

EXPERT CONSENSUS DOCUMENT: EXECUTIVE SUMMARY

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*

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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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This article provides a brief summary of the relevant recommendations and references related to percutaneous mechanical circulatory support. The goal was to provide the clinician with concise, evidence-based contemporary recommendations, and the supporting documentation to encourage their application. The full text includes disclosure of all relevant relationships with industry for each writing committee member. A fundamental aspect of all expert consensus statements is that these carefully developed, evidence-based documents can neither encompass all clinical circumstances, nor replace the judgment of individual physicians in management of each patient. The science of medicine is rooted in evidence, and the art of medicine is based on the application of this evidence to the individual patient. This expert consensus statement has adhered to these principles for optimal management of patients requiring percutaneous mechanical circulatory support.

Although historically the intra-aortic balloon pump has been the only mechanical circulatory support device (MCS) 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 (ECMO). These devices differ significantly in their hemodynamic effects, insertion, monitoring, and clinical applicability. The full text document reviews the physiologic impact on the circulation of these devices and their use in specific clinical situations (1). These situations include patients undergoing high-risk percutaneous coronary intervention (PCI), those presenting with cardiogenic shock, and acute decompensated heart failure. Specialized uses for right-sided support and in pediatric populations are discussed. The clinical utility of MCS devices is reviewed as are the American College of Cardiology/American Heart Association clinical practice guidelines.

We provide the following consensus-based recommendations based on the anticipated hemodynamic effects and risks, clinical outcomes data as well as knowledge gaps.

1. Percutaneous MCS provides superior hemodynamic support compared to pharmacologic therapy. This is particularly apparent for the Impella and TandemHeart devices. These devices should remain available clinically and be appropriately reimbursed.
2. Patients in cardiogenic shock represent an extremely high-risk group in whom mortality has remained high despite revascularization and pharmacologic therapies. Early placement of an appropriate MCS may be considered in those who fail to stabilize or

show signs of improvement quickly after initial interventions.

3. MCS may be considered for patients undergoing high-risk PCI, such as those requiring multivessel, left main or last patent conduit interventions, particularly if the patient is inoperable or has severely decreased ejection fraction or elevated cardiac-filling pressures.
4. In the setting of profound cardiogenic shock, intra-aortic balloon pump (IABP) is less likely to provide benefit than continuous flow pumps including the Impella CP and TandemHeart. ECMO may also provide benefit, particularly for patients with impaired respiratory gas exchange.
5. Patients with acute decompensated heart failure may benefit from early use of percutaneous MCS when they continue to deteriorate despite initial interventions. MCS may be considered if patients are candidates for surgically implanted ventricular assist device (VAD) or if rapid recovery is expected (e.g., fulminant myocarditis or stress-induced cardiomyopathy).
6. When oxygenation remains impaired, adding an oxygenator to a TandemHeart circuit or use of ECMO should be considered based on local availability.
7. There are insufficient data to support or refute the notion that routine use of MCSs as an adjunct to primary revascularization in the setting of large acute myocardial infarction is useful in reducing reperfusion injury or infarct size. Exploratory studies are underway.
8. MCSs may be used for failure to wean off cardio-pulmonary bypass, considered as an adjunct to high-risk electrophysiologic procedures when prolonged hypotension is anticipated or, rarely, for valvular interventions.
9. Severe biventricular failure may require use of both right- and left-sided percutaneous MCS or veno-arterial ECMO. Certain patients may respond to left ventricular assist device (LVAD) implantation with inotropes and/or pulmonary vasodilators to support the right heart. MCS may also be considered for isolated acute right ventricular failure complicated by cardiogenic shock.
10. Registries and randomized controlled trials comparing different strategies in different clinical scenarios are critically needed.
11. Early analyses suggest cost-effectiveness of MCS for emergent use in comparison to surgical ECMO or VAD support, and for elective use in comparison to IABP. Further data are necessary.

REFERENCE

1. Rihal CS, Naidu SS, Givertz MM, et al. 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

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