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

Mario Iannaccone[1]*, Marco Gamardella[2]*, Alaide Chieffo[2, 3]

[1]San Giovanni Bosco Hospital, ASL Città di Torino, Turin, Italy
[2]Vita Salute San Raffaele University, Milan, Italy
[3]Interventional Cardiology Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy
*Both authors equally contributed to the study.

Related article
by Pietrasik et al.

Correspondence to:
Mario Iannaccone, MD,
San Giovanni Bosco Hospital,
ASL Città di Torino,
Turin, Italy,
e-mail:
mario.iannaccone@hotmail.it

DOI: 10.33963/v.kp.97978

Received:
October 24, 2023

Accepted:
October 24, 2023

Early publication date:
October 25, 2023

In this issue of *Kardiologia Polska (Polish Heart Journal)* journal, Dr. Pietrasik et al. published the results from the Polish multicenter registry (IMPELLA-PL) of Impella-assisted (Abiomed, Danvers, MA, US) high-risk percutaneous coronary interventions (HR-PCI) and cardiogenic shock (CS) [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 to raising evidence in this field, together with other European [3, 4], Japanese [5], and US registries [6].

The results obtained from this initial analysis of percutaneous treatment of high-risk patients are encouraging [7]. In the HR-PCI setting, 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 the PCI procedures was high in terms of clinical scenarios: over 50% of patients presented with acute coronary syndrome, mostly non-ST-segment elevation myocardial infarction, and, anatomically, with a median SYNTAX Score II of 43; 63% with a three-vessel disease and involvement of the left main trunk [4], and 30% needed rotational atherectomy. From a safety perspective, the results are acceptable. Access site bleeding occurred in 14.6% of HR-PCI patients, which is slightly higher than in the IMP-IT registry [3]. Limb ischemia was reported in 2.4%, and hemolysis in 1.6%, which conforms with the data from various registries [3]. After first experiences with using this technique, data on access site bleeding is expected to decrease as the expertise grows with appropriate femoral access management. The use of echocardiography-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%, which is in line with other national data [3]. At 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 size, limited conclusions may be drawn; however, the authors enrolled a very compromised population compared to other registries. The primary cause of shock was acute coronary syndromes (ST-segment elevation myocardial infarction [72.7%] and non-ST-segment elevation myocardial infarction [16.4%]); 47.3% of the patients experienced out-of-hospital cardiac arrest, had high baseline lactate levels of 7.4 mmol/l, and a not negligible rate of right ventricular

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 reported in the literature [3]. A possible explanation for this finding may be the advanced clinical status. 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 initial stages. In such a scenario, the use 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 had very good prognosis; only 9% of the study population needed hospitalization for heart failure and only 1.8% needed a 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 in optimizing patient outcomes The presence of a dedicated multidisciplinary shock team and optimal protocol adoption has been correlated in other centers with improved survival in CS patients. In the INOVA Health System or Japanese healthcare, 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 at better survival.

Article information

Conflict of interest: None declared.

Funding: None.

REFERENCES

1. Pietrasik A, Gąsecka A, Pawłowski T, et al. Multicenter registry of Impella-assisted high-risk percutaneous coronary interventions and cardiogenic shock in Poland (IMPELLA-PL). Kardiol Pol. 2023; 81(11): 1103–1112, doi: 10.33963/v.kp.97218, indexed in Pubmed: 37937354.
2. Elia E, Iannaccone M, D'Ascenzo F, et al. Short term outcomes of Impella circulatory support for high-risk percutaneous coronary intervention a systematic review and meta-analysis. Catheter Cardiovasc Interv. 2022; 99(1): 27–36, doi: 10.1002/ccd.29757, indexed in Pubmed: 34028964.
3. Chieffo A, Ancona MB, Burzotta F, et al. Observational multicentre registry of patients treated with IMPella mechanical circulatory support device in ITaly: the IMP-IT registry. EuroIntervention. 2020; 15(15): e1343–e1350, doi: 10.4244/EIJ-D-19-00428, indexed in Pubmed: 31422925.
4. Baumann S, Werner N, Al-Rashid F, et al. Six months follow-up of protected high-risk percutaneous coronary intervention with the microaxial Impella pump: results from the German Impella registry. Coron Artery Dis. 2020; 31(3): 237–242, doi: 10.1097/MCA.0000000000000824, indexed in Pubmed: 31658135.
5. Toda K, Ako J, Hirayama A, et al. Three-year experience of catheter-based micro-axial left ventricular assist device, Impella, in Japanese patients: the first interim analysis of Japan registry for percutaneous ventricular assist device (J-PVAD). J Artif Organs. 2023; 26(1): 17–23, doi: 10.1007/s10047-022-01328-1, indexed in Pubmed: 35467195.
6. Vetrovec GW, Anderson M, Schreiber T, et al. The cVAD registry for percutaneous temporary hemodynamic support: A prospective registry of Impella mechanical circulatory support use in high-risk PCI, cardiogenic shock, and decompensated heart failure. Am Heart J. 2018; 199: 115–121, doi: 10.1016/j.ahj.2017.09.007, indexed in Pubmed: 29754648.
7. Chieffo A, Dudek D, Hassager C, et al. Joint EAPCI/ACVC expert consensus document on percutaneous ventricular assist devices. EuroIntervention. 2021; 17(4): e274–e286, doi: 10.4244/EIJY21M05_01, indexed in Pubmed: 34057071.
8. Iannaccone M, Franchin L, Hanson ID, et al. Timing of impella placement in PCI for acute myocardial infarction complicated by cardiogenic shock: An updated meta-analysis. Int J Cardiol. 2022; 362: 47–54, doi: 10.1016/j.ijcard.2022.05.011, indexed in Pubmed: 35533755.
9. Sardone A, Franchin L, Moniaci D, et al. Management of vascular access in the setting of percutaneous mechanical circulatory support (pMCS): sheaths, vascular access and closure systems. J Pers Med. 2023; 13(2): 293, doi: 10.3390/jpm13020293, indexed in Pubmed: 36836527.
10. Olarte N, Rivera NT, Grazette L. Evolving presentation of cardiogenic shock: a review of the medical literature and current practices. Cardiol Ther. 2022; 11(3): 369–384, doi: 10.1007/s40119-022-00274-6, indexed in Pubmed: 35933641.