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Preliminary results from the Polish Multicenter Registry on Impella in high-risk PCI and cardiogenic shock: Lessons learned and how to further improve outcomes

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Related article
by Pietrasik et al.

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In this issue of *Kardiologia Polska* journal, Dr. Pietrasik et al. published the results from the Polish multicenter registry of Impella (Abiomed, Danvers, MA, US) assisted high-risk percutaneous coronary interventions (HR-PCI) and cardiogenic shock (CS) (IMPELLA-PL) [1]. A total of 308 patients, enrolled at 20 Polish centers from January 2014 to December 2021, were included in the registry. All patients were treated with Impella Cardiac Power (CP), except for two cases of Impella 5.0 use (one for each group) [2]. The authors should be congratulated for their efforts, the IMPELLA-PL registry contributes significantly the raising evidence in this field together with other European [3, 4], Japanese [5], and US experiences [6].

The results obtained from this initial experience are encouraging, for percutaneous treatment of high-risk patients [7]. In the HR-PCI setting, the Impella was mainly implanted before the revascularization procedure (81.8%) and removed at the end of the procedure (93.7%) to minimize complications [8]. The complexity of patients undergoing PCI was high in terms of clinical scenarios: over 50% presented with an acute coronary syndrome, mostly NSTEMI, and anatomically with a median Syntax Score II of 43, with 63% of those being a three-vessel disease with the involvement of the left main

trunk [4] and the need in 30% of cases of rotational atherectomy. From a safety perspective, the results are acceptable. Access site bleeding occurred in 14.6% of HR-PCI patients, slightly higher than the IMP-IT registry data [3]. Limb ischemia was reported in 2.4%, and hemolysis in 1.6%, respectively, overlapping with the data from various registries [3]. As a first experience, the data on access site bleeding is expected to decrease as the experience grows with appropriate femoral access management. The use of echo-guided puncture and access pre-closure have been demonstrated to reduce vascular complications in large bone access, in selected cases where prolonged support is needed, limb reperfusion must be considered [9]. Furthermore, in-hospital mortality was 8.3%, in line with other national experiences [3], and at the annual follow-up, only 9.1% of patients had experienced a major adverse cardiocerebrovascular event, with one-year mortality remaining stable.

Regarding cardiogenic shock, due to the small sample, limited conclusions may be deduced, however, the authors enrolled a very compromised population compared to other registries. The primary cause of shock was acute coronary syndromes (ST-elevation myocardial infarction 72.7% and non ST-elevation myocardial infarction [16.4%]), 47,3% of the patients experiencing out-of-hospital cardiac arrest, high baseline lactate levels 7.4 mmol/l, and a not negligible rate of right ventricle dysfunction (21.8%). Confirming the compromised status of these patients, as many as 80% of patients were on mechanical ventilation and 13% required extracorporeal membrane oxygenation (ECMO). The rate of 30-day mortality was about 75% which is higher than the literature reports [3]. A possible explanation for this finding may be the advanced clinical compromise, the high mortality rate in the IMPELLA-PL CS cohort is in line with a SCAI Class D population [10], and may be attributed mainly to a negative selection bias which is understandable in an initial experience. In such a scenario, the placement of Impella CP may not be enough to reverse the deep cardio-metabolic shock stage, while ECMO or combined strategies may have a role.

The 12-month follow-up data, on the other hand, are very encouraging, because those discharged from the hospital have a very good prognosis, only 9% of the population needed hospitalization for heart failure and only 1.8% needed permanent left ventricular assist device or cardiac transplantation. Indeed, it must be highlighted that in both high-risk PCI and cardiogenic shock scenarios teamwork is fundamental to optimizing the patient's outcomes The presence of a dedicated multidisciplinary shock team and optimal protocol adoption has been in other experiences correlated with improved survivals in CS patients. In the INOVA Health system experience or the Japanese experience, the presence of strict protocols has resulted in a marked reduction in mortality from cardiogenic shock from 65% to 30% [5].

Finally, the increased trend of Impella implantation from 2019 onwards suggests that the medical community in Poland has gained valuable experience in using Impella in the context of high-risk percutaneous coronary procedures. aiming to have a better survival.

Article information

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