Review Article

When more is not better—appropriately excluding patients from mechanical circulatory support therapy

Mannu Nayyar, Kevin Michael Donovan, Rami N. Khouzam

Division of Cardiovascular Diseases, University of Tennessee Health Science Center, Memphis, TN, USA

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Correspondence to: Dr. Rami N. Khouzam, MD, FACC, FACP, FASNC, FASE, FSCAI. Division of Cardiovascular Diseases, University of Tennessee Health Science Center, 1211 Union Avenue, Suite 965, Memphis, TN 38104, USA. Email: rkhouzam@uthsc.edu.

Abstract: Mechanical circulatory support (MCS) devices are continually evolving and are providing greater hemodynamic support. This review was conducted to evaluate the prophylactic use of MCS in hemodynamically stable patients who were awaiting future coronary artery revascularization. A thorough review of published literature was conducted to evaluate for patients and clinical scenarios that are indicated for MCS, including hemodynamically stable and unstable patients awaiting revascularization. Although there have been several studies demonstrating the benefit of MCS use in hemodynamically unstable patients, there was limited trials in patients that were hemodynamically stable. The use of prophylactic MCS was limited to intra-aortic balloon pump (IABP) in "high risk" patients awaiting coronary artery bypass grafting (CABG). This review article was conducted to evaluate for possible prophylactic MCS in patients awaiting revascularization. In hemodynamically stable patients, literature is limited to the use of IABP for "high-risk" patients awaiting CABG. A thorough review of literature suggest that hemodynamically stable patients likely would not benefit from prophylactic placement MCS while awaiting revascularization although further clinical trials are needed to identify the ideal patients and clinical scenarios for the use of MCS.

Keywords: Coronary artery bypass; coronary vessels; heart; heart-assist devices; percutaneous coronary intervention (PCI)

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Introduction

As the types of mechanical circulatory support (MCS) devices at our disposal in the ever-evolving cardiac catheterization laboratory continue to advance at an impressive pace, our ability to stabilize, treat and ultimately improve outcomes for increasingly complex patients remains promising. The intra-aortic balloon pump (IABP) has been the mainstay of MCS therapy however newer devices such as the Impella (Abiomed Inc., Danvers, Massachusetts, USA), TandemHeart (CardiacAssist Inc., Pittsburgh, PA, USA) and extracorporeal membrane oxygenation (ECMO) have the ability to provide greater hemodynamic support which may lead to an improvement in clinical outcomes. To date there have been no randomized controlled trials to identify the ideal patient and clinical scenario where the various types of MCS would be beneficial from a morbidity and mortality perspective and remains one of the major limitations in implementing MCS. Other than obvious contraindications to MCS such as aortic regurgitation, aortic dissection or left ventricular thrombus to name a few, it is the clinician's responsibility to gauge benefit *vs.* risk prior to implementation.

Advanced hemodynamics

There are several mechanisms and characteristics that

distinguish the classes of MCS based on pump hemodynamic properties, size of catheters/cannula used, site where blood is withdrawn and delivered, whether insertion technique is percutaneous or surgical and whether a gas exchange unit is used (1). While these factors are considered when deciding which MCS devices to utilize, these differences are only partially understood and have not been fully researched in clinical trials (2). Ultimately, the goal of MCS is to improve hemodynamics by augmenting or providing full cardiac output, producing a physiologically acceptable blood pressure and reducing pulmonary venous pressure when traditional pharmacological therapies are inadequate. Alternatively, MCS is also used prophylactically in high risk procedures for expected and transient impairment in the cardiovascular hemodynamics (2). Achieving these goals results in improved end-organ perfusion and, in cases of volume overload states, improved diuresis.

Patient selection

In cases of compromised hemodynamics such as in acute myocardial infarction (AMI) complicated by cardiogenic shock or acute decompensated heart failure, the improvement in vital organ perfusion and clinical stabilization is seen acutely in patients with cardiogenic shock due to both ischemic and non-ischemic etiologies with the use of MCS (3,4). As the mortality rates range from 30–50% in patients with cardiogenic shock, the benefits of hemodynamic stability via MCS aid in improving cardiac output, reducing intracardiac filling pressure, reducing left ventricle volume and therefore wall stress and myocardial oxygen consumption. Augmented coronary perfusion is achieved by MCS and in the case of AMI this may theoretically limit infarct size (5). The 2011 American College of Cardiology (ACC)/American Heart Association (AHA)/Society for Cardiovascular Angiography and Interventions (SCAI) Guideline for Percutaneous Coronary Intervention recommends consideration of percutaneous MCS in patients who present with cardiogenic shock due to ST-segment myocardial infraction (class Ib) (6).

In cases of hemodynamically stable patients when high risk percutaneous coronary intervention (PCI) such as left main stenosis, bifurcation lesions, ostial stenosis, multivessel disease or transcatheter valve repair with or without poor left ventricle function are attempted, MCS support acts to provide stability during expected decreases in forward cardiac output. In animal models, a 40-mmHg pressure gradient exists between coronary arterioles and venules. Sustained hypotension resulting in gradients <40 mmHg can lead to significant myocardial ischemia, depression and ultimately circulatory collapse and death (7). Prophylactic placement of MCS devices, so called "protected PCI", assists in avoiding this catastrophic decompensation while allowing the most thorough revascularization possible. Data for patients undergoing protected PCI has not demonstrated benefit in IABP use (8). The largest meta-analysis covering 12 randomized controlled trials including over 2,100 patients suggests IABP did not significantly decrease short term mortality (defined as in-hospital mortality) or long-term mortality (defined as death at or beyond 6 months) in high risk mechanical coronary revascularization. In high risk coronary artery bypass grafting (CABG) surgery patients, IABP was associated with reduced mortality (9). However, there are several limitations including small sample sizes, the definition of "high-risk" among various studies differed and several of the studies were published by the same author from the same institution (10). The placement of IABP in these patients was performed 2–24 hours prior to CABG. In contrast, the PROTECT II trial demonstrated Impella support improves 90-day major adverse event free survival compared to IABP protected patients (11). The potential mechanism for late benefit may be due to more stable intra-procedural hemodynamics allowing for more complete and complex revascularization (11,12). The 2011 ACC/AHA/SCAI Guideline for Percutaneous Coronary Intervention recommends consideration of percutaneous MCS as an adjunct to high risk PCI (class IIb) (6).

In cases of hemodynamically stable patients awaiting high risk PCI or surgical revascularization, no data exists to support MCS therapy during the period when significant lesions are identified to when they are revascularized. Available data are limited to prophylactic IABP placement, usually in "high risk" patients as discussed above and often offer conflicting evidence given the relatively small sample sizes used in these studies (10,13,14). A prospective, randomized study to determine the optimal time of pre-operative IABP support in high risk patients (defined as two or more of the following: left ventricle ejection fraction <30%, unstable angina, redo CABG, or left main stenosis >70%) found no differences in IABP support when placed 2, 12 or 24 hours prior to CABG. It was therefore concluded that IABP therapy can be initiated as little as 2 hours preoperatively (15). It is also important to note the significant complications and costs associated with MCS use, especially if considered in hemodynamically stable patients. Complications can vary widely based on institution and procedural proficiency, and can include air

embolism, thromboembolism, hemorrhage, right ventricle failure, infection, primary device failure and increased mortality (16). Cost of hospitalization was also significantly increased by the placement of an MCS anywhere from 2.8% to 25.2% (17,18). While these devices have shown promise, careful consideration must be utilized before their implementation. In patients who are hemodynamically stable despite significant coronary disease, there appears to be more risk than benefit in considering MCS use prior to revascularization.

Clinical application

In addition to the above mention indications as outlined by the 2011 Guideline for Percutaneous Coronary Intervention, the 2015 SCAI/ACC/Heart Failure Society of America (HFSA)/The Society of Thoracic Surgeons (STS) Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care looked to provide additional guidance on the appropriate clinical settings for MCS utilization with the following suggested indications in several clinical settings (19):

(I) Complications of AMI (i.e., cardiogenic shock, ischemic mitral regurgitation, septal rupture);
(II) Severe heart failure in the setting of nonischemic cardiomyopathy;
(III) Acute cardiogenic allograft failure;
(IV) Post-transplant right ventricle failure;
(V) Patients slow to wean from cardiopulmonary bypass following heart surgery;
(VI) Refractory arrhythmias;
(VII) Prophylactic use for high risk PCI;
(VIII) High risk or complex ablation of ventricular tachycardia;
(IX) High risk percutaneous valve interventions.

In patients with decompensated hemodynamics requiring augmented cardiac output or those undergoing high risk PCI, the available data suggests consideration of MCS placement. Given the lack of large scale, prospective, randomized, multicenter data with MCS use, these suggestions must be implemented on a case by case basis. It is prudent to discontinue MCS use when high risk PCI therapy is complete as well as to exclude hemodynamically stable patients from MCS despite significant coronary disease as the unnecessary burden of complications and cost far outweigh the benefits.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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