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Editorial commentary: The Checklist Manifesto: Cardiogenic Shock Edition

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In his renowned bestseller, *The Checklist Manifesto: How to get things right*, Dr. Atul Gawande describes the use of checklists or protocols to achieve good outcomes when performing complex tasks, ranging from flying B-17 bombers during World War II to troubleshooting on modern aircraft, to making surgery safer in the operating rooms of today [1]. In this issue of Trends in Cardiovascular Medicine, Drs. Tanveer Rab and William O'Neill present a review of mechanical circulatory support (MCS) options for the treatment of cardiogenic shock (CS) in the context of a shock protocol. Here, Rab and O'Neill take a page out of Dr. Gawande's playbook, by proposing a protocol driven approach to mechanical circulatory support.

Historically, the incidence of CS in the acute myocardial infarction (AMI) population has been in the range of 7–10% [2,3]. The etiology of CS in the setting of AMI includes primary left ventricular pump failure, right ventricular infarction/failure, mechanical complications such as acute mitral valve regurgitation due to papillary muscle infarction or rupture, ventricular septal defects, and free wall rupture, as well as incessant ventricular tachycardia (*i.e.*, VT storm). The Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) randomized controlled trial (RCT) demonstrated the benefit of early primary percutaneous coronary intervention (PPCI) for the AMI-CS population [4]. However, since the publication of these data, the overall mortality of patients with AMI-CS has remained relatively stable [5]. Almost two decades ago, Samuels et al. demonstrated a correlation between increasing inotrope/vasopressor support and mortality among post-cardiotomy CS patients [6]. More contemporary data from the Catheter-based Ventricular Assist Device (CVAD) registry have confirmed that increasing inotropic support in the AMI-CS population is associated with worse survival [7].

In this issue's article, titled "Mechanical Circulatory Support for Patients with Cardiogenic Shock", the authors review the treatment goals in AMI-CS, the various MCS options available, the utility of right heart catheterization (RHC), and a protocol-based or algorithmic approach to the AMI-CS patient. Since the publication of the SHOCK trial, a commonly cited CS definition is one that employs both clinical and hemodynamic criteria. Clinical criteria include hypotension with a persistent systolic blood pressure (SBP) < 90 mmHg or the need to employ supportive measures to keep the SBP ≥ 90 mmHg, as well as evidence of systemic hypoperfusion (*e.g.* cool extremities or urine output < 30 mL/hr). Hemodynamic criteria include a cardiac index ≤ 2.2 L/min/m2 and a pulmonary capillary wedge pressure ≥ 15 mmHg). The authors state the goals of AMI-CS treatment are (1) to improve cardiac output (CO) and provide ventricular unloading via MCS, and (2) to restore flow in the infarct related artery by PPCI. Improving CO, of course, improves end-organ perfusion with the goal of preventing multi-organ failure. Ventricular unloading allows the ischemic myocardium to recover from the metabolic derangements associated with ischemia and subsequent reperfusion (*i.e.* reperfusion injury). In a *post hoc* analysis of the SHOCK trial, cardiac power output (CPO), defined as (mean arterial pressure *x* cardiac output)/451, and cardiac power index were the strongest independent hemodynamic variables associated with in-hospital mortality. Patients were more likely to survive if the CPO was greater than 0.6 W [8].

The MCS options discussed in the Rab and O'Neill manuscript include intra-aortic balloon pump (IABP), veno-arterial extracorporeal membrane oxygenation (VA-ECMO), left sided TandemHeart, and left sided Impella devices. As the authors discuss, due to the results of the IABP-SHOCK 2 RCT, which demonstrated no benefit of IABP over medical therapy alone [9], the routine use of IABP is now a Class III indication in the European Society of Cardiology guidelines [10], but retains a class 2a indication in the American Heart Association/American College of Cardiology (AHA/ACC) guidelines [11]. Despite these compelling RCT data, the use of IABP in the setting of CS has only minimally decreased [12].

If employed early in CS, VA-ECMO certainly can provide adequate flow to prevent end-organ dysfunction and provide adequate oxygenation. However, VA-ECMO places significant afterload on the myocardium, potentially hindering or delaying myocardial recovery unless a left-ventricular vent is placed. The use of the LV-aorta axial Impella pump (ECPELLA) has been shown to be effective for this purpose. A recent retrospective analysis demonstrated lower 30-day mortality with ECPELLA compared to traditional VA-ECMO alone [13].

The left sided TandemHeart circuit drains oxygenated blood from the left atrium and returns it to the common iliac artery

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or distal aorta though a cannula placed via the common femoral artery. Providing up to 5 L/min of flow, end-organ perfusion is preserved. However, this system also may place the injured myocardium under the strain of increased afterload, thereby theoretically hindering myocardial recovery. A small retrospective analysis of TandemHeart circuits placed over 9 years demonstrated a survival of only 24% when TandemHeart was placed as a bridge to recovery, versus 51% ($p = 0.04$) when placed as a bridge to LVAD or cardiac surgery. However, this finding may be biased by indication for MCS and timing of implantation [14].

The percutaneously implantable Impella devices are currently available in a 2.5 L/min unit and a CP unit that can provide ≥ 3.5 L/min. A surgically implantable 5 L/min device is also available. As the authors point out, Impella devices are contraindicated if left ventricular thrombus is present. However, contrary to the statement in the current manuscript, Dr. O'Neill and others have reported data on the safe use and positive hemodynamic effects of Impella pumps in patients with critical aortic valve stenosis including those undergoing balloon aortic valvuloplasty [15,16].

As the authors point out, right heart catheterization (RHC) may be useful in treating the CS patient. Beyond an assessment of volume status and systemic vascular resistance, RHC data can be used to calculate CPO. If the CPO remains < 0.6 W despite revascularization of the infarct-related artery (IRA), medication titration, and MCS, then the mortality of CS patients remains high, suggesting a theoretical benefit in escalating MCS to a higher flow device. Furthermore, the pulmonary artery pulsatility index (PAPi) is an indicator of right ventricular dysfunction. In the inferior AMI population, a PAPi ≤ 0.9 predicted in-hospital mortality or the requirement for right ventricular MCS with a sensitivity of 100% and a specificity of 98.3% [17]. The Protek-Duo cannula allows right-sided TandemHeart support via internal jugular vein access that allows patients to sit upright in bed and ambulate. Another advantage is that this system does not require anti-coagulation, as long as it is pumping ≥ 1.5 L/min. The Impella RP is a right-sided MCS device that is placed via the common femoral vein (CFV), making this device advantageous in the fully anticoagulated patient (*e.g.* the AMI patient undergoing PPCI), as the CFV is a compressible site. Both right-sided systems are capable of pumping ≥ 4 L/min. Data from the CVAD registry demonstrated that use of RHC increased survival to 63% vs. 49% in patients managed without RHC ($p < 0.001$) [18].

In *The Checklist Manifesto*, Gawande provides multiple examples of how checklists or protocols make complex tasks safer and outcomes more reliable [1]. One author of the current paper, Dr. O'Neill, has been at the forefront in improving contemporary outcomes of AMI-CS, through the Detroit Cardiogenic Shock Initiative (DCSI) protocol and now the National Cardiogenic Shock Initiative (NCSI). Use of protocols in complex tasks or problems decreases variation, allows tracking of outcomes, and facilitates assessment of therapies that are working–or failing–to achieve the desired results. The NCSI protocol includes early identification of AMI-CS patients and rapid hemodynamic stabilization with MCS, followed by reperfusion of the IRA. If myocardial recovery or hemodynamic goals are not achieved (*e.g.*, if CPO ≤ 0.6 W or PAPi ≤ 0.9), then escalation of MCS is indicated. In the DSCI registry, utilization of early MCS as part of a shock protocol increased the average pre-procedure CPO from 0.57 W to 0.95 W ($p < 0.001$). Importantly, in DSCI, survival to MCS device explant was 85%, and survival to hospital discharge was 76%, compared to a pre-DSCI historical institutional survival of 51% ($p < 0.001$). Similar data were recently reported after implantation of a CS protocol at the INOVA hospital system. Prior to protocol implementation, CS survival was 47%, and following CS protocol implementation in 2017, survival increased to 57.9%. With more experience, outcomes improved even further: 2018 survival to date was reported as 81.3% ($p < 0.01$) [19].

Cardiogenic shock is a complex clinical problem with a high mortality that has remained unchanged throughout this century… until recently. The use of protocols, clinical decision making based on hemodynamic (RHC) data, and practical knowledge of available MCS devices may help to improve the survival of AMI-CS patients.

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