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EDITORIAL

New Landscape of Acute Myocardial Infarction Complicated by Cardiogenic Shock With the Advent of a Small But Mighty Heart Pump

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Acute myocardial infarction complicated by cardiogenic shock (AMICS) remains a life-threatening condition associated with high mortality and morbidity even in the era of primary percutaneous coronary intervention (**Figure**).[1–10] Conventional mechanical circulatory support (MCS) devices such as the intra-aortic balloon pump (IABP) and veno-arterial extracorporeal membrane oxygenation (VA-ECMO) have long been the mainstay for managing this lethal condition. However, neutral results of large randomized controlled trials (RCT) of IABP use[4] have called this practice into question and the routine use of IABP in patients with AMICS has been downgraded in guidelines worldwide (Class III in Japan and Europe and Class IIb in the USA). Meanwhile, Impella® (Abiomed, Danvers, MA, USA) heart pumps have emerged as a breakthrough MCS device used alone

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or in combination with VA-ECMO (so-called ECPELLA) especially in the setting of AMICS. These devices are a percutaneous catheter-based microaxial left ventricular assist device designed to unload the left ventricle and to provide antegrade flow up to 2.5–5.5 L/min depending on the device. A salient feature of the Impella devices is the direct unloading of the left ventricle with adequate antegrade volume support, which IABP or VA-ECMO cannot achieve. A small RCT comparing Impella CP with IABP in patients with AMICS did not show significant differences in mortality rates at both 30 days and 6 months.[6] This exploratory study was obviously under-powered in sample size and inconclusive because 92% of the patients

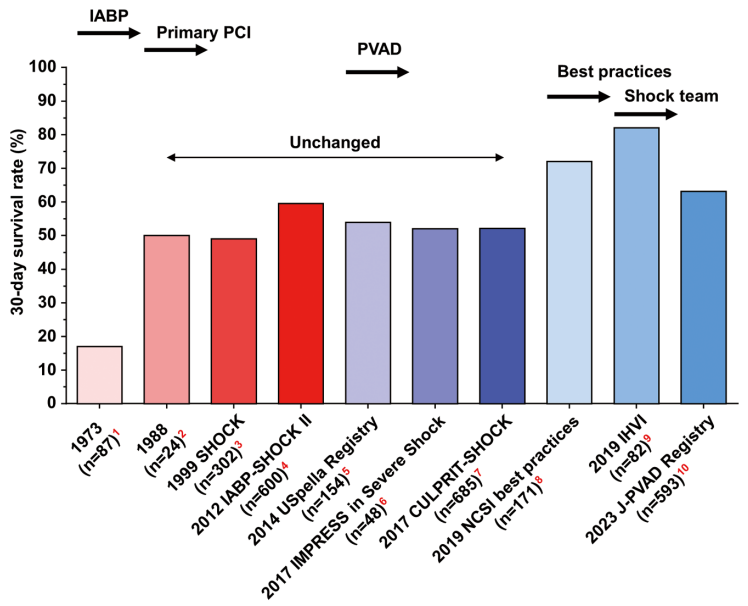

Figure. Improved 30-day survival rate in patients with acute myocardial infarction complicated by cardiogenic shock over the past 50 years. (Each number in red is the reference number of the study.) IABP, intra-aortic balloon pump; IHVI, Inova Heart and Vascular Institute; J-PVAD, the Japanese registry for Percutaneous Ventricular Assist Device; NCSI, National Cardiogenic Shock Initiative; PCI, percutaneous coronary intervention; PVAD, percutaneous ventricular assist device.

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experienced resuscitated cardiac arrest, and might have been too severe for recovery or non-salvageable. Until better data emerge from adequately powered RCTs, we are left to rely on data from observational studies and real-world registries.

In this issue of the Journal, Ikeda et al provide useful and timely information from the Japanese registry for Percutaneous Ventricular Assist Device (J-PVAD), which is an ongoing prospective, multicenter, observational registry enrolling all consecutive patients undergoing Impella devices in Japan since October 2017.[10] The first interim analysis of J-PVAD has been recently published elsewhere.[11] In this second interim analysis of J-PVAD, Ikeda et al aimed to analyze efficacy and safety profiles of Impella devices in Japanese patients with AMICS. The study period was from October 2017 to January 2020. The study population was a total of 593 (44.0%) consecutive patients with AMICS undergoing MCS with Impella 2.5, CP, or 5.0 at 109 hospitals certified by the IMPELLA committee. The main results showed a favorable overall 30-day survival rate of 63% with acceptable safety profiles (**Figure**). The reported rates of major adverse events were relatively low, including hemolysis (10.8%), hemorrhage/hematoma (7.6%), peripheral ischemia (4.4%), stroke (1.5%), and thrombosis (0.7%). Ikeda et al should be given credit for providing detailed useful information on the initial experience with Impella devices for the treatment of AMICS in Japan. It should be also mentioned that there are some important considerations before wider adoption of Impella devices in clinical practice.

First, the major limitations of the present study were that the use of MCS devices was not randomized, and that no control group was available for comparison. The 30-day survival rate of the single Impella group (80.9%) was much better than that of the ECPELLA group (45.7%) as well as that of previous studies.[5–8] The clinical picture of AMICS may be heterogeneous across the spectrum of shock severity. Specifically, it would add a lot if the patients were stratified according to the Society for Cardiovascular Angiography and Interventions (SCAI) stages, which highlight the dynamic nature of cardiogenic shock.[12] Unlike previous studies,[3,4,6,7,9] the duration of hypotension (e.g., ≥30 min) was not clearly taken into account in the definition of AMICS. A simple assumption is that the patients in the ECPELLA group were more critically ill with more advanced stage, characterized as multiple organ failure, than those in the single Impella group. The true efficacy of Impella devices for the survival of patients with AMICS remains to be elucidated.

Another consideration is that overall the reported rates of major adverse events were much lower than in previous studies from other Western countries. In the present study, adverse events were registered only when they were judged to be directly related to the Impella devices at the discretion of attending physician, which raises the possibility of observer bias behind the results. In addition, the rate of femoral access site bleeding might be higher in patients undergoing Impella CP as compared with other Impella devices because the remaining repositioning sheath of the Impella CP is smaller than the initial peel-away sheath, as discussed elsewhere.[13] The need for caution with regard to vascular complications is important as described in a letter: "A win for the heart should not be lost at the groin."[14]

Despite the lack of large, adequately powered RCTs, Impella devices now join the list of potential therapeutic options for AMICS. Our commitment is to improve patient outcomes and our agreement is to do no harm. Hopefully we will win for critically ill patients with AMICS with the advent of this small but mighty heart pump.

Disclosure

S.Y. is a member of *Circulation Journal*'s Editorial Team.

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