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EXECUTIVE SUMMARY

Temporary Mechanical Circulatory Support in Cardiogenic Shock: Executive Summary of the Joint Consensus Reports of the PeriOperative Quality Initiative and the Enhanced Recovery After Surgery Cardiac Society

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ABSTRACT

BACKGROUND The identification, triage, and management of cardiogenic shock (CS) are complex and resource intensive, particularly given the recent surge in the use of temporary mechanical circulatory support (tMCS) devices. This document is an executive summary of a series of consensus statements that guide the bedside clinician regarding the management of tMCS in the setting of CS.

METHODS The PeriOperative Quality Initiative (POQI) and Enhanced Recovery After Surgery (ERAS) Cardiac Society convened an interdisciplinary, international panel of experts and used a structured appraisal of the literature and the modified Delphi method to derive consensus on a series of topics related to both CS and tMCS.

RESULTS The effort resulted in 3 manuscripts with guidance related to the diagnosis, escalation or de-escalation, and best practices associated with CS and the provision of tMCS. Group consensus was derived around existing clinical questions, summary guidance statements, and the quality of the existing evidence.

CONCLUSIONS The POQI/ERAS cardiac consensus series derived 27 unique statements regarding the care of patients with CS and the provision of tMCS. Key themes emerged, including the need for immediate and systematic assessment of CS severity, early initiation of tMCS, an algorithmic approach to the escalation and de-escalation of tMCS therapies, and adoption of high-quality best practices associated with tMCS management.

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Abbreviations and Acronyms

CS = cardiogenic shock
CSWG = Cardiogenic Shock Working Group
ERAS = Enhanced Recovery After Surgery
LV = left ventricular
P-CS = postcardiotomy shock
POQI = Perioperative Quality Initiative
RV = right ventricular
SCAI = Society for Cardiovascular Angiography and Interventions
tMCS = temporary mechanical circulatory support

PURPOSE AND TARGET POPULATION

Cardiogenic shock (CS) is a heterogeneous syndrome with a highly variable clinical presentation, pathophysiology, severity, and outcome profile. There is growing evidence to support a more systematic approach to define and manage CS, thus enhancing communication for clinical support and individualizing care. In addition, the approach to the management of the patient with CS has included more targeted therapies that are based on both disease origin and clinical severity, including the broader adoption of temporary mechanical circulatory support (tMCS). Given the inherent complexity and intensity of resource use for patients with CS, especially those supported with tMCS, as well as the burgeoning nature of research associated with the topic, a joint conference between the PeriOperative Quality Initiative (POQI) and the Enhanced Recovery After Surgery (ERAS) Cardiac Society was convened to appraise and consolidate the available literature and provide practical guidance on the topic.

For related articles, see pages 202, 213, 225

These reports intend to guide the core principles of patient and institutional factors that affect the use of tMCS in the setting of CS. Existing literature is complex, with guidance often siloed by subspecialty or geared toward centers with greater experience or resource capabilities. The purpose of this series of manuscripts is to distill and consolidate this large body of evidence into actionable information for the evolving landscape of centers and broad spectrum of providers who care for these complex patients, with particular emphasis placed on providing immediately translatable guidance for bedside clinical care. As the number of centers that provide tMCS therapies has rapidly expanded over the past several years, it is also recognized that there is a high degree of variability in experience, patient volume, and capacity. As such, the reader is encouraged to scale and contextualize this content to their individual center or health care system.

DEVELOPMENT PROCESS AND METHODS

POQI is a nonprofit organization that assembles international, interdisciplinary groups to develop consensus statements on key topics pertinent to perioperative medicine. On January 24 to 26, 2024, the fourteenth POQI meeting convened in person in conjunction with the ERAS Cardiac Society to address topics relevant to managing cardiogenic shock and tMCS. A group of experts was selected with clinical backgrounds in anesthesiology, surgery, cardiology, and nursing, with a particular focus on CS and tMCS. For this effort, tMCS includes any nondurable device designed to support cardiac function, including intraaortic balloon pump, temporary left ventricular (LV) assist devices (ie, Impella, Abiomed), temporary right ventricular assist devices (ie, ProtekDuo, LivaNova; CentriMag, Abbott), and venoarterial extracorporeal membrane oxygenation.

The joint meeting produced a series of 3 manuscripts, each detailing a different aspect of the clinical management of cardiogenic shock and tMCS:

Part 1: Definitions of Cardiogenic Shock and Indications for Temporary Mechanical Circulatory Support[1]
Part 2: Escalation and De-escalation of Temporary Mechanical Circulatory Support[2]
Part 3: Best Management Practices on Temporary Mechanical Circulatory Support[3]

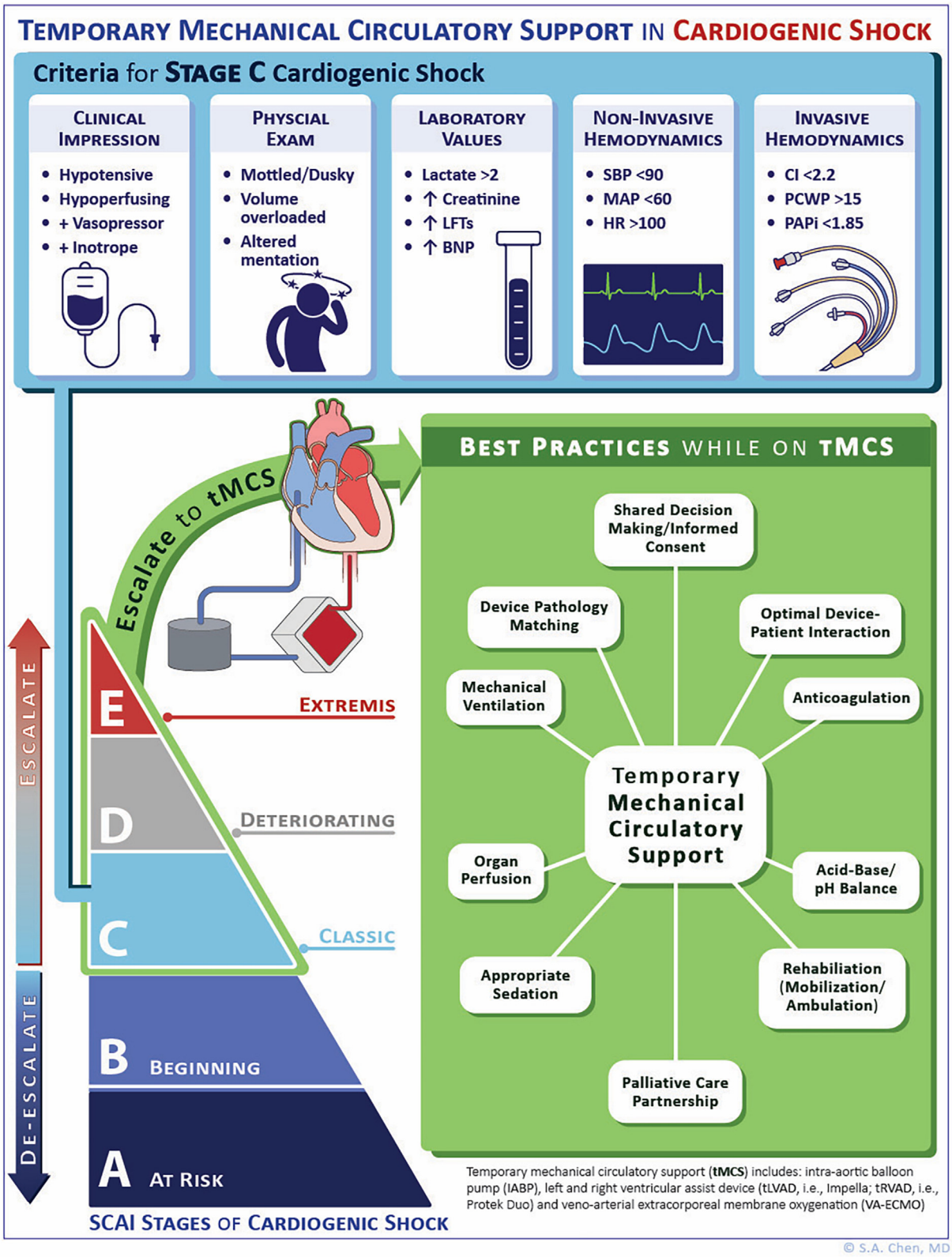
Within each topic area and associated manuscript, predetermined subtopics were addressed by the group in the form of foundational questions (ie, "How do we define cardiogenic shock and its severity?", "How do we monitor and assess adequacy of current tMCS support?") to establish the scope of the discussion and then refined during the conference and subsequent proceedings. The "POQI method" represents a modified Delphi approach, described in previous POQI consensus statements, and includes iterative steps from an initial literature review to building consensus around key statements related to the central topic.[4] Content refinement continued until agreement was achieved, resulting in a formal consensus document. On the basis of an appraisal of the literature and group consensus, a series of statements were rendered in response to foundational questions to summarize key findings. Lastly, the quality of existing evidence was also assessed, and designations were based on whether additional

research on the topic is unlikely (High Quality), likely (Moderate Quality), or very likely (Low Quality) to have a meaningful impact on the statement of the effect of the intervention.[2] Final questions, accompanying statements, and quality designations were endorsed after large group discussion with a majority vote representing confirmation. Additional details regarding the methods can be found within the individual manuscripts. The Feature Illustration provides an overview of the manuscript series. Individual questions, statements, and quality of evidence grading are summarized in Tables 1 to 3.

TOP TAKE-HOME MESSAGES

Several key take-home messages emerged from this initiative that either represent novel guidance or reinforce core principles of tMCS management:

1. *Patients with evidence of CS should be considered for tMCS (Part 1, Statement 4.1; Part 2, Statement 1.1).* There was broad consensus, including 2 separate statements emanating from the manuscript series, that an opportunity exists for earlier initiation of tMCS therapy in the setting of CS, particularly for patients who meet stage C criteria on the basis of the Society for Cardiovascular Angiography and Interventions (SCAI) Shock Classification system.[1,5-7] Beyond the initial escalation of care for patients in stage C CS, which includes diuretic agents, inotropic agents, and vasopressor agents, early consideration should be given to initiating tMCS.[8-10] Early initiation of tMCS has been independently associated with reductions in inpatient mortality, length of stay, respiratory failure, and kidney injury requiring renal replacement therapy.[8-11] Early tMCS likely represents a significant shift in current practice at many institutions that have traditionally reserved those therapies for profound decompensation or clinical salvage.
2. *The initial diagnosis and monitoring of CS, as well as the management of tMCS, are necessarily intensive and multifaceted (Part 1, Statements 2.1, 3.1; Part 2, Statements 1.2, 2.3, 3.1).* The consensus statements highlight the use of a multidimensional approach to the diagnosis of CS, including a combination of invasive and noninvasive strategies to assess for disease progression. In this context, greater emphasis is placed on invasive hemodynamic monitoring (ie, pulmonary artery catheter), the early and comprehensive use of which has been associated with improved survival irrespective of severity staging and cause.[12,13] Although this may seem intuitive, it contrasts the general trend and outcomes associated with pulmonary artery catheter use among low-risk patients undergoing low-risk cardiac surgical procedures. The SCAI shock classification system and additional work from the Cardiogenic Shock Working Group (CSWG) provide a valuable guide for clinical practice, streamlining communication of CS severity and facilitating timely decision making regarding triage and treatment.[6] This comprehensive clinical assessment facilitates escalation and, perhaps just as importantly, de-escalation of tMCS therapy. Part 1 provides a full description of CS stages, including the clinical impression, physical assessment, biochemical markers, and hemodynamics. Part 2 provides an algorithmic approach to the escalating and de-escalating various tMCS therapies.
3. *The goals of tMCS are to stabilize hemodynamics and restore organ perfusion. Therefore, frequent reassessment and further escalation of therapy for inadequate support are advised. (Part 2, Statement 2.1; Part 3, Statement 9.1).* In contrast to diuretic agents, vasopressor agents, and inotropic agents, which may provide only partial resolution of CS derangements, tMCS objectives include (a) stabilizing hemodynamics and restoring end-organ perfusion, (b) supporting heart recovery, and (c) allowing time for bridging to advanced therapies (ie, durable ventricular assist device, transplantation).[14,15] This may require multiple devices, including device reconfiguration or exchange. Different escalation and de-escalation strategies are recommended on the basis of predominant LV, right ventricular, or biventricular failure.[2] This highlights not only the importance of matching CS pathophysiology to tMCS device type, but also the need for reevaluation and optimization of tMCS management by monitoring for and mitigating the risk of device dislodgment or improper positioning, differential oxygenation (ie, north-south syndrome), LV distention (ie, ensure proper LV unloading), and oxygenator failure, among other potential tMCS device-specific insults.[3]
4. *Although early tMCS is an opportunity to improve survival, its use is both resource intensive and associated with significant morbidity. Close adherence to established best practice is a vital component of tMCS*



FEATURE ILLUSTRATION Overview of the assessment for cardiogenic shock, indications, and best practices for temporary mechanical circulatory support (tMCS). (BNP, brain natriuretic peptide; CI, cardiac index; HR, heart rate; LFTs, liver function tests; MAP, mean arterial pressure; PAPi, pulmonary artery pulsatility index; PCWP, pulmonary capillary wedge pressure; SCAI, Society for Cardiovascular Angiography and Interventions; SBP, systolic blood pressure.)

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TABLE 1 Part 1 (Definitions of Cardiogenic Shock and Indications for tMCS) Summary of Questions, Statements, and Quality of Evidence

Question	Statement	QOE
1. How do we define cardiogenic shock and its severity?	1.1 Initial and ongoing assessment for severity and progression of shock is necessary to determine escalation in care.	Moderate
2. What is the impact of cause of cardiogenic shock on prognosis, in-hospital trajectories, and outcomes?	2.1 Identifying the origin of underlying cardiac dysfunction and mechanism of acute cardiac injury improves risk stratification and initiates a specific therapeutic pathway.	Moderate
3. What are the phenotypes of cardiogenic shock?	3.1 Phenotyping cardiogenic shock, regardless of the cause, is a complementary method to assess severity.	Low
4. Which patients in cardiogenic shock (ie, severity, cause, phenotype) stand to benefit from tMCS?	4.1 Patients with evidence of cardiogenic shock should be considered for tMCS.	Moderate
	4.2 An interdisciplinary discussion before nonemergency initiation of tMCS establishes therapeutic goals, including exit strategies.	Moderate
	4.3 Patients with increased risk undergoing nonemergency cardiac procedures, as well as those patients admitted with cardiogenic shock, benefit from incorporating tMCS within the informed consent process.	Moderate

QOE, quality of evidence; tMCS, temporary mechanical circulatory support.

management (Part 3, multiple Statements). The efficacy vs safety profile of tMCS was highlighted in a recent landmark trial, which showed a mortality benefit among patients with acute myocardial infarct CS supported by microaxial-flow-pump tMCS, but also an increased risk of adverse events, including severe bleeding, limb ischemia, and hemolysis, among others.[16] Marked comorbidity has been similarly observed in the setting of other tMCS support, including venoarterial extracorporeal membrane oxygenation. As a

TABLE 2 Part 2 (Escalation and De-escalation of tMCS) Summary of Questions, Statements, and Quality of Evidence

Question	Statement	QOE
1. What are the triggers for initiating tMCS in cardiogenic shock?	1.1 Patients with ongoing cardiogenic shock, evidenced by tissue hypoperfusion and metabolic derangements from cardiocirculatory compromise, should be considered for initiation of tMCS.	Moderate
	1.2 Perform complete hemodynamic assessment, including pulmonary artery catheter or comprehensive echocardiography, expeditiously (≤6 hours) after identifying cardiogenic shock.	Moderate
	1.3 Centers should perform self-assessment of ongoing capabilities, limitations, and capacity. Communication with local/regional shock programs for patients anticipated to need care beyond its capabilities is recommended.	Moderate
2. How do we monitor and assess adequacy of current tMCS support?	2.1 The immediate goals of tMCS are stabilizing hemodynamics and restoring organ perfusion. Frequent reassessment and escalation of therapy for inadequate support are advised.	Moderate
	2.2 If patient clinical severity exceeds center capacity, call a regional referral center for timely transfer.	Moderate
	2.3 For improved continuous monitoring, a pulmonary artery catheter should be maintained during ongoing tMCS.	Moderate
3. How do we best assess and determine a patient's candidacy for weaning from tMCS?	3.1 Assessment of cardiac recovery by biomarkers, imaging, hemodynamics, and clinical assessment helps determine suitability of de-escalation.	Moderate
	3.2 If prolonged cardiac support is necessary, consider alternative tMCS device to reduce complications.	Low
4. What if the patient does not have cardiac recovery or is unable to be weaned from tMCS?	4.1 Periodic reassessment (ie, every 48–72 hours; more frequently, if needed) should be performed, reassessing patient's overall clinical trajectory and prognosis with goals of care discussions, family meetings, and shared decision making, including transfer to an appropriate center.	Low
	4.2 Eligibility for more advanced therapy options (ie, durable MCS, transplantation) should be considered in an interdisciplinary manner with workup initiated as indicated.	Low
	4.3 If advanced therapies are not an option and clinical recovery is not expected, palliative considerations should be discussed.	Moderate

MCS, mechanical circulatory support; QOE, quality of evidence; tMCS, temporary mechanical circulatory support.

TABLE 3 Part 3 (Best Practices on tMCS) Summary of Questions, Statements, and Quality of Evidence

Question	Statement	QOE
1. What are the required elements to establish goals and objectives for tMCS therapies?	1.1 Teams should be capable of providing shared decision making and palliative support services tailored to each center's expertise and resources.	High
2. How should medical centers facilitate escalation of care when indicated?	2.1 Teams should develop a partnership with a hospital system with advanced capabilities.	High
3. What is the optimal ventilation management strategy?	3.1 Ventilation strategies should promote optimal gas exchange, minimize lung injury, and promote patient–ventilator synchrony.	Moderate
4. What are the recommended gas exchange targets to preserve end-organ function?	4.1. Acid–base balance should be normalized to promote end-organ functional recovery and reverse cellular anoxia.	Moderate
5. What is the recommended timing to start or resume anticoagulation?	5.1 Anticoagulation must be initiated as soon as the benefits (eg, avoiding thrombus formation) outweigh the systemic risks (eg, hemorrhage).	High
6. What anticoagulation agent and monitoring approach should be used routinely?	6.1 The first-line agent for anticoagulation should be unfractionated heparin.	Moderate
	6.2 The therapeutic efficacy of systemic anticoagulation should be monitored with aPTT or anti-Xa levels according to center capabilities.	Moderate
7. What is the optimal strategy for patient comfort and device interactions?	7.1 Sedative agents should be minimized as tolerated, with a focus on symptom control and improving awake comfort.	Moderate
8. Can a patient on tMCS be mobilized?	8.1 tMCS-supported patients may be mobilized with a protocolized approach involving the interdisciplinary team.	Moderate
9. What routine monitoring needs to be performed?	9.1 Monitoring and clinical reassessment are required to optimize patient–device interactions.	High

aPTT, activated partial thromboplastin time; QOE, quality of evidence; tMCS, temporary mechanical circulatory support.

result, beyond ensuring tMCS optimization and proper device patient interaction (*Take-home Message 3*), the adoption of core best practice principles is necessary to avoid health care-associated complications. These practices include, but are not limited to, optimal sedation, mechanical ventilation, acid-base balance, anticoagulation therapy and monitoring, and physical rehabilitation or mobilization.[3] Best practices for tMCS are described in Part 3.

5. *Given the highly technical/specialized nature of the tMCS and the significant risk of morbidity and mortality, there is an increased emphasis on the role of shared decision making and the interdisciplinary team (Part 1, Statement 4.2; Part 2, Statements 4.1, 4.2, 4.3; Part 3, 1.1).* It may be logistically challenging, if not impossible, to have robust informed consent discussions regarding tMCS with patients and their surrogates given the often emergency nature of the therapy. Yet, even in those circumstances, the decision to pursue tMCS should still be heavily influenced by the likelihood of therapeutic success and the incorporation of shared decision-making principles, including the goals, expectations, and desires of the patient and their loved ones.[17,18] Common themes throughout the consensus document series are the role of informed consent and the establishment of goals of care. Interdisciplinary heart teams, including cardiac intensivists, cardiac surgeons, interventional and clinical cardiologists, cardiac anesthesiologists, palliative care specialists, nursing, and other consultants, are well established at many institutions to encourage clinicians with different perspectives to collaborate and assist patients and their caregivers in making informed decisions regarding their care.[19] Given the highly individualized nature of managing heart failure and tMCS, interdisciplinary heart teams are well suited to establish realistic expectations, communicate effectively, augment transitions in escalation and de-escalation of therapies, and facilitate palliation. This team-based approach can be effective on an individual patient basis and inform greater programmatic discussions. Assessing center capabilities and establishing a network for prompt remote patient discussion and expedited transfer decrease time to support and improve survival. This model involves center assessment, a designated network, and predetermined interdisciplinary teams, working in close collaboration.[20-23]

FUTURE DIRECTIONS AND LIMITATIONS. Overwhelmingly, the literature has focused on survivability associated with acute myocardial infarction CS, largely

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because of the extensive research, clinical resources, and success of various forms of coronary revascularization over recent decades.[24] Comparatively, other forms of CS, including heart failure CS and postcardiotomy shock (P-CS), are associated with discouragingly high mortality rates.[25,26] P-CS, in particular, remains an understudied and heterogenous subgroup with high mortality that requires separate considerations to best risk stratify and define, including perioperative details related to surgical, anesthesia, and perfusion-associated techniques and complications.[27] P-CS may have causes and clinical features that overlap with those of other subgroups (ie, coronary malperfusion, valvular or ventricular dysfunction). Nonetheless, more research is required to determine the degree to which patients with P-CS respond to similar therapeutic interventions.

Although certain themes were introduced throughout these consensus documents, including the importance of informed consent and shared decision-making principles, a full appraisal of ethical considerations specific to tMCS was beyond the scope of this effort. Additional research and broader consensus are required among a number of ethical topics, including ensuring equity and consistency regarding candidacy for tMCS therapy, programmatic auditing and benchmarking processes, the impact of scarce resources and their subsequent allocation, establishment and transition of goals of care, and family and patient communication, among others.

This series of guidance provides a distillation of the existing literature and a systematic approach to identifying patients with CS who may benefit from additional support, basic escalation and de-escalation algorithms, and tMCS best management practices. However, the role of tMCS in CS still requires much more attention, particularly to continue to risk stratify patient subtypes, improve existing algorithms, identify the appropriate device-disease relationships, and better integrate specific devices into the health care infrastructure.

CONCLUSION. CS is a heterogeneous disease with highly variable clinical manifestations, pathophysiology, severity, and outcomes. The POQI/ERAS Cardiac Society joint consensus statements reinforce guidance for timely multidimensional diagnosis of CS, initiation and escalation or de-escalation of tMCS, and adherence to best management practices. Each of these elements is essential to improving patient mortality and preventing health care-associated harm.

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DISCLOSURES

Michael C. Grant is on the editorial board of The Society of Thoracic Surgeons (STS) journals *(The Annals of Thoracic Surgery)*; and is on the editorial board of *The Journal of Thoracic and Cardiovascular Surgery* (JTCVS). Manreet K. Kanwar reports a relationship with Abiomed that includes: consulting or advisory; and with Abbott that includes: consulting or advisory. Subhasis Chatterjee reports a relationship with Edwards Lifesciences that includes: consulting or advisory; with Baxter that includes: consulting or advisory; with La Jolla that includes: consulting or advisory; and with Eagle that includes: consulting or advisory. Rakesh C. Arora reports a relationship with Edwards Lifesciences that includes: speaking and lecture fees; with HLS Therapeutics that includes: speaking and lecture fees; with Bioporto that includes: speaking and lecture fees; with Renibus Therapeutics that includes: consulting or advisory; and with Alexion that includes: consulting or advisory; and is on the editorial board of *The Journal of Thoracic and Cardiovascular Surgery* (JTCVS). Andrew D. Shaw reports a relationship with Alexion that includes: consulting or advisory; with Chugai that includes: consulting or advisory; with Retia Medical LLC that includes: consulting or advisory; with Renibus Therapeutics that includes: consulting or advisory; with Novartis that includes: consulting or advisory; with RenalGuard Solutions that includes: consulting or advisory; with CalciMedica that includes: consulting or advisory; and with Fresenius SE & Co KGaA that includes: consulting or advisory. Daniel T. Engelman reports a relationship with Edwards Lifesciences that includes: consulting or advisory; with Renibus Therapeutics that includes: consulting or advisory; with Alexion that includes: consulting or advisory; with Genentech that includes: consulting or advisory; with RenalGuard Solutions that includes: consulting or advisory; with Medela that includes: consulting or advisory; with Arthrex that includes: consulting or advisory; with AtriCure that includes: consulting or advisory; and with Bayer that includes: consulting or advisory; and is on the editorial board of STS journals *(The Annals of Thoracic Surgery).* Audrey E. Spelde and Jean Deschamps declare that they have no conflicts of interest.

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