CONSENSUS STATEMENT

CONSENSUS STATEMENTS FROM THE INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION CONSENSUS CONFERENCE: HEART FAILURE–RELATED CARDIOGENIC SHOCK

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ABSTRACT

The last decade has brought tremendous interest in the problem of cardiogenic shock. However, the mortality rate of this syndrome approaches 50%, and other than prompt myocardial revascularization, there have been no treatments proven to improve the survival of these patients. The bulk of studies have been in patients with acute myocardial infarction, and there is little evidence to guide the clinician in those patients with heart failure cardiogenic shock (HF-CS).

An International Society for Heart and Lung Transplant consensus conference was organized to better define, diagnose, and manage HF-CS. There were 54 participants (advanced heart failure and interventional cardiologists, cardiothoracic surgeons, critical care cardiologists, intensivists, pharmacists, and allied health professionals) with vast clinical and published experience in CS, representing 42 centers worldwide. This consensus report summarizes the results of a premeeting survey answered by participants and the breakout sessions where predefined clinical issues were discussed to achieve consensus in the absence of robust data.

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Key issues discussed include systems for CS management, including the "hub-and-spoke" model vs a tier-based network, minimum levels of data to communicate when considering transfer, disciplines that should be involved in a "shock team," goals for mechanical circulatory support device selection, and optimal flow on such devices.

Overall, the document provides expert consensus on some important issues facing practitioners managing HF-CS. It is hoped that this will clarify areas where consensus has been reached and stimulate future research and registries to provide insight regarding other crucial knowledge gaps.

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KEYWORDS:

cardiogenic shock; consensus; temporary mechanical circulatory support; shock severity; conference; management

BACKGROUND

Cardiogenic shock (CS) is an area of keen interest among the members of the International Society for Heart and Lung Transplantation (ISHLT), and there is a paucity of published data for patients with CS unrelated to acute coronary syndromes. An international consensus conference was commissioned by the ISHLT, which took place on April 26, 2022, in Boston, Massachusetts, USA, to ascertain the current practices in the management of heart failure–related CS (HF-CS). The conference was attended by 54 participants from 42 centers in 11 countries. Key opinion leaders in the fields of interventional and heart failure cardiology, critical care, cardiothoracic surgery, and pharmacy were invited to participate (see appendix). Of note, in-person attendance was limited from Asia, Australia, and other international sites due to the ongoing coronavirus disease 2019 pandemic.

Within that context, the participants were organized into 3 task forces, with section leaders to address 3 key topics related to HF-CS:

Task force 1

(Chairs: Filio Billia and Varinder Randhawa) "*Focus on Centers: Models of CS care*" with discussions on systems of care in CS, with global perspectives on implementation and integration of CS care, teams, and networks.

Task force 2

(Chairs: Sharon Chih and Christopher Barnett) "*Focus on Patients: Presentations in HF-CS*" with discussions on the approach to the initial evaluation of patients in HF-CS, phenotypes, risk-stratification, and goals of treatment.

Task force 3

(Chairs: Stephan Ensminger and Jaime Hernandez Montfort) "*Focus on Management: Strategies in HF-CS management*" with discussions on management of HF-CS, hemodynamic mechanisms, and escalation/de-escalation strategies using temporary mechanical circulatory support (tMCS).

The morning session at the conference consisted of presentations from each of the 3 task forces who had multiple discussions via teleconference in the months before the in-person meeting, and this is detailed in a separate manuscript. The afternoon session included breakout sessions where the previously agreed upon clinical issues were discussed with an aim to achieve consensus. This manuscript focuses on the results of the premeeting survey and the consensus report derived from the breakout sessions. The participants focused on reaching consensus regarding 10 questions where there was a lack of overt evidence, which would otherwise support formal guidelines.

RESULTS OF THE PREMEETING SURVEY

There were 54 participants (heart failure and interventional cardiologists, cardiothoracic surgeons, critical care intensivists, pharmacists, and allied health professionals) with vast clinical and published experience in CS, representing 42 centers worldwide. The survey was completed by 42 participants (representing 1 from each center). There were 13 questions across the 3 task forces (Table 1). The survey results reflect the real-world opinions of a carefully assembled group of experts who were invited for their expertise in the area of CS. This snapshot (April 2022) is useful as we strive to increase the adoption of practices, such as shock teams, protocolized escalation, and de-escalation of care and others across a broader group of clinicians.

Task force 1: focus on centers: models of CS care (questions 1-3)

Figure 1 is a graphical illustration of the results of these questions. Participants were queried regarding their center's role in a hub-and-spoke model of delivery of care for patients with CS: 39 centers (95.1%) identified as "hubs," 1 as a "spoke" center, and 1 felt they did not identify with either classification. When asked about the minimum capabilities a CS "hub" site should have, the majority (70.7%) of respondents felt a dedicated cardiac intensive care unit, revascularization capability, temporary and durable mechanical circulatory support (MCS) options as well as heart transplantation were necessary components. The remainder (24.4%) felt that a dedicated cardiac intensive care unit, percutaneous coronary intervention capability, as well as temporary MCS options were necessary but not durable MCS/transplant.

When asked to identify limitations of a "hub-and-spoke" model of care, responses in descending order of frequency were interfacility transfer is often too late (87.8%), assessment and communication of shock severity are highly varied (78.1%), patient evaluation is often limited at the spoke center (78.1%), there is lack of a dedicated mobile unit for safe patient transfer, especially for patients with implanted MCS (58.5%), and interfacility transfer times are too long and/or distance is too far (48.8%).

Task force 2: focus on patients: presentations in HF-CS (questions 4-6)

Figure 2 illustrates these survey responses in a graphical format.

When queried about the presence of an organized CS team in their institution: 48.8% of respondents indicated that they had a mature developed shock team to care for CS patients, 43.9% stated that there was a developing shock team, but it was "a work in progress," and 3 sites (7.3%) did not have such a team. For sites with a shock team, the team members included (in descending order of frequency): heart failure cardiologist (92.1%), cardiothoracic surgeon (89.5%), critical care attending (71.1%), interventional cardiologist (65.8%), perfusionist (36.8%), intensive care unit fellow and shock coordinator (both 23.7%). Less than 10% reported palliative care, general cardiology, intensive care unit charge nurse, and others' participation in their shock team.

In terms of "activation" of the shock team, 42.5% of respondents noted that there was no dedicated formal mechanism to activate their team, 32.5% said they have a "shock pager" that gets activated for all CS patients—whether "in-house" or transfers, 12.5% noted their shock pager activation pattern was "hit or miss," 7.5% only activate the shock pager if temporary MCS is being considered, and 5% of respondents activate the shock pager when patients have arrived at the facility.

When asked to choose 3 markers (from a list) that are most critical in the identification of HF-CS patients who should be transferred to the "hub" center, the following answers were received (in descending order of frequency): worsening end organ function (65.8%), lactic acid value (61%), tie (58.5%) between number and/or dose of vasoactive infusions and hemodynamics (from pulmonary artery catheter [PAC] or central venous catheter), referral center determined Society for Cardiac Angiography and Intervention (SCAI) classification (22%), followed by ejection fraction, arterial blood gas, or ventilator data or history of cardiac arrest.

Task force 3: focus on management: strategies in HF-CS management (questions 7-13)

Figure 3 illustrates these survey responses in a graphical format. Regarding PAC placement, 56.1% of respondents reported PAC use was "Part of our shock algorithm—so nearly every patient receives one," 26.8%

Table 1 Premeeting Survey Questions

	Question	Answers
1	Is your center part of a hub-and-spoke model of delivery of care for patients with cardiogenic shock?	a. Yes, our center is a receiving (hub) center b. Yes, our center is a referring (spoke) center c. We are working on it d. No, our center is not part of a hub-and-spoke model of care
2	What minimum capabilities should a cardiogenic shock "hub"' site have?	a. CCU + PCI capability b. CCU, PCI capable + provides temporary MCS c. CCU, PCI capable, has options for temporary and durable MCS/heart transplant d. Different "layers" of hubs within our regionalized health care
3	3. What limitations do you see or have you seen with the hub-and-spoke model of care? (Choose all that apply)	a. Inter-facility transfer times are too long/distance is too far b. Inter-facility transfer is often too late c. Lack of a dedicated mobile unit for safe patient transfer, especially if with MCS d. Patient evaluation is often limited (e.g., no PAC) and/or inaccurate at the Spoke center e. Assessment of shock severity and communication regarding that is highly varied f. Other (please define in free text)
4	Do you have a cardiogenic shock team that gets involved for all CS patients?	a. No b. Yes—but it's a work in progress c. If Yes—the key members are (check all that apply) • HF cardiologist • General cardiologist • Interventional cardiologist • Critical care attending • CT surgeon • ICU fellow • Shock Coordinator • Perfusion • Palliative Care
5	Regarding your cardiogenic shock team activation mechanism	a. We don't have a dedicated cardiogenic shock pager/mechanism b. We have a shock pager and activate it once the CS patients arrive at or are identified at our facility c. We have a shock pager that gets activated for all CS patients—whether in house or transfers d. We have a shock pager but it's a hit or miss when it gets activated e. We have a shock pager but only use it if acute MCS is being contemplated
6	Choose 3 of the following markers that are most critical to identify non-AMI shock patients who should be transferred to the "hub"	a. Ejection fraction b. Lactic acid c. Referral center determined SCAI classification d. Number and/or dose of vasoactive infusions e. ABG f. Oxygen dose/ventilator settings g. Presence or absence of cardiac arrest h. Hemodynamics (from PA or central venous catheter) i. Worsening end organ function j. Other (please specify)
7	In my opinion, PAC assessment in cardiogenic shock is	a. Mandatory prior to tMCS to guide device timing and selection b. Part of our shock algorithm—so nearly every patient receives one c. Helpful but not essential d. Rarely needed

Continued

Table 1 Premeeting Survey Questions

	Question	Answers
		e. Not available at my hospital/we rely on non-invasive hemodynamic monitoring
8	In addition to clinical parameters, which one of the following most heavily influences the decision to escalate mechanical support intensity (tMCS) at your center: (Pick one)	a. Non-invasive (Flotrac/trans-thoracic echocardiogram) b. Invasive hemodynamics/calculated indices (PAC) c. Escalating pressor requirement d. Lab trends (serial lactate or others) e. Clinical gestalt
9	For CS patients with a PAC, changes in vasopressor doses are made in the following ways	a. Nursing protocol with physician notification for rapid changes b. No protocol—Each patient has specific orders for each vasopressor change c. Hemodynamics are on the electronic medical record and changes made by staff as needed d. Different protocols for working hours and evening shift
10	In addition to clinical parameters, which one of the following most heavily influences the decision to escalate tMCS at your center	a. Non-invasive methods (Flotrac or other devices, trans-thoracic echocardiography, etc) b. Invasive hemodynamics/calculated indices from PA catheter c. Escalating pressor requirements d. Lab trends including lactate or others e. Clinical gestalt
11	Does your center have a tMCS device weaning protocol?	a. Yes—for each device, based on PAC/TTE/Clinical and Lab parameters b. Yes—for the most part, based on clinical gestalt c. Yes—but we don't use it consistently d. Not really—we go by clinical parameters
12	In patients with non-AMI cardiogenic shock, what is the most common trigger for a hemodynamic evaluation (with PAC or other tools)	a. Hypotension (MAP) b. Hypo-perfusion (Lactate) c. Worsening congestion (high diuretic dose, RRT) d. Worsening liver/renal function e. A little bit of everything
13	In patients with cardiogenic shock, how do you define the severity of shock during daily rounds/at bedside?	a. SCAI classification at admission, and clinically thereafter b. SCAI classification, assessed daily c. Hemodynamic indices (e.g., cardiac index) d. Hemo-metabolic indices (including labs) e. Number of drugs or devices f. Type of device (e.g., IABP = 'early' shock, ECMO = 'severe' shock) g. A little bit of everything

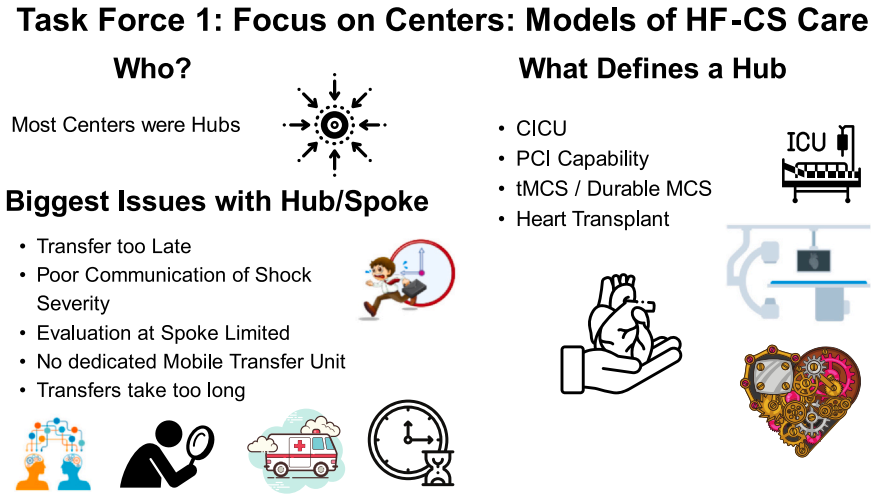
AMI, acute myocardial infarction; MAP, mean arterial pressure; SCAI, Society for Cardiac Angiography and Intervention.

responded that PAC was mandatory before tMCS to guide device timing and selection, and 14.6% deemed PAC use "Helpful but not essential" and one responded felt PAC use was "rarely needed."

We asked participants, "In addition to clinical parameters, which one of the following most heavily influences the decision to escalate temporary MCS at your center (pick only one)": 51.2% responded "Invasive hemodynamics/calculated indices (PAC)," 29.3% escalating pressor requirement, 12.2% laboratory value trends, and the remainder (7.3%) reported "clinical gestalt" was most important. Next, we asked "For CS patients with a PAC, changes in vasopressor doses are made in the following ways": Most commonly (48.8%) "Nursing protocol with physician notification for rapid changes," followed by 29.3% "hemodynamics are on the electronic medical record and changes made by staff as needed," 17.1% answered "No protocol—Each patient has specific orders for each vasopressor change," and 4.9% noted "Different protocols for working hours and evening shift."

We inquired if sites have a tMCS device weaning protocol, and 35.9% of respondents noted no formal protocol. The remainder of responses were split among the following answers: "Yes—for each device, based on PAC/echocardiography/clinical and lab parameters" (23.1%), "Yes—for the most part, based on clinical gestalt" (28.2%) and "Yes—but we don't use it consistently" (12.8%).

Figure 1 Task force 1: focus on centers: models of HF-CS care. CICU, cardiac intensive care unit; HF-CS, heart failure cardiogenic shock; ICU, intensive care unit; MCS, mechanical circulatory support.



Regarding hemodynamic assessment, we asked, "In patients with HF cardiogenic shock, what is the most common trigger for a hemodynamic evaluation (with PAC or other tools)." The majority (71.8%) answered "A little bit of everything," 15.4% responded "Hypo-perfusion (Lactate)," followed by worsening congestion (high diuretic dose, renal replacement therapy; 7.7%) and deteriorating liver/renal function (5.1%), and no respondent indicated that mean arterial pressure was a trigger.

We asked, "In patients with CS, how do you define the severity of shock during daily rounds/at bedside?" with 7 choices. The responses are listed in order of descending frequency: "A little bit of everything" (53.8%), "Hemo-metabolic indices (including labs)" (20.5%), "SCAI classification, assessed daily" (10.3%), "SCAI classification at admission, and clinically after that" (7.7%), "Hemodynamic indices (e.g., cardiac index)" (7.7%) but no one chose "Number of drugs or devices" or "Type of device (e.g., intra-aortic balloon pump = "early" shock, ECMO = "severe" shock)."

The survey results indicate that across the globe and across centers, the complexities of various aspects of CS care remain similar. Elements of the transfer process, including time for transport, pretransfer local

Figure 2 Task force 2: focus on Pt presentation with HF-CS. HF-CS, heart failure cardiogenic shock; ICU, intensive care unit.

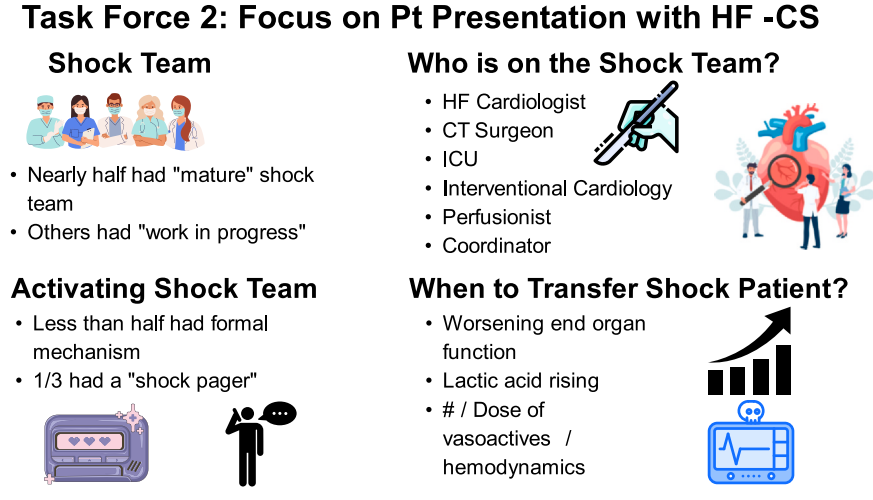
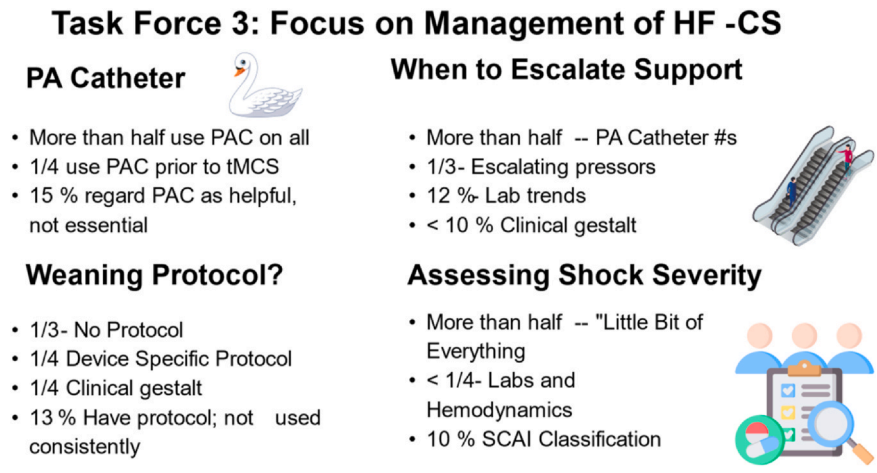


Figure 3 Task force 3: focus on management of HF-CS. HF-CS, heart failure cardiogenic shock.



assessment/evaluation, and assessment of shock severity in the local/"spoke" center, are major issues noted across centers. While shock teams have been shown to add significant value,[1-5] the implementation can be challenging and is far from universal. Most survey respondents reported having a shock team, but less than half noted that it was formal and not simply a "work in progress."

There was reasonably good agreement that PAC evaluation was essential either as a part of a shock treatment algorithm or to guide the selection of tMCS devices as well as inform decisions on escalation of support therapies. Interestingly, few centers had formalized prescriptive protocols for weaning of device support, with most going by clinical gestalt. If PAC placement was not standard, there was no specific indication for placement, with most respondents noting the decision to place a PAC was based on "a little bit of everything." Finally, assessing the severity of shock was rarely formal or based on SCAI staging but a composite of the overall clinical picture.

Breakout sessions

Next, all participants were given separate rooms and extended time to answer 10 breakout questions before rejoining and developing group consensus (Table 2). The summary of all the consensus statements below is provided in Table 3.

The discussions throughout the day highlighted lacking and equivocal evidence, pertaining to not only the treatment of HF-CS but even the identification of the shock state. Thus, global initiatives to improve CS's early and rapid recognition are warranted.

Discussion on systems of care in HF-CS (questions 1-3)

Question 1: Which is a better system for cardiogenic shock management: hub-and-spoke network or a tier-based network of shock centers? What are the pitfalls of the various models of care?

Consensus statement 1: There is a continuum of CS care and levels of care capability can be defined by the treatment goals in each clinical setting. Resource-constrained therapies such as heart transplants or durable ventricular assist devices may only be offered at a level 1 center.

The consensus opinion was that a model of concentric circles, as shown in Figure 4**,** was most appropriate. The figure illustrates the progression from clinical settings ranging from the emergency department to the community hospital, specialized intensive care unit, full capability cardiac catheterization laboratory, and, finally, the center with full options for durable ventricular assist device and heart transplants. The figure also overlays the modalities of care at each "ring" in the chain of HF-CS care.

Question 2: What is a minimum data set that should be communicated before hospital transfer (should this be standardized?).

Table 2 Breakout Questions for Group Consensus

Question #	Question
1	Which is a better system for cardiogenic shock management: Hub and spoke network or tier-based network of shock centers? What are the pitfalls of the various models of care?
2	What is a minimum data that should be communicated prior to hospital transfer (should this be standardized?) a. What are the strongest signs of deterioration which should prompt re-evaluation and consideration of transfer? Is a particular number of "drugs and devices" in total sufficient to trigger this decision? b. What parameters define "futility" of transferring the patient to a higher tier center?
3	Which disciplines should constitute a shock team at a shock "hub" center?
4	When using a PA catheter to guide treatment, what are the most useful hemodynamic elements in non-AMI cardiogenic shock? a. What are the most useful non-hemodynamic (clinical, biochemical) prognostic markers to define clinical trajectory and guide treatment decisions?
5	Propose nomenclature for terminology of "non AMI" shock
6	There are two fundamental approaches to tMCS- Start with maximum support and wean, or begin with smaller "guns" and escalate. Which approach for which patients (i.e., does shock severity drive a particular approach and if so, please explain)?
7	In non-AMI shock, what is the most important goal for tMCS device selection?—unloading the ventricle(s) versus supporting circulation or improving end-organ perfusion
8	What are the targets for flow-dosing or determinants of an "optimal flow" for a tMCS device during active support? a. How should body size and baseline cardiac output "deficit" guide device selection in tMCS?
9	What is the ideal algorithmic approach to guide de-escalation of patients on tMCS?
10	How to determine therapeutic anti-coagulation strategies for tMCS devices while they are running on full flow?

AMI, acute myocardial infarction; tMCS, temporary mechanical circulatory support.

a. What are the strongest signs of deterioration which should prompt re-evaluation and consideration of transfer? Is a particular number of "drugs and devices" sufficient to trigger this decision?
b. What parameters define "futility" of transferring the patient to a higher tier center?

Consensus statement 2 A checklist for gathering information before calling for a possible transfer is valuable to optimize time and efficiency when requesting a transfer to a higher level of care.:

The teams felt that a level of flexibility is needed to adapt to the circumstances each health care setting will encounter. Figure 5 illustrates 1 example. In this figure, certain key elements (entitled the 5 vital signs of shock: blood pressure, heart rate, assessment of oxygenation, lactate, and urine output) are at the pyramid's base. The next level of information is about the patient's premorbid status and any directives. This information is not always readily available in CS patients in the emergent setting, but knowing the baseline level of function as well as any preplanned directives helps establish goals of care, as some of the interventions for CS are quite invasive and result in temporary or permanent decrements in the baseline level of functioning, which may not be acceptable to the patient long term.

The next layer includes imaging and testing, including chest X-ray, electrocardiogram, and echocardiography. On a case-by-case basis, additional modalities, such as computed tomography, may be appropriate, but particularly in some environments or time frames, may not be available. Advanced modalities, such as cardiac catheterization, including pulmonary artery catheterization and coronary angiography results, are ideal when available. Finally, the final element is the capacity of the receiving center to accommodate the patient as well as the capability to support the patient is critical. For example, in the system with levels of care, some CS patients may be well served by transfer to a hospital with PCI capabilities but no heart transplant or durable left ventricular assist device program. In contrast, others may need to transfer to the quaternary facility directly.

Both the receiving center and the index center must also establish and agree on the safety of transport of such critically ill patients before transport. In the event of transfer requiring prolonged transport (> 2-3 hours), there must ideally be provisions for monitoring the basic 5 vital signs of shock. Additionally, despite inotropes/tMCS and mechanical ventilation, the receiving center and the index center must address with the patient caregivers the possibility of sudden clinical decline during the process of transfer.

Table 3 Consensus Statements From Conference

Question #	Statement
1	There is a continuum of CS care and levels of care capability can be defined by the goals of treatment in each clinical setting. Resource constrained therapies such as heart transplant or durable ventricular assist devices are examples of treatments which may only be offered at a level 1 center.
2	A checklist for information to gather prior to calling for possible transfer is valuable to optimize time and efficiency when requesting a transfer to a higher level of care.
3	Rather than focusing on disciplines, focus on roles that are essential may be more productive. There needs to be a clinician able to provide critical care, one to place temporary MCS devices as well as cardiothoracic surgical procedures, along with a heart failure practitioner, along with nursing/allied health, and potentially representation from a device specialist (perfusionist, mechanical circulatory support coordinator), palliative care and pharmacy.
4	Assessment of biventricular filling pressures and cardiac output, along with serial assessment is most important if a PA catheter is in place. Hemodynamic information should be correlated with clinical and laboratory indices of perfusion and trends closely followed.
5	As a single term, HF-CS (heart failure cardiogenic shock) is preferable for etiologies that are not based in acute coronary ischemia. It is also important to further describe such patients with the chronicity of illness (acute, acute on chronic), as well as type (left, right or biventricular failure).
6	It is ideal to match the patient's shock severity to the intensity of the initial support strategy, considering the risks of the device or therapy. Specific therapies available will vary according to the level of center which the patient presents for care.
7	It is ideal to match the goal of tMCS to the degree of CS severity such as assessed by SCAI stages. With higher SCAI stages, the focus is on circulatory stability, with increasing focus on optimization of perfusion and optimal hemodynamics in lesser severities of shock.
8	There is no specific numerical flow target for treatment of CS in patients with HF-CS. Instead, establishing and maintaining end organ perfusion is paramount, recognizing that some organ systems may lag behind clinical improvements (liver and renal dysfunction may take days to fully resolve even if the patient is requiring less support and clinically improving). Body size and deficit of cardiac output should guide the intensity and specific initial support strategy chosen.
9	A systematic approach with frequent trials of support assessment and potential reduction in the context of multimodality imaging and multidisciplinary team involvement is most favored. The specifics of a particular patient's illness and the eventual end goals of care will influence the weaning process.
10	In the absence of robust data to guide decisions, it is reasonable to match the risks of clot (including where the clots could embolize to) to the risk of anticoagulation type and intensity which is chosen. These decisions are device specific and may be time dependent with higher risk of clot earlier after tMCS initiation and lower over time in some cases.

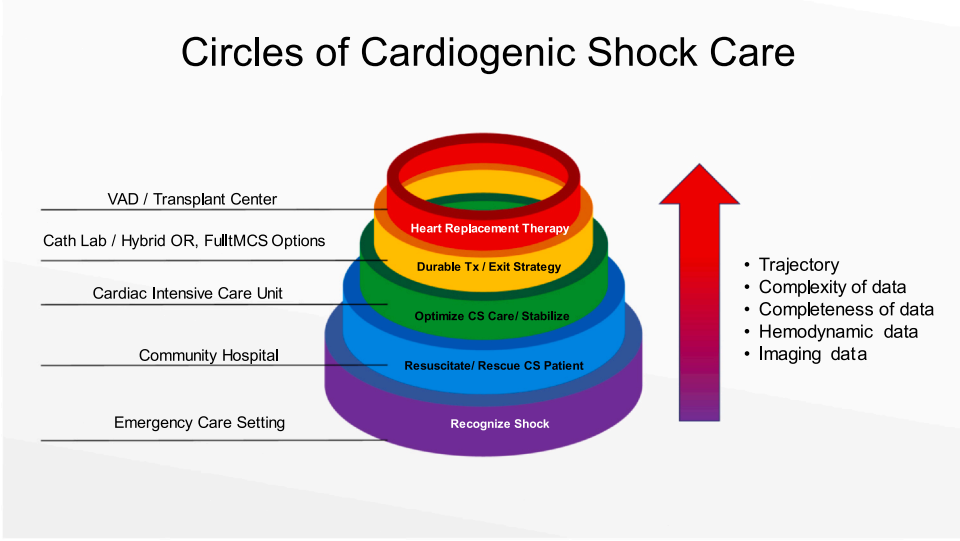
tMCS, temporary mechanical circulatory support.

Question 3: Which disciplines should constitute a shock team at a shock 'hub' center?

Consensus: Focusing on essential roles may be more productive than focusing on disciplines. There needs to be a clinician able to provide critical care, one to place temporary MCS devices as well as cardiothoracic surgical procedures, a heart failure practitioner, along with a nursing/allied health professional, and potentially representation from a device specialist (perfusionist, mechanical circulatory support coordinator), palliative care, and pharmacy.

The participants agreed that different health care settings would have additional staff in the various roles needed for effective CS care. At its simplest, shock teams need the capability to provide critical care, assess cardiovascular and heart failure status, and intervene via pharmacologic or temporary MCS devices. Some temporary modalities are initiated by cardiothoracic surgeons, and others are initiated by interventional or structural cardiologists. The involvement of pharmacy, palliative care, and nursing best serves the complexities of such patients. Some roles may be covered by a single practitioner (i.e., a cardiologist trained in interventional cardiology and heart failure/transplant), whereas other duties are split across providers. The participants felt that the single most crucial aspect of a shock team was a cohesive, collegial, and committed group, a medical "family unit," as it were.

Figure 4 Circles of cardiogenic shock care. MCS, Mechanical circulatory support; OR, Operating room; VAD, ventricular assist device.



Task force 2: focus on patients: presentations in HF-CS (questions 4-6)

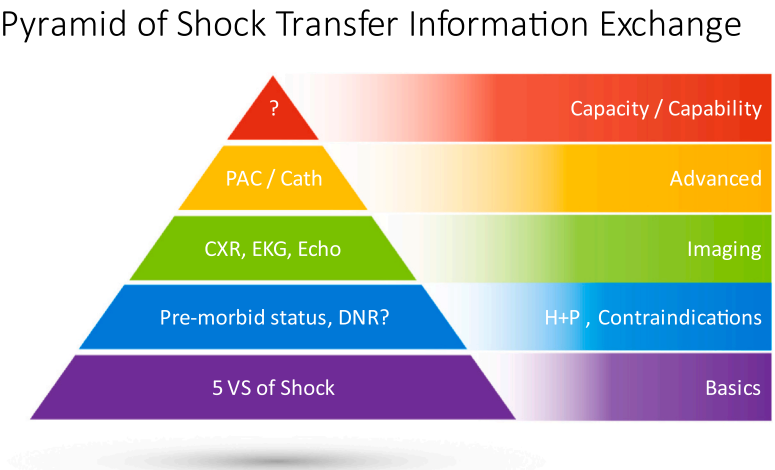
Question 4: When using a PAC to guide treatment, what are the most useful hemodynamic elements in HF-CS?

a. What are the most useful nonhemodynamic (clinical, biochemical) prognostic markers to define clinical trajectory and guide treatment decisions?

Consensus: Assessment of biventricular filling pressures and cardiac output, along with serial assessment, is most important if a PAC is in place. Hemodynamic information should be correlated with clinical and laboratory perfusion indices and trends closely followed.

The participants felt that the PAC offers some unique data elements that are not readily available with other modalities. Therefore, the PAC should focus on these elements, particularly biventricular filling pressures, including right atrium and pulmonary capillary wedge pressure and pulmonary artery pulsatility index calculation.

Figure 5 Pyramid of shock transfer information exchange. CXR, chest x-ray; DNR, Do not resuscitate; EKG, electrocardiogram; H+ P, history and physical; PAC, pulmonary artery catheter; VS, vital signs.



5 vital signs of shock : Blood pressure, heart rate, assessment of oxygenation, lactate and urine output

Regarding nonhemodynamic markers, serial assessment of lactate, blood gas measurements, and clinical correlates, such as mentation and urine output, were most universally available and most important. Setting up mechanisms to ensure serial assessment and response to deterioration was felt to be a critical component of successful CS care. Vulnerable periods, such as overnight shifts, represent a significant opportunity to enhance outcomes as several hours with decompensated shock often result in irreversible transitions of shock severity stage based on the collective experiences of participants.

Question 5: Propose nomenclature for the terminology of "non-acute myocardial infarction (AMI)" HF-shock.

Consensus: As a single term, HF-CS (heart failure cardiogenic shock) is preferable for etiologies unrelated to acute coronary syndrome. It is also important to further describe such patients with the chronicity of illness (acute, acute on chronic), as well as the type (left, right, or biventricular failure).

There was vigorous discussion on this point. Ultimately, the participants favored HF-CS as a simple yet imperfect moniker for the complex state of CS, which is not due to an acute coronary syndrome. The group realized that HF-CS does not reflect the acuity or chronicity of the underlying HF state nor the etiology. For example, a patient with severe coronary artery disease and chronically impaired ventricular function may have HF-CS in the setting of increased demand but not have an AMI-related CS. In addition, it is critically important to assess which cardiac components are most impaired in the patient's clinical scenario. Understanding left, right, or biventricular failure often involves imaging as well as PAC monitoring.

Question 6: There are 2 fundamental approaches to temporary MCS—Start with maximum support and wean or begin with smaller "guns" and escalate. Which approach for which patients (i.e., does shock severity drive a particular approach and if so, please explain).

Consensus statement: It is ideal for matching the patient's shock severity to the intensity of the initial support strategy, considering the device's or therapy's risks. Specific therapies available will vary according to the level of the center.

After much debate, it was acknowledged that there is only expert opinion and no randomized data to answer this question. There was a strong conviction that the intensity of the response (whether pharmacologic or device based) should match the severity and trajectory of the CS patient. Patients with less acute and progressive CS (such as SCAI stage B) who are not rapidly deteriorating may be well served with devices with a lower cost and risk profile or pharmacologic management alone. In contrast, patients with SCAI states D and E have little "margin for error" and choice of more intensive and complete cardiac support may be preferable to reduce the progression to multiorgan failure. SCAI stage C patients fall in the middle of the 2 approaches, with ideal care tailored to the specific patient. It is also important to consider the support modalities available in a particular center. In resource-constrained environments, the choices may be markedly limited, and there may be only one type of device which is available.

Task force 3: focus on management: strategies in HF-CS management (questions 7-13)

Question 7: In HF-CS, what is the most important goal for temporary MCS device selection—unloading the ventricle(s) versus supporting circulation or improving end organ perfusion?

Consensus statement: It is ideal for matching the goal of temporary MCS to the degree of CS severity as assessed by SCAI stages. With higher SCAI stages, the focus is on circulatory stability, with increasing emphasis on optimizing perfusion and optimal hemodynamics in lesser severities of shock.

The discussions highlighted that there is no randomized data to support one approach or the other, but the team was able to come to a consensus on the priorities to focus. In particular, for patients in SCAI stages D and E, the focus should be establishing stable circulatory status. In contrast, in SCAI stages A and B, it is recommended to focus on optimizing filling pressures and hemodynamics. Stage C is in between the other groups, and the need for circulatory support devices needs to be individualized, accounting for clinical trajectory (i.e., if the patient is worsening or rapidly improving).

Question 8: What are the targets for flow-dosing or determinants of an "optimal flow" for a tMCS device during active support?

a. How should body size and baseline cardiac output "deficit" guide device selection in tMCS?

Consensus statement: There is no specific numerical flow target for the treatment of CS in patients with HF-CS. Instead, establishing and maintaining end organ perfusion is paramount, recognizing that clinical improvement is not uniform across organ systems, and some may lag behind (liver and renal

dysfunction may take days to fully resolve even if the patient requires less support and clinically improving). Body size and deficit of cardiac output should guide the intensity and specific initial support strategy chosen.

The group felt the best approach was to focus on the patient and the perfusion status by clinical and biochemical indices instead of specific numbers, such as mean arterial pressure and cardiac index. The patient's premorbid state and chronic adaptations to low cardiac output (more common in HF-CS) may result in a situation where smaller increases in cardiac output may be more than sufficient to restore adequate perfusion vs in a patient with no prior history of heart impairment.

Regarding the correlation of body size to the need for support, ideal body weight was preferred as an index of size. The least invasive approach to restore a cardiac index of at least 2.2 liter/min/m^2 and improved perfusion are favored. Preferred indices of perfusion status were felt to be oxygen saturation of pulmonary artery blood ("mixed venous") and lactate kinetics (especially focusing on clearance over time). Estimation of the flow capabilities of a specific device may guide use. For example, if a patient needs an additional 4 liter/min of augmented flow, only certain approaches can provide this level of support.

Question 9: What is the ideal algorithmic approach to guide de-escalation of patients on tMCS?

Consensus statement: A systematic approach with frequent trials of support assessment and potential reduction in the context of multimodality imaging and multidisciplinary team involvement is most favored. The specifics of a particular patient's illness and the eventual end goals of care will influence the weaning process.

It is acknowledged that recent statements have covered this area extensively and should be reviewed separately.[6,7] There were key points expressed by the conference participants. First, improvements in clinical and biochemical parameters as well as invasively measured hemodynamics should all be assessed when considering de-escalation of temporary MCS. Patients should be clinically stable with ideally the etiologic mechanism of the shock either managed or resolved (such as healed myocarditis). Finally, a systematic stepwise weaning approach was strongly favored, involving the multidisciplinary team and, when possible, multimodality imaging.

Question 10: How to determine therapeutic anticoagulation strategies for temporary MCS devices while providing full flow?

Consensus statement: In the absence of robust data to guide decisions, it is reasonable to match the risks of thrombus (including where the thrombus could embolize) to the risk of anticoagulation type and intensity, which is chosen. These decisions are device specific and may be time dependent, with a higher risk of clot earlier after temporary MCS initiation and lower over time in some cases.

The consensus was that insufficient data exists to set forth a specific answer to this question. It was emphasized that anticoagulation should be minimized, when possible, but much is particular about the devices employed and their associated risks of thromboembolism. It was also a general opinion that "full flow" was not always a suitable substitute for anticoagulation.

Consensus meeting summary for the approach to and management of HF-CS

In summary, the ISHLT Consensus Conference Statement: Controversies in Heart Failure Related Cardiogenic Shock describes the current state of the art in an area where the evidence is thin to nonexistent. It is interesting that even among a group of experts from across the globe, there are elusive goals such as universal availability of shock teams, uniform ways to decide on escalation and de-escalation of therapy, as well as ways to decide on device choice in a protocolized fashion. We achieved consensus on 10 key topics and, in combination with the information in the first manuscript in this series, have hopefully clarified key issues in the care of HF-CS, which has important differences from that of AMI-related CS where multiple clinical trials have been conducted.

Disclosure statement

David Baran reports past honoraria from Abiomed, Livanova, Getinge, Abbott and Teleflex. Current steering committee for CareDx and Natera, data safety monitoring board for XVIVO and the PACCS trialManreet Kanwar reports consulting fee from Abbott, Abiomed and CareDx. On Advisory board for Abbott, Abiomed and CorWave. She is on Steering Committee for RECOVER IV, PACCS trial and Cardiogenic Shock Working Group.Filio Billia reports grant funding from Abbott and that she is the chair of the ISHLT MCS Interdisciplinary Network.Dr. Garan,

Sinha and Hernandez-Montfort are on the Steering Committee for Cardiogenic Shock Working Group. Jaime Hernandez-Montfort also reports consulting fees / honoraria paid to him from Abiomed and Abbott.Jennifer Cowger reports grants paid to her institution from Abbott, Medtronic and Procyrion. She reports consulting fees from Abbott, Medtronic, BioVentrix and Procyrion paid to her, and honoraria paid to her from Abbott, Zoll and BioVentrix. Meeting travel support from Abbott. She is on the Steering committee for Nuwellis and Endotronix, DSMB for Berlin Heart and BiVACOR, and advisory boards for Abbott, BioCentrix, and CorWave. She is a Deputy Editor for JHLT and Associate Editor for JACC.Dr. Proudfoot reports consulting fees paid to his institution from Becton DickinsonDr. Hoong Sern Lim reports payments to his institution for educational courses, and support for educational meeting travel from Abbott.Drs. Blumer, Barnett, Chih, Ensminger, Randhawa, Jennings, Renedo, Vorovich and Hanff report no COI.

APPENDIX. LIST OF COLLABORATORS

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