

PANEL DISCUSSION

The Evolving Data Landscape of Cardiogenic Shock

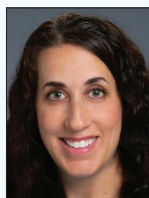
The evidence guiding contemporary cardiogenic shock care, including patient phenotyping, mechanical circulatory support, protocol-driven management, takeaways from DanGer Shock, and priorities for future clinical trials.

With Aasim Afzal, MD, MBA, FHFSa, FAST; Allison Dupont, MD, FSCAI, FACC; and Rajan A.G. Patel, MD, FACC, FAHA, FSCAI



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changing development in cardiogenic shock (CS) over the past 2 to 3 years?

Dr. Dupont: I think most will answer by saying that the DanGer Shock trial was the most relevant, practice-changing study to hit the shock world.¹ There is now randomized data to support the use of Impella microaxial flow pump (J&J MedTech Heart Recovery) in some acute myocardial infarction (AMI) shock patients. Many of us had been using the device for years and were anecdotally seeing benefit, but now we have the data to support this practice. Importantly, we've known about the risks associated with the device, and these were significant in DanGer Shock. Safe technique and monitoring during and after implantation of the device can be the difference between life and death.

Dr. Patel: In my opinion, the single most practice-changing development was the publication of the DanGer Shock randomized controlled trial (RCT),¹ which specifically studied patients with AMI who underwent primary percutaneous coronary intervention (PCI). The trial demonstrated a 12.7% reduction in all-cause mortality among AMI patients undergoing primary PCI who received Impella CP compared to those who did not receive mechanical circulatory support (MCS), translating to a "number needed to treat" of 8. The benefit of the left ventricular (LV) aortic pump was greater in patients aged < 77 years compared to older patients. However, this effect is not surprising to those of us who take care of adult intensive care patients.

The inclusion and exclusion criteria of this trial are critical to understanding which AMI patients may benefit from

Looking at the available data, what do you believe has been the single most practice-

Impella CP use. Important inclusion criteria include an electrocardiogram that meets ST-segment elevation MI (STEMI) criteria, hypotension with systolic blood pressure < 100 mm Hg, lactate level > 2.5 mmol/L, LV ejection fraction (LVEF) < 45%, and randomization at the time shock was diagnosed. In this study, median LVEF was 25%, and median lactate was 4.5 mmol/L. Important exclusion criteria were patients who had out-of-hospital cardiac arrest and were comatose, patients with right ventricular (RV) failure, and patients with mechanical complications from AMI.

The trial was notable for an increased number of complications in the Impella CP group, despite the better absolute survival in this group. There was increased incidence of bleeding complications (access site bleeding, < 25%), patients with limb ischemia, patients with sepsis, and patients needing renal replacement therapy. Importantly, at 6 months, there were no patients on renal replacement therapy. To improve care of AMI shock patients in the future, it will be critical to mitigate these complications. The ongoing OASIS-AMICS clinical trial (NCT06964685) is assessing whether implementation of best practices for Impella use might reduce the complication rate among CS survivors.

Dr. Afzal: The most practice-changing development has been the adoption of and movement toward viewing CS as a phenotype-driven disease process with a standardized evaluation mechanism that allows for early recognition and frequent serial reassessment. The Society for Cardiovascular Angiography and Interventions (SCAI) SHOCK classification² and the ever-growing body of literature resulting from the adoption of registries across CS centers have enabled us to better understand the impact of this evolution in practice.

At the same time, recent randomized and prospective data have challenged the historical nihilism surrounding temporary MCS (tMCS). The DanGer Shock trial, in particular, demonstrated that carefully selected patients with STEMI-related CS can derive a survival benefit from microaxial flow pump support, while also highlighting the substantial complications associated with these devices.

The main takeaway from recent trials, including the negative ones, is that not every patient with shock needs a device; however, appropriate patient selection, timing, and standardized management can materially influence outcomes.

Several studies have emphasized protocol-driven care, early invasive hemodynamic assessment, and standardized escalation pathways. How convincing is the evidence that these structured approaches improve out-

comes versus identifying centers that already deliver high-quality care?

Dr. Patel: The data supporting protocol-driven care (ie, early identification of CS, early invasive hemodynamic assessment, standardized escalation pathways) is extremely compelling. When centers that provide high-quality cardiovascular care implement protocolized care for CS, survival improves. Papolos et al demonstrated improvement in survival by implementing protocolized care, including a multidisciplinary shock team, at 24 centers known for cardiac care.³ Prior to that, the Detroit Cardiogenic Shock Initiative (now the National Cardiogenic Shock Initiative [NCSI]) demonstrated a survival advantage with use of right heart catheterization and early MCS implementation, with an escalation plan if the cardiac power output (CPO) goal was not met or RV failure became an issue.⁴ We also have published data from individual sites supporting this treatment paradigm, including Inova Fairfax, University of Utah, and University of Ottawa.⁵⁻⁷

Dr. Afzal: Like most complex disease processes, the accruing evidence is mostly observational in nature, but it does appear increasingly compelling. Shock centers with standardized activation pathways, evaluation criteria, invasive hemodynamic assessment, and predefined escalation pathways have repeatedly shown improvements in survival compared with historical or less standardized approaches. At Baylor Scott & White The Heart Hospital, we have demonstrated an 8% absolute risk reduction with the implementation of a CS program.

I do want to highlight an important center effect. Institutions capable of implementing these protocols often have greater expertise, higher volumes, faster access to MCS, and more comprehensive multidisciplinary resources. However, this does not diminish the importance of protocolized care. In a condition characterized by rapid physiologic deterioration, reducing variability and shortening the time between recognition, hemodynamic assessment, and intervention are inherently valuable. I think a concerted effort needs to be made to help standardize the implementation of shock programs across the country and tease out exactly which components have the greatest impact on improved outcomes. This will eventually enable us to conduct prospective studies to obtain the hard data we all seek in this space.

Dr. Dupont: This question outlines the limitation of the predominantly observational data in the CS space. Quality care of patients is more important than which device you have available and how quickly you implant it. Observational studies such as the NCSI are important because they demonstrate what can be done in a high-

quality shock center. We know that in most aspects of medicine, variability can lead to implicit bias, lack of care, and poorer outcomes. Many studies in the CS space do not take into account that the majority of patients with shock will present to community, nontertiary care hospitals; therefore, the protocols used, such as that in the NCSI, may not necessarily apply to those patients. For example, a patient who presents to a non-PCI center or a PCI center without a critical care unit to care for shock patients will hopefully be transferred in a timely manner to a hospital with the ability to comprehensively care for that individual. Changing the paradigm to get faster access to higher-acuity care is probably the nut that is going to be toughest to crack, but it's likely the one that will lead to the greatest improvement in CS survival.

How should clinical trials and clinical practice better distinguish between AMI-related shock, acute decompensated heart failure (ADHF), RV shock, and mixed shock phenotypes?

Dr. Afzal: With the growing body of literature, we can now demonstrate that different morbidity and mortality burdens are associated with different CS phenotypes. AMI-related shock often represents an abrupt loss of myocardial function in a previously compensated circulation, whereas acute-on-chronic HF may involve longstanding ventricular remodeling and markedly different reserve. Similarly, isolated or predominant RV failure requires a very different therapeutic strategy than left-sided shock. All of these have different hemodynamic, preload, and afterload profiles. Postcardiotomy CS (PCCS) similarly has a very different hemodynamic profile and management strategy.

Trials and clinical pathways should therefore incorporate exact etiology, ventricular phenotype, congestion, perfusion, and invasive hemodynamics into enrollment and treatment algorithms. At a minimum, we should attempt to distinguish AMI CS, HF CS, and PCCS and separately characterize LV-predominant, RV-predominant, and biventricular shock. Parameters such as CPO, pulmonary artery pulsatility index, central venous pressure/pulmonary capillary wedge pressure ratio, cardiac output/cardiac index, and lactate curves, in addition to right- and left-sided filling pressures and dynamic SCAI SHOCK staging, can help improve our understanding and move the field from diagnosis-based classification toward physiology-based treatment.

Dr. Dupont: Advanced stages of CS often progress into a mixed shock picture but can also be associated with biventricular shock or just RV shock. With rare exceptions, it is extremely difficult to diagnose these more complex shock phenotypes without invasive hemodynamics. Therefore, clinical trials and clinical

practice both should include detailed hemodynamics to phenotype these patients.

Dr. Patel: Distinguishing between different CS phenotypes to tailor therapy is at the forefront of the field in the treatment of CS. Publication of the SCAI SHOCK staging manuscript enabled us to stratify patients based on basic hemodynamic and metabolic marker criteria in a uniform manner that allowed assessment of diagnostic test data (eg, lactate clearance) and therapies between patients and across institutions. It is now time to develop a similarly simple-to-use, well-defined set of nomenclature to describe the various etiologies of CS to customize therapy, with the goal of heart recovery. It will be critical to identify early patients who are not likely to achieve native heart recovery and who may benefit from advanced HF therapies (eg, durable LV assist device [LVAD], heart transplantation).

Key definitions might include patients with isolated AMI LV shock, RV failure, biventricular failure, and various types of acute valve failure. Among HF shock patients, single or biventricular failure and valve-related shock will also need phenotyping. Mixed phenotypes add another level of complexity. Harnessing the power of artificial intelligence (AI) to phenotype these patients may prove useful as the number of variables involved might be immense.

Recent studies generated enthusiasm for earlier ventricular unloading and protocolized escalation strategies, but questions remain. What don't we know about patient selection, timing of device implantation, and escalation between support platforms?

Dr. Patel: Ventricular unloading is theoretically useful in promoting LV recovery after AMI, as well as during ADHF. Data from preclinical experimental models are compelling, but before implementing ventricular unloading into clinical practice, many unanswered questions remain. With regard to the AMI shock patient, the timing of unloading needs to be defined. In preclinical AMI models, the time from vessel occlusion to unloading is relatively short. Whether a window for the benefit of unloading with regard to limiting myocardial injury exists is unknown.

The next question will be defining successful unloading. How fast should the left ventricle be unloaded, and for how long before treatment is deemed successful or futile? Furthermore, if an LV aortic pump is utilized and able to support a patient's mean arterial pressure (MAP) and achieve a CPO goal > 0.7, how much further unloading is beneficial? In other words, if an Impella CP can maintain an adequate MAP and CPO, is there benefit from the additional unloading afforded by an Impella 5.5? An area of ongoing study is LV unloading among patients placed on

peripheral venoarterial extracorporeal membrane oxygenation (VA-ECMO). Theoretically, unloading the left ventricle in these circumstances should promote myocardial recovery and reduce length of time on ECMO. These are low-hanging fruit for an RCT.

Dr. Dupont: There remains significant variability in unloading strategies. Observational data suggest that unloading the left ventricle in the setting of CS with LV failure may improve outcomes, but this has not been studied in an RCT. As mentioned, we've learned from observational studies that protocol-driven escalation at select tertiary care centers with expertise in CS care can result in excellent survival, even in patients with SCAI SHOCK stages C, D, and E. Many of the patients in these observational studies received LV unloading with microaxial flow pump prior to PCI. Some people reference STEMI-DTU as a randomized trial showing that unloading doesn't work.⁸ It's very important to distinguish the patient population studied in STEMI-DTU, which evaluated patients with anterior STEMI who were not in CS; ventricular unloading in CS was not evaluated in STEMI-DTU. Another area that has been evaluated with primarily observational studies is LV unloading in the setting of VA-ECMO, and this is another topic that requires an RCT.

Dr. Afzal: DanGer Shock has added to the literature demonstrating that tMCS can help improve hemodynamics, but we are still trying to better understand which CS phenotypes will benefit the most from tMCS and experience a meaningful survival benefit. Timing of tMCS is critical, as it truly impacts the outcomes we see across shock profiles. We still lack reliable tools to distinguish patients who are early enough in their shock trajectory to benefit from support from those who either do not require a device or have progressed to irreversible multiorgan injury.

We need a better understanding and more data regarding who should undergo tMCS escalation and when, when current tMCS support is insufficient and escalation will provide a survival benefit, and when to vent VA-ECMO. We need physiologic escalation criteria that incorporate LV and RV function, cardiac power, filling pressures, oxygen delivery, lactate clearance, vasopressor requirements, and evidence of end-organ recovery. Equally important, future algorithms need defined criteria for deescalation and recognition of futility.

Pulmonary artery catheter use has experienced a resurgence in contemporary shock programs. Should invasive hemodynamic profiling be considered standard of care for most patients receiving tMCS, or are there still important limitations?

Dr. Patel: Invasive hemodynamic profiling is standard care in 2026 for most patients receiving tMCS, but there are important limitations to its utility. Some limitations can be mitigated with an understanding of the cardiac pathology that affects Swan-Ganz catheter waveforms and measurements, such as presence of severe mitral regurgitation or a ventricular septal defect. In the not-too-distant future, it is easy to imagine fully implantable, yet removable or biodegradable, sensors that eliminate the need for an additional central venous line. However, patients on biventricular MCS are one subset that typically require additional data on myocardial performance. Echocardiography is extremely useful in assessing the relative filling and unloading of each ventricle to optimize pump flows.

Dr. Afzal: Invasive hemodynamic profiling should be the standard of care for shock profiling. Unfortunately, we have not been able to demonstrate its impact with hard data, as prior RCTs did not show the impact we had all anticipated. Without invasive hemodynamics, it is very difficult to know if we are truly unloading the ventricle, if the right ventricle is failing, or if escalation is necessary.

I do think it's important to understand the data the Swan-Ganz catheter is providing. The data are only useful if they are accurate and actions are taken based on them. With the overwhelming amount of data we have to decipher in a patient with shock, complacency can set in and care providers may overlook changes in hemodynamic data, mitigating the impact of the Swan. The goal is not catheterization for its own sake; it is to use physiology to guide management.

Dr. Dupont: Although many hemodynamic measurements can be made from echo, unless there is an indwelling transesophageal echocardiography probe to obtain echo measurements (which comes with its own potential set of complications), one cannot evaluate the hour-by-hour hemodynamic changes that occur with complex CS patients without the presence of a pulmonary artery catheter. CS patients are extremely tenuous, with significant blood pressure fluctuations and rapid changes in organ perfusion. Monitoring invasive hemodynamics allows continuous monitoring of response to support devices and medications and allows clear delineation of the patient's phenotype at any given time. For example, an anterior STEMI patient who starts out with predominantly LV failure may develop progressively worsening shock. The decompensation may be due to significant RV failure, leading to difficulty in supporting the patient with a left-sided microaxial flow pump alone. This patient may need additional medical therapy or right-sided support. Alternatively, the progression in shock may be due to worsening LV failure, requiring

escalation in LV support. Or, the patient could be developing a mixed shock picture with vasoplegia that should be treated with vasopressors. Without a pulmonary artery catheter, patients may experience treatment involving “trial and error,” potentially leading to further decompensation.

As the evidence base continues to evolve, how can the field better standardize CS management across practice settings (ie, academic medical centers, community hospitals, referral networks) without sacrificing individualized patient care? What are the barriers to broader implementation?

Dr. Afzal: Standardization should focus on the process of care rather than mandating a single treatment strategy. As we look at different practice settings, we see significant variation in resources, ability to acquire resources, personnel, logistics, 24/7 coverage, and geographic factors. Community hospitals do not necessarily need every tMCS platform, but they do need predefined criteria for when to contact a regional shock center and a reliable pathway for rapid transfer.

Every hospital caring for patients with CS should have a clear mechanism for early identification, SCAI SHOCK staging, initial hemodynamic assessment, shock team consultation, escalation, and transfer, but that doesn't mean we should treat every patient the same. Every patient with shock will have a slightly different phenotype and psychosocial context. Management of CS should include shared decision-making as a core tenet. We do not want to be in a scenario where a patient who wants a conservative or palliative approach is escalated to tMCS, as this would represent ineffective resource use and would not align with the patient's goals of care.

Ultimately, we need to work toward regional-level care for CS, with full communication between hub-and-spoke centers. Ideally, outcomes for CS should be the same whether a patient's initial point of contact is a hub or a spoke center.

Dr. Dupont: Timely access to care is likely the single most important factor that affects mortality in CS. This is a two-fold problem. First, most CS patients initially present to nontertiary care hospitals. Thus, once shock is recognized, a system of care must be in place to get those patients transferred to a center capable of caring for CS patients. The system of care should be set up similar to STEMI systems of care, allowing the referring hospital to quickly obtain a phone consultation from a shock specialist (interventional cardiologist, general cardiologist, HF physician, and/or cardiothoracic surgeon). In some cases, a phone consultation may be all that's needed. In other cases, transfer is required. A huge barrier to this system is access to critical care beds, which are a limited resource. Having a list of multiple poten-

tial hospitals to which referrals can happen is important. Centralizing the transfer process regionally would be ideal, but this ideology is complicated as many regions have multiple hospital systems, often in competition.

Second, many patients initially presenting to a tertiary or quaternary care center experience a delay in their CS diagnosis, often receiving treatment for septic shock initially. The treatment of septic shock by emergency departments and even critical care physicians has become so ingrained by quality metrics that it is sometimes the default diagnosis, at the detriment of the care of the CS patient. This is particularly true of patients who present with ADHF shock, as their presentation is not as obvious as AMI with shock. Point-of-care echo in the emergency room and critical care units is likely to assist in making the correct diagnosis and should become standard of care. I do believe that AI will one day assist in identifying CS patients much earlier in their course.

Dr. Patel: The field can better standardize CS management across practice settings through collaboration and communication. For example, in the state of Virginia, the Virginia Heart Attack Coalition is a nonprofit organization that includes every hospital willing to participate and includes every tertiary care medical center in the state. The organization was founded with the intent of improving STEMI care but now focuses on many aspects of cardiac care, including CS. A statewide consensus protocol for AMI CS has been launched, with institutions reporting on adherence and outcomes. The organization hopes to develop a CS network such that physicians at any facility treating a cardiogenic patient can efficiently find a tertiary care facility with an open bed and resources (eg, an available ECMO circuit) if escalation of care is needed. Barriers to broader implementation of protocolized care include having a cohort of health care providers at each institution who are passionate about taking care of CS patients to track adherence to a shock protocol and report outcomes. Administrative recognition of the importance of CS outcomes is also important. Hospital administration can provide resources for a shock coordinator and facilitate quality improvement initiatives.

Mortality remains the primary endpoint in most CS trials, but survival alone may not fully capture meaningful clinical benefit. In your opinion, which endpoints would be valuable to capture/emphasize in future studies to better evaluate treatment success?

Dr. Dupont: Mortality certainly is the most meaningful primary endpoint and should be the primary focus of clinical trials. However, there are other important endpoints that should be studied as the field advances. For example, we know that large-bore access used for MCS

devices increases vascular complications. Thus, as technology evolves, we need to scrutinize the safety of these devices and assess whether they provide a benefit over currently available support devices.

Dr. Patel: Without question, survival from CS is the most important clinical trial endpoint, as CS is the leading cause of in-hospital mortality in the United States. However, among CS survivors, quality of life is important. For AMI CS patients, extent of LV recovery is important, as it determines functional status as well as survival during the next 5 to 10 years if chronic HF develops. Another important endpoint is need for renal replacement therapy after hospital discharge. Limb ischemia leading to disability is a critical endpoint as the use of percutaneous MCS increases. A further endpoint among survivors will be long-term neurological functional status and the development of psychiatric conditions, including depression and posttraumatic stress disorder.

Dr. Afzal: Mortality is always going to be an important endpoint, but I think it's important to look at mortality not just during the inpatient stay but also at 30 days, 60 days, and 1 year. The focus should not be solely on mortality but also include morbidity burden and quality of life. A therapy that provides a survival benefit but not meaningful quality of life may not be as appealing and will need to be discussed in the context of shared decision-making. Future trials should include neurologically intact survival, major bleeding and vascular complications, renal replacement therapy, duration of mechanical ventilation, intensive care unit and hospital length of stay, and freedom from recurrent shock.

We should also measure trajectory and recovery. Lactate clearance, improvement in SCAI SHOCK stage, reduction in vasoactive support, normalization of filling pressures, successful device weaning, myocardial recovery, and successful bridge to durable LVAD or transplantation are meaningful intermediate outcomes.

What unanswered clinical question do you most want the next generation of CS trials to address?

Dr. Patel: The next generation of CS trials needs to address patient phenotyping based on shock etiology, while also evaluating treatment specifics, including MCS device type and time to MCS for each phenotype and SCAI SHOCK stage. If the goal of treatment is native heart recovery as opposed to supporting the patient until a heart transplant can be found, then understanding the nuances of each shock type to tailor therapy may prove important.

Dr. Dupont: As I alluded to previously, the rapid identification of CS remains a challenge even in tertiary and quaternary care centers, and the majority of patients presenting with CS will initially present to community hospitals without a shock program. In order to improve outcomes, CS needs to be identified rapidly and appropriate treatment protocols initiated. AI is likely going to be the key to identifying these individuals earlier in their course, and a trial evaluating the impact of AI on timing of shock recognition and mortality could advance the field immensely.

Dr. Afzal: I think the most important question we need to address is, can we meaningfully predict outcomes in CS based on the initial presentation and the level of support needed to ensure a survival and quality-of-life benefit?

The field has evolved tremendously, and we have made incredible strides in improving patient selection and refining our evaluation pathways. We need to continue to build on the evidence we have accrued to help further refine these processes and make sure they can be easily implemented beyond the quaternary care centers where most CS protocols currently reside. For that, we need simplified data and implementation plans that we, as a society, need to work toward. ■

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Disclosures

Dr. Afzal: Consultant to Abiomed, Abbott, BridgeBio, and Alnylam.

Dr. Dupont: Consultant to Chiesi and Getinge; speaker for Medtronic.

Dr. Patel: Consultant and speaker for Johnson & Johnson MedTech; speaker for Boston Scientific; renal denervation advocacy board member for Medtronic.