

EDITORIAL COMMENT

## Mechanical Rescue of the Heart in Shock\*

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Cardiogenic shock (CS) is a state of extreme hypoperfusion owing to pump failure manifested by altered mental status, cool extremities, and/or renal failure. This hypoperfusion leads to release of catecholamines and other inflammatory mediators, which further perpetuates myocardial ischemia and injury, resulting in additional impairment in systemic and tissue perfusion. Any cause of acute severe cardiac failure may lead to CS.

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Treatment of CS largely relies on anecdotal experience and a few small clinical studies. This group of patients constitutes a population with an extremely high mortality that requires a rapid and systematic response. For these reasons, randomized trials have been challenging, and the clinical decision-making algorithm is subject to continuing debate and consensus processes. The therapy consists of rapidly restoring cardiac output and peripheral perfusion by the use of inotropic agents and vasopressors. Intra-aortic balloon counterpulsation (IABP) has long been the mainstay of mechanical therapy for acute CS that fails initial stabilization with medical therapy. Placement of IABP improves coronary and peripheral perfusion by improving left ventricular (LV) performance and by acutely decreasing afterload. However, IABP does not artificially augment cardiac output and therefore may not work in patients with more advanced disease. There are no randomized trials evaluating the effect on IABP alone in CS. In the SHOCK (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock?) trial, IABP therapy resulted in a significantly lower mortality rate in patients with acute myocardial infarction (MI), especially in those who had received concomitant thrombolytic treatment (1). In the large National Registry of Myocardial Infarction, use of

IABP was associated with improved survival only at centers with high IABP use, irrespective of revascularization status (2). A recent meta-analysis of cohort studies in the setting of ST-segment elevation MI complicated by CS supported the benefit of IABP therapy only in patients who received thrombolysis but not in those who underwent primary percutaneous coronary intervention (3). Despite these controversial results, support with pressors and inotropic agents, IABP, and early revascularization is the current standard of care in patients presenting with CS. However, once shock develops, the mortality rate remains higher than 50% with one-half of the deaths occurring within the first 48 h (4). Given this high mortality, it is increasingly recognized that a mechanical device that is quick to implant, easy to care for with minimal complications, and able to rapidly restore adequate circulatory support could significantly improve the prognosis of patients presenting with severe CS. Percutaneously implanted devices are particularly appealing in this situation. Percutaneous left ventricular assist devices (pVADs) can interrupt the cycle of ischemia, hypoperfusion, and myocardial depression by providing adequate support and perfusion while allowing the medical team to perform high-risk percutaneous or surgical revascularization, bridge to recovery of LV function, or transition to more definitive support. Several pVADs are currently available. The TandemHeart pVAD (CardiacAssist, Inc., Pittsburgh, Pennsylvania) removes blood from the left atrium through a femoral vein cannula placed transeptally. Blood is then returned to the arterial circulation through a cannula placed in the femoral artery. Another pVAD in clinical use is the Impella 2.5 (Abiomed Inc., Danvers, Massachusetts), which is placed across the aortic valve. Extracorporeal membrane oxygenation, which involves circulation through an oxygenator mitigating the work of the pulmonary and systemic circulation, has also been used in patients with CS.

In this issue of the *Journal*, Kar et al. (5) describe a single center's experience using the TandemHeart pVAD as a salvage therapy for patients in severe refractory CS. We want to emphasize "refractory" CS because the patients included in the study were failing what is considered standard therapy for CS with pressors and IABP. In addition, 48% of the patients were actively receiving cardiopulmonary resuscitation (CPR) during implantation. The cohort of 117 consecutive patients is not only the largest but also the sickest collection of patients with refractory CS in published reports. Interestingly, 32% of the patients had nonischemic cardiomyopathy, with only 32% of those with an acute cause of heart failure such as myocarditis or allograft rejection. An impressive 60% of the patients were alive at 30 days, with 55% surviving 6 months and a slightly better outcome in patients with nonischemic cardiomyopathy.

The TandemHeart seems to be the ideal device for such situations. *Quick to implant?* It took an average of 15 to 65 min to implant the TandemHeart, with shorter times upon growing experience with the device. *Easy to care for with*

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*minimal complications?* The average duration of pVAD support was  $5.8 \pm 4.8$  days, with a considerably low complication rate. In addition to the expected bleeding complications, sepsis and systemic inflammatory response syndrome were seen in 30% of the patients, likely because of implantation under suboptimal conditions and while patients were undergoing CPR. *Able to rapidly restore adequate circulatory support?* The hemodynamic profile and biochemical markers of shock and low output state improved rapidly after implant. Mean cardiac index increased from  $0.5 \pm 0.8$  l/min/m<sup>2</sup> to  $3.0 \pm 0.9$  l/min/m<sup>2</sup> with support. These beneficial changes were already apparent in the first hour after institution of support.

The idea that a mechanical support device can be useful in patients with CS is not new. It was initially described in CS associated with acute MI (6). Several small randomized trials using the TandemHeart (7,8) or Impella (9) device in comparison with IABP in patients with CS have been published. A recent meta-analysis combining these 3 trials (10) included 100 patients, with 53 of those receiving a pVAD. Interestingly, the improvement in early hemodynamics in patients treated with pVAD was not associated with an improvement in survival. It is important to note that the patients included in the current study were refractory to vasopressors and IABP or were getting CPR at the time of implantation; therefore, the expected mortality rate in this population would likely be higher than the mortality rates seen in these earlier randomized trials that included patients in less critical condition. In addition, some investigators have shown the feasibility of surgically implanted devices in patients with acute post-MI CS (11), but these devices are more expensive and take longer to implant and recover after surgery. Therefore, pVADs, in particular the TandemHeart, would be ideal for patients in severe or refractory CS. One of the characteristics that stands out in the TandemHeart as opposed to other pVADs that is important in this population is the possibility of providing up to 5 l/min of assisted output.

Several questions remain about the potential widespread use of these technologies, especially given the cost associated with these devices. How can we apply the results of this study to the “real world?” Who would benefit the most from these advances in technology? When and who would decide if these technologies are being applied in a timely manner, before implantation is futile? There is a spectrum of severity in patients with CS. Those requiring CPR represent the group of patients with the worst possible outcome, as evidenced in the current study. But even in the group who received CPR, a remarkable 43% were alive at 30 days, illustrating the difficulty in using a single clinical parameter in deciding to continue therapy versus considering therapy futile. Another important parameter that was not assessed in the current study, albeit difficult to assess in the emergent situation, is right ventricular function, either by imaging or hemodynamic criteria. Right ventricular dysfunction is an independent predictor of survival in post-MI patients (12).

Similarly, right ventricular dysfunction that occurs in surgically implanted LV assist device is associated with end-organ failure and a high mortality rate (13). These 2 parameters illustrate the difficulty of evaluating an individual patient in such a critical state and predicting clinical outcome.

While we wait for additional studies or new guidelines, there are some considerations that may help improve outcomes while decreasing costs and unnecessary procedures in patients with CS. Set early goals of therapy aimed at prompt recognition of CS, correction of modifiable factors, and establishment of optimal end-organ perfusion. The goals proposed by Kar et al. (5), a mixed venous saturation >70% and mean arterial pressure >60 mm Hg, are indicative of adequate perfusion. An escalating approach to therapy like the one used in the current study seems reasonable, starting with pressors and IABP before “escalating” to a pVAD unless the patient is in extremis requiring CPR. Determine targets of therapy early in the course of treatment, like revascularization, bridge to recovery, or transition to more permanent support such as transplantation or surgically implanted LV assist device. Finally, it is important to define futility and discuss end-of-life issues with patients and their families. It is important to keep in mind that this type of technology can prolong dying, as opposed to alleviating suffering or improving survival. A multidisciplinary approach to the group of patients not improving despite maximal efforts should also include social workers and palliative care personnel.

In conclusion, Kar et al. (5) have demonstrated that escalating therapy that includes implantation of a TandemHeart pVAD in patients with refractory CS is safe and efficacious. Although we are cautiously optimistic about the potential of mechanical rescue of the heart in shock, additional studies are needed to answer the questions raised from the current study: how to apply this expensive technology in the “real world” and how to define when ongoing efforts are futile. In the meantime, the responsibility of the scientific community is to strive to develop a multidisciplinary, systematic approach to gravely ill patients who might benefit from mechanical circulatory support therapy to ensure the best possible outcome.

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