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EDITORIAL COMMENT

Does Impella Support Really Prevent Catastrophe?*

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In this issue of *JACC: Case Reports,* Peigh et al. (1) have provided an interesting case from both a scientific and ethical perspective. The case raises questions about the physiology of tamponade and the impact of the Impella CP (Abiomed, Danvers, Massachusetts). Acute cardiac tamponade causes a rise in pericardial pressure to greater than the pressure in the right ventricle. Because this impairs cardiac output by preventing venous return to the right ventricle, it is not completely clear how the left ventricular Impella device maintains cardiac output (2).

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Certainly, it should be noted that the use of Impella during cardiogenic shock secondary to cardiac tamponade is contraindicated. In this case, the Impella was already in place. The physiology is unclear. We may speculate that unloading of the left ventricle, with reduced end-diastolic pressure and volume, allowed some continued filling of the interdependent right ventricle. This may have allowed transient maintenance of cardiac output in the face of cardiac tamponade. The device could therefore have provided a brief window in which percutaneous drainage could be safely undertaken, rather than providing indefinite circulatory support. In this complication, it seems that the device may have proven life-saving.

However, the life-saving nature of the device leads to ethical questions about the use of the device in this context. It is clear that this complex, high-risk percutaneous coronary intervention (PCI) was unlikely to be undertaken without mechanical circulatory support. The procedure was justified by the presence of impaired systolic function and the location of the disease. Furthermore, the authors have noted that there was a thorough risk-benefit discussion, and the patient preferred invasive treatment. Nonetheless, the complication would not have occurred if the PCI had not taken place.

In-hospital mortality for acute coronary syndrome in nonagenarians was 5.2% in a large Japanese cohort. Even within this cohort, only 1.7% of patients needed rotational atherectomy, and 5.9% needed left main stem intervention (3). In the United States, nonagenarians presenting with non-ST-segment elevation myocardial infarction had a PCI in 5.6% of cases, with an in-hospital mortality of 3.7%. This was substantially lower than in those patients who did not receive PCI, but there is likely to be selection bias in this observational data, reflecting those patients likely to survive, with lower baseline morbidity (4). Although some nonagenarian patients will benefit from an invasive treatment strategy, it is not clear from the published data that there was prognostic benefit to this procedure. The patient was not experiencing an ST-segment elevation myocardial infarction, nor was he hemodynamically unstable with ongoing pain. The proposed benefit needs to be weighed carefully against the high risk of complication. The complication was sadly predictable. A trial of medical therapy as first-line treatment would not have precluded a return to an invasive strategy in the future.

The use of Impella has become commonplace for high-risk PCI, particularly in the United States, despite the absence of randomized trial evidence to support its use. The only randomized study to

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consider its use found it to be no better than intra-aortic balloon pump (IABP), a therapy that has been largely discredited for its routine use to support high risk PCI (5). Recent observational data presented in the form of propensity-score match analyses have also shown increased risk of death and major bleeding compared with patients treated with IABP (6,7). Nonetheless, increasingly high-risk cases are being undertaken with the safety blanket of Impella support. Patients recruited into published Impella trials and registries were much younger than this patient, often with less complex disease (8,9). The use of mechanical circulatory support for PCI in nonagenarians increased from 3.8% to 5.7% between 2003 and 2014, and this rise is likely to have continued with the advent of Impella (4). The field of interventional cardiology (and medicine as a whole) is littered with examples of techniques and devices, including IABP, thrombus aspiration, and bioresorbable vascular scaffolds, that appeared to be effective in both anecdote and registry, but were shown to be neutral or harmful in randomized studies (10–13). Better evidence for the high-cost Impella device, a well-run randomized controlled trial, is needed before its adoption into the routine armamentarium of the interventional cardiologist for high-risk cases around the world.

The authors are to be congratulated on their rapid treatment of the tamponade and the positive angiographic result. Nonetheless, this is a complication to be feared, and where there is extreme risk, interventionalists cannot rely on the Impella to mitigate all risk. Cases like this one at the limits of both technology and physiology have much to teach us, but we must keep a careful watch for the point at which high-risk PCI becomes too high of a risk.

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