances myocardial recovery during CS [18]. Of note, there was a concern amongst a group of expert bioengineers that a combined device approach could decrease diastolic forward flow by up to 10% when the IABP is inflated during diastole, however, Sauren and colleagues showed an improved overall perfusion [14,16].

In humans, IABP decreases cardiac after load and secondarily LV load, improves coronary perfusion, augments mean arterial pressure and increases cardiac output by 0.5L/min [10,11]. Overall, IABP shifts the pressure-volume loop curve to the left by mainly decreasing LV volume without a significant LV pressure unloading effect [18]. IMP, on the other hand, pumps the blood continuously from the LV to the aorta, independent of the phase of the cardiac cycle. It results in loss of the normal isovolumic periods which transforms the pressure-volume loop from its normal trapezoidal shape to a triangular shape, therefore, decreasing its area significantly (i.e. LV workload and O_2 consumption) [19]. This improves aortic pressure, coronary perfusion, cardiac output, antegrade flow and decreases LV load [11]. Overall, IMP shifts the pressure-volume loop curve much more to the left by directly unloading LV pressure and decreasing the LV volume [14,18]. This subsequently decreases left atrial and pulmonary wedge pressures [19]. The two different mechanisms of action for each device can be used to work simultaneously in patients with refractory CS in order to provide more mechanical support.

The duration of the low output phase is indeed the main determinant of multiple organ failure, which may become irreversible even after the initial cause of shock has been treated and tissue perfusion restored [2]. At the onset of shock, more aggressive unloading of the failing heart in combination with revascularization might improve the outcome [10]. In emergency situations, both devices can be inserted percutaneously either in the Catheterization lab or bedside with TEE guidance which makes this strategy favorable over the more complex and time consuming Extracorporeal Membrane Oxygenation (ECMO) and other surgically placed support devices. Taking advantage of the combined mechanism of action may help overcome individual device limitations. For example, IABP performance is dependent on patient position, the maximum performance achieved when the patient is horizontal. On the other hand, IMP is independent from patient position [2,18,20].

Although data from randomized clinical trials on concurrent combined use of IABP and IMP for refractory CS treatment is absent, these findings in literature along with our presented cases support safety and efficacy of this treatment approach over the use of either device alone. Overall, our report provides insight into the potential for combined IMP and IABP use for treating refractory CS patients, as well as encourage the pursuit of further clinical investigations to evaluate the applicability of this approach in clinical practice including efficacy, safety and cost-effectiveness.

Conflict of Interest

The authors declare that they have no conflict of interest. The authors worked at the University of Missouri Hospital where they managed Case 1, which observations of the case were then reported on with no identifying information (For this type of study formal consent is not required). All other cases reported in this review-included consent based on the particular author's reports.

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