Invited Commentary

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Since the FDA clearance of the Impella 2.5 (Abiomed, Danvers, Mass.) in June 2008, more than 1,000 patients have been treated with the Impella 2.5, with more than 300 hospitals employing the technology.[1] Simultaneously, the PROTECT II clinical trial, a randomized clinical trial comparing the intra-aortic balloon pump (IABP) to Impella 2.5 in high-risk percutaneous coronary intervention (PCI), continues to actively enroll patients. Furthermore, 2009 brought the publication of encouraging data from PROTECT I,[2] the safety trial for Impella 2.5, as well as IDE approval of the acute myocardial infarction trial (RECOVER II), a randomized trial comparing Impella 2.5 with the IABP in patients who are experiencing hemodynamic compromise during acute myocardial infarction. While PROTECT II and RECOVER II address the superiority of Impella with respect to clinical outcomes, the hemodynamic superiority of Impella 2.5 has already been demonstrated by a number of investigators.[2-4] Seyfarth,[3] for example, compared the hemodynamic impact of Impella 2.5 and IABP in STEMI patients. This study (ISAR-SHOCK) was a prospective randomized clinical trial of 26 patients to evaluate the safety and efficacy of the Impella 2.5 versus the IABP for treatment of cardiogenic shock caused by myocardial infarction. The primary endpoint of the study was the change (from baseline at 30 minutes after the initiation of support) in observed cardiac index. The study met its primary endpoint demonstrating a significant (P = .02) difference in the cardiac index improvement with Impella versus IABP. Although the study was not powered to demonstrate mortality differences (an estimated 635 patients are needed to show a mortality difference at accepted MAE rates), Impella was found to be safe, effective, and free of complications. Furthermore, the left ventricular ejection fraction was significantly improved in Impella patients at both 4 days and 120 days compared to IABP patients. The finding of sustained improvement in left ventricular ejection fraction has also been documented in other studies.[2,4] As only the second Impella 2.5 case at this institution, it was apparent that Impella made a significant difference in a high-risk PCI procedure during an acute coronary syndrome in a patient experiencing cardiogenic shock. This particular case showed that the support was adequate to allow this patient to be conscious and comfortable while a pacing wire was placed and pacing was initiated. In the past, circulatory support has not been available in the cath lab without having our cardiac surgery colleagues or a vascular surgery team available. This may indeed be the most important aspect of the Impella technology; the potential to extend the interventional procedure. Early experience is encouraging for patients supported with Impella during PCI for STEMI.[3]

This case is illustrative of the fact that successful use of the Impella catheter beyond the high-risk PCI case is not limited to centers that have extensive Impella case experience.

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2. Dixon SR, Henriques J P.S., Mauri L, et al. A prospective feasibility trial investigating the use of the Impella 2.5 System Undergoing HRPCI (PROTECT I Trial). J Am Coll Cardio Interv. 2009;2:91-96.
3. Seyfarth M, Sibbing D, Bauer I, et al. A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. J Am Coll Cardiol. 2008;52:1584-1588.
4. Burzotta F, Palosciab L, Trania C, et al. Feasibility and long term safety of elected Impella assistance high risk percutaneous intervention: two center study. J Cardiovasc Med. 2008;9:1004-1010.