JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
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PUBLISHED BY ELSEVIER INC.

VOL. 65, NO. 19, 2015
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2015.03.036

EXPERT CONSENSUS DOCUMENT

2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care

Endorsed by the American Heart Assocation, the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencion; Affirmation of Value by the Canadian Association of Interventional Cardiology-Association Canadienne de Cardiologie d'intervention*

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ABSTRACT

Although historically the intra-aortic balloon pump has been the only mechanical circulatory support device available to clinicians, a number of new devices have become commercially available and have entered clinical practice. These include axial flow pumps, such as Impella®; left atrial to femoral artery bypass pumps, specifically the TandemHeart; and new devices for institution of extracorporeal membrane oxygenation. These devices differ significantly in their hemodynamic effects, insertion, monitoring, and clinical applicability. This document reviews the physiologic impact on the circulation of these devices and their use in specific clinical situations. These situations include patients undergoing high-risk percutaneous coronary intervention, those presenting with cardiogenic shock, and acute decompensated heart failure. Specialized uses for right-sided support and in pediatric populations are discussed and the clinical utility of mechanical circulatory support devices is reviewed, as are the American College of Cardiology/American Heart Association clinical practice guidelines.

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*The Canadian Association of Interventional Cardiology (CAIC) is approached by other guideline developers and asked to review and consider guidelines for endorsement. Guidelines developed by external organizations will be considered for affirmation of value. The CAIC may not agree with every recommendation in such a document, but overall considers the document to be of educational value to its members.

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The document will also appear in the *Journal of Cardiac Failure* and *Catheterization and Cardiovascular Interventions*.

Conflict of interest: See Appendices.

The American College of Cardiology requests that this document be cited as follows: Rihal CS, Naidu SS, Givertz MM, Szeto WY, Burker JA, Kapur NK, Kern M, Garratt KN, Goldstein JA, Dimas V, Tu T. 2015 SCAI/ACC/HFSA/STS clinical expert consensus statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care (endorsed by the American Heart Association, the Cardiological Society of India, and Sociedad Latino Americana de Cardiología Intervencionista; affirmation of value by the Canadian Association of Interventional Cardiology—Association Canadienne de Cardiologie d'intervention). J Am Coll Cardiol 2015;65:e7-26.

INTRODUCTION

Percutaneous hemodynamic support has historically been limited to the intra-aortic balloon pump (IABP) or extracorporeal bypass with membrane oxygenator (ECMO) (1-3). Although the IABP is widely available, limitations include modest hemodynamic support or myocardial protection; ECMO can provide full hemodynamic support but is limited by complexity and need for perfusion expertise and is rarely used in the catheterization laboratory environment. These limitations have spurred development of alternative percutaneous mechanical circulatory support (MCS) devices with the potential to provide greater cardiac and systemic support and reduce morbidity and mortality among high-risk patient subsets (1).

In parallel, cardiovascular practice has seen rapid growth in cohorts that may benefit from the use of such devices (4). These include patients with chronic systolic dysfunction and acute decompensated heart failure (ADHF), those in whom high-risk multivessel percutaneous coronary intervention (PCI) or other procedures may be required, those with acute cardiogenic shock, and those with residual or concomitant cardiac dysfunction from myocardial infarction despite reperfusion. Among patients with cardiogenic shock, in particular, acute implantation of surgical MCS remains associated with relatively poor outcomes. Accordingly, there has been a rise in the development and use of percutaneous devices over the past decade for both acute (e.g., acute myocardial infarction (MI) complicated by cardiogenic shock or mechanical complications) and acute on chronic (e.g., high risk (HR) PCI) indications.

Percutaneous MCS devices have become an integral component of the cardiovascular therapeutic armamentarium. The 2011 American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) Guideline for Percutaneous Coronary Intervention recommends consideration of percutaneous MCS in two clinical settings: a) as an adjunct to HR PCI (Class IIb) and b) for cardiogenic shock in patients presenting with ST-elevation myocardial infarction (Class Ib) (5). However, no additional guidance is provided. The goal of this document is to provide such guidance on the appropriate clinical settings for MCS utilization and to review the available devices, treatment strategies, practical recommendations for use, gaps in knowledge, and evolving practice.

CLINICAL SETTINGS AND HEMODYNAMIC SUBSTRATES

Potential benefits of MCS include the ability to: 1) maintain vital organ perfusion, thereby preventing systemic shock syndrome, 2) reduce intracardiac filling pressures, thereby reducing congestion and/or pulmonary edema, 3) reduce left ventricular volumes, wall stress, and myocardial oxygen consumption, 4) augment coronary perfusion, 5) support the circulation during complex interventional and electrophysiologic procedures, and, theoretically, 6) limit infarct size. As new MCS devices become available, several specific patient populations likely to benefit from this therapy can be identified. These include patients undergoing high-risk PCI (HR-PCI), and those with large acute myocardial infarctions (AMI), acute decompensated heart failure (ADHF), and cardiogenic shock.

The hemodynamic condition of the left ventricle (LV) in these populations is illustrated by the pressure-volume (PV) loop (**Figure 1**), which provides information about contractile function, relaxation properties, stroke volume, cardiac work, and myocardial oxygen consumption (6-10). The anticipated effect with available support devices is shown in **Figure 2**. Each clinical syndrome presents a unique set of hemodynamic variables where cardiac function and myocardial oxygen supply or demand is compromised. For example, in AMI, patients may present with reduced LV contractile function, acute diastolic dysfunction, elevated LV end-diastolic volume (LVEDV) and pressure (LVEDP), and increased LV work (oxygen demand) in addition to diminished coronary blood flow. In cardiogenic shock LV contractile function is severely reduced with significantly increased LVEDV and LVEDP, markedly reduced stroke volume, but increased myocardial oxygen demand; coronary blood flow may also be impaired by hypotension and elevated wall stress. These pressure-volume loops provide hemodynamic characterization only of the LV and do not provide information on right ventricular function or extra-cardiac problems that may be impacted by MCS such as systemic hypoperfusion of the cerebral, visceral, renal, and peripheral arteries.

HR PCI

Each aspect of PCI from guide catheter engagement to coronary wiring, balloon inflation, and stent deployment incurs a potential risk of damage to the coronary vasculature with impairment of myocardial perfusion, either transient or persistent. At present, no single, unifying definition for HR-PCI exists but variables that contribute to elevated risk during PCI have been well defined and can be categorized into three major groups: 1) patient specific, 2) lesion specific, and 3) clinical presentation specific.

Patient-specific variables include increased age, impaired left ventricular function, symptoms of heart failure, diabetes mellitus, chronic kidney disease, prior myocardial infarction, multivessel or left main disease,