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Clinical outcomes in patients undergoing complex, high-risk percutaneous coronary intervention and haemodynamic support with intra-aortic balloon versus Impella pump: Real-life single-centre preliminary results

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WHAT'S NEW?

The use of percutaneous left ventricle assist devices (pLVAD) in patients undergoing complex, high-risk percutaneous coronary interventions (PCIs), with reduced left ventricular ejection fraction (LVEF), is a treatment option for patients disqualified for surgery by cardiac surgeons. The presented analysis is a single-center, prospectively collected study, which comprised consecutive patients undergoing complex, high-risk PCIs performed with pLVAD, either using intra-arotic balloon pump (IABP) or Impella pump. The current study included 50 patients, 28 (56%) of whom were treated with PCI assisted *via* Impella and 22 (44%) by IABP. The results of percutaneous treatment in this group of patients differ depending on the type of the implemented left ventricular support, remaining at a comparable and acceptable level in relation to the results of studies published by other authors. The differences in treatment

outcomes between the group of patients treated with Impella and the group of patients who underwent IABP certainly result, to a significant extent, from the baseline characteristics of patients and their procedure-related risks.

ABSTRACT

Background: Patients and mechanical circulatory support assortment, as well as periprocedural and post-procedural clinical outcomes in complex, high-risk percutaneous coronary interventions (PCIs), underpinned by percutaneous left ventricle assist devices (pLVAD), are a disputable debate.

Aim: The aim of the study was to seek differences between patients qualified for complex, high-risk PCIs with an intra-aortic balloon pump (IABP) or Impella pump support, and to compare peri- and post-procedural clinical outcomes.

Methods: The presented analysis is a single-centre study, which comprised consecutive patients undergoing complex, high-risk PCIs performed with the pLVAD, either IABP or Impella. Patients included in the current analysis were recruited between January 2018 and December 2021. There were 28 (56%) patients in the Impella group and 22 (44%) in the IABP group. The primary endpoints comprised overall mortality and major adverse cardiovascular events (MACE). These included all-cause mortality, myocardial infarction, revascularisation and cerebrovascular events.

Results: Patients from the IABP group were significantly older, had higher left ventricular ejection fraction (LVEF) and less frequent history of PCI, while the in-hospital risk of death assessed by Euroscore II remained similar in the Impella and IABP groups median (interquartile range [IQR]) (2.8 [2–3.8] vs. 2.5 [1.8–5.2]; $P = 0.73$). Patients undergoing complex, high-risk PCIs with pLVAD support presented similar results during the follow-up, assessed by log-rank estimates in terms of MACE ($P = 0.41$) and mortality rate ($P = 0.65$).

Conclusions: The use of pLVAD devices in patients undergoing complex, high-risk PCIs, with reduced left ventricular ejection fraction, is a promising treatment option for patients disqualified for surgery cardiac surgeons.

Key words: clinical outcomes, complex and high-risk PCI, Impella pump, intra-aortic balloon pump, percutaneous left ventricle assist device

INTRODUCTION

In recent years, there has been a significant increase in the use of short-term percutaneous left ventricular assist devices (pLVADs). They are most frequently implemented in patients with acute heart failure (cardiogenic shock) or complex high-risk percutaneous coronary interventions (PCIs). The main purpose of their use is to assist the relief of the heart in generating cardiac output and thus, to reduce the demand of the heart muscle for oxygen during the procedure, while securing flow during systemic and coronary circulation [1, 2]. The practicality, safety and haemodynamic effectiveness of pLVAD in patients treated with PCI due to complex, multi-vessel disease of the coronary arteries, often accompanied by low left ventricular ejection fraction (LVEF), has been previously demonstrated in comparative studies. This was done by comparing Impella pumps (Abiomed Inc., Danvers, MA, US) to intra-aortic balloon pumps (IABP) (MAQUET, Fairfield, NJ, US) [3, 4], as well as in single-device studies, dedicated to Impella pLVAD [5–8]. Similar research in which pLVAD efficacy has been assessed among patients treated with PCI and IABP support did not provide such obvious evidence [9]. Comparable peri- and procedural clinical outcomes in patients undergoing revascularisation of the coronary artery in multi-vessel disease *via* coronary artery bypass grafting or protected PCI with the Impella pump have been demonstrated [10].

The current European Society of Cardiology guidelines on myocardial revascularisation indicate that current evidence for pLVAD implementation is insufficient to provide a recommendation on its clinical use in cardiogenic shock (Class III, level B) [11]. Moreover, in these guidelines, there is no mention regarding the use of pLVAD in patients with chronic coronary syndromes. Also, guidelines on the management of patients with chronic coronary syndromes do not even include pLVAD usage [12].

The aim of the current study was to seek differences between patients qualified for complex, high-risk PCIs with IABP or Impella pump support, and to compare peri- and post-procedural clinical outcomes.

METHODS

Patients

The presented analysis is a single-centre, prospectively collected study, which comprised consecutive patients undergoing complex, high-risk PCIs performed with pLVAD, either using IABP (22 patients) or Impella (28 patients). Screening of patients to qualify for LVAD treatment was based on coronary angiography, assessment of general clinical condition, presence of comorbidities, including the Euroscore II, fragility scale, assessment of the

complexity and advancement of atherosclerotic lesions e.g. using the SYNTAX score, echocardiographic assessment of the heart, including vitality of the heart muscle using selected imaging methods such as, for example, cardiac magnetic resonance imaging or stress echocardiography, assessment of vascular access using ultrasound, or in selected cases with the use of computed tomography angiography [13–15]. Based on this, all patients were qualified for percutaneous treatment by a local "heart team" council, comprising a cardiac surgeon, interventional cardiologist and conservative cardiologist. Patients qualified for percutaneous treatment were disqualified from surgical operations or did not agree to undergoing high-risk cardiovascular procedures. Participants included in the current analysis were gathered between January 2018 and December 2021. Those experiencing cardiogenic shock and acute myocardial infarction (AMI) within 24 hours were excluded from evaluation. The study is retrospective and therefore it does not have the consent of the local ethics committee, each patient included in the study signed an appropriate written consent for the PCI procedure and, if necessary, in selected cases, an annex about the lack of consent to cardiac surgery treatment.

Vascular access

The current analysis included only patients with femoral access. In the case of a 14-French sheath from the Impella CP system initially a 6-French sheath was inserted into the common femoral artery under the control of ultrasound. Subsequently, contralateral angiography was performed to visualize adequate anatomical conditions. After the introduction of the pLVAD, PCI was performed via contralateral femoral, ipsilateral by puncturing Impella sheath, or radial access. Punctures after IABP (7.5 F) use were closed by vessel compression or with a single Angio-Seal VIP 8 F (AS; Terumo Corporation, Tokyo, Japan), which was left to the operator's discretion. While after removing Impella pump's sheath, artery was managed by Perclose Proglide (PP; Abbott Vascular, CA, US) and/or Angio-Seal VIP 8 French (AS; Terumo Corporation, Tokyo, Japan) applying 1 of the combination: double Angio-Seal VIP, double Perclose Proglide or Angio-Seal VIP + Perclose Proglide. The choice of vascular closure method was left to the discretion of the operator.

Definitions

The primary endpoint of the current analysis included major adverse cardiovascular events (MACE), which were defined as cardiac death, myocardial infarction, revascularisation: either surgical or percutaneous (Re-PCI; target lesion revascularisation; target vessel revascularisation) and/or cerebrovascular events, i.e. stroke or transient ischemic events. We

also assessed vascular access site complications which occurred during hospitalisation. Periprocedural bleeding was evaluated according to the scale provided by the Bleeding Academic Research Consortium (BARC) [16]. Data on MACE was collected on the basis of analysis of medical records in our clinic and clinic, as well as telephone observation, which was accurate because we collected telephone contacts with family members or other persons authorized by the patient to provide information on an ongoing basis during the patient's hospitalization. Data on periprocedural complications, mainly bleeding and complications related to vascular access, were collected on an ongoing basis.

Statistical analysis

Categorical variables are presented as numbers and percentages. Continuous variables are expressed as median (interquartile range [IQR]), due to the fact that all presented variables did not meet normality distribution criteria. Normality of distribution was assessed using the Shapiro–Wilk test and all data presented in the tables were not normally distributed. For this reason, the Mann–Whitney U test was applied to compare continuous variables. Categorical variables were compared via Pearson's χ^2 or Fisher's exact test if 20% of cells had an expected count less than 5. Ordinal variables were compared with the Cochran–Armitage trend test. To analyse survival rate in selected risk groups, Kaplan–Meier curves were drawn. The log-rank statistic was applied to test the differences in the outcome between groups. Two-sided *P*-values <0.05 were considered statistically significant. All statistical analyses were performed using JMP®, Version 16.1.0 (SAS Institute INC., Cary, NC, US).

RESULTS

The current study included 50 patients, 28 (56%) of whom were treated with PCI assisted via Impella and 22 (44%) by IABP.

General characteristics at baseline

Patients treated with the Impella pLVAD were younger when compared to those treated via IABP (67.6 [8.3] vs. 74.6 [9.6] years; $P = 0.01$). The mean LVEF was lower among patients from the Impella pLVAD group compared to IABP (20.8 [6.5] vs. 33.6 [16.3]%; $P = 0.005$) (Supplementary material, *Table S1*).

Coronary angiography, procedure-related indices and anticoagulation

There were no significant differences between the Impella and IABP groups considering vascular access, dissemination of coronary atherosclerosis or type of PCI (frequency of stent implantation and drug-eluting balloon use). Rotablation tends to be more frequently applied in IABP groups when compared to Impella (45.5% vs. 21.4%; $P = 0.07$) (Supplementary material, *Table S2*).

Puncture-site complications

Patients from the Impella were related to a significantly greater frequency of artery puncture-site bleeding, assessed according to BARC class (Table 1).

In-hospital and post-discharge study endpoints

The duration of follow-up was longer in the IABP group when compared to the Impella group (422.6 [321.3] vs. 250 [330.4]; $P = 0.04$). No significant differences were noted with regard to the study endpoints (Table 1, Figures 1 and 2).

DISCUSSION

In the current analysis, it was demonstrated that patients undergoing complex, high-risk PCIs, with pLVAD support, present similar results during the follow-up in terms of MACE and mortality occurrence between the Impella and IABP groups. Statistically significant differences were noted between the compared groups in terms of selected features. Patients from the IABP group were significantly older, had greater LVEF at baseline, and had less frequent history of PCI. Patients from the Impella group were treated more often with the use of modern, advanced methods of intravascular imaging in the form of optical coherence tomography, while in the case of the IABP group, intravascular ultrasonography was used statistically and significantly more regularly. Local complications, in terms of bleeding, occurred more often in the Impella group. Moreover, those patients were more frequently treated with vascular surgery and thrombin occlusion of local pseudoaneurysms.

There are dozens of factors, including anatomic, haemodynamic, biochemical and physiological issues that, if occur separately, are potentially breakable by an organism, but when combined, they will significantly increase the chance of major adverse cardiac and cerebrovascular events during complex, high-risk PCI with pLVAD support. Therefore, several left ventricle techniques have been invented and applied during this kind of procedure. The benefit of IABP is buttressed by the concept of diastolic augmentation [17, 18]. In an older U.S. analysis, it was

demonstrated that IABP use was evaluated among 10.5% of all high-risk PCI procedures [19]. The point still remains moot as to what is deemed a complex, high-risk PCI procedure. In the works published so far, operators, individual departments and hospitals define complex, high-risk PCIs individually, therefore, the comparison of those results is somewhat difficult and often not objective [18]. Despite that, in selected studies, it has been revealed that IABP demonstrates significant benefits in terms of hospital mortality-rate and catheterisation of adverse events [20–22]. On the other hand, there is strong evidence of the neutral and even poorer effects in patients subjected to IABP [19, 23–25]. The doubtful impact of IABP on clinical outcomes among patients treated due to complex, high-risk PCIs was confirmed in a meta-analysis [26]. Obviously, taking the variety of patients included in the study into account, with different modes and indications, the results should be interpreted with caution. The BCIS-1 (Balloon Pump-Assisted Coronary Intervention Study-1) was the first randomised, controlled trial designed to determine whether elective IABP insertion before high-risk PCI is associated with a reduction in major adverse cardiac and cerebrovascular events after 28 days [9]. The extent of risk was calculated using the Duke Jeopardy score [27]. However, when looking closely at this study, many questions and doubts arise. Firstly, there is no protocol-mandated estimation of coronary disease complexity or the extent of planned revascularisation in relation to the presence of significant lesions. Secondly, bailout IABP was permitted in the no-planned IABP group. Thirdly, similar rates regarding the primary endpoint of major adverse cardiac and cerebrovascular events in both groups were observed. Moreover, no significant differences occurred in the secondary endpoint concerning mortality or overall rates of bleeding at the 6-month follow-up. Furthermore, there were more minor bleeds in the elective IABP arm in comparison to bailout IABP use. The overall periprocedural complications were noticed more frequently in the no-planned IABP arm. In summary, the use of prophylactic IABP insertion before high-risk PCI was not supported in the study. Further concluding, the method for decision-making, with regard to the use of IABP, remains debatable.

The BCIS registry allowed to demonstrate that patients demanding rescue IABP insertion, presented more complex coronary lesions in comparison to other patients from the no-planned IABP group. Additionally, at 5 years of the follow-up period, the Kaplan–Meier curves indicated a significant survival advantage in favour of elective IABP [28]. Cross-over patients also benefited from IABP insertion. It is worth underlining that no systematic differences were found between groups at baseline or regarding the extent of revascularisation [28]. However, those trials were not conducted to assess overall mortality as a study endpoint.

Impella aspirates blood from the left ventricle into the ascending aorta. Among the advantages of its use, the following may be enumerated: reduction of end-diastolic wall stress, improvement in diastolic compliance, increase in aortic and intracoronary pressure, as well as coronary flow velocity reserve, and stimulating a decrease in coronary micro-vascular resistance [29].

However, the Impella pump also has a number of disadvantageous effects, which involve an increase in vascular access-related complications and the propensity for haemolysis due to the high rotational speed of the axial flow pump. However, the benefits from the reduction in mortality appear to outweigh the side-effects by far. The PROTECT II (Prospective Randomized Clinical Trial of Haemodynamic Support with Impella 2.5 versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention) study is the largest randomised comparison of Impella and IABP used to support non-emergent and complex, high-risk PCI to date [4]. It did not meet its target recruitment of 654 patients because the trial was terminated early due to its futility after the inclusion of 452 patients. In it, no differences were found with regard to the occurrence of 30- or 90-day adverse cardiovascular events in the primary intent to treat analysis, but lower adverse events at 90 days were noted in the Impella® 2.5 arm [4]. The primary composite endpoint of major adverse events at hospital discharge or 30 days in the intention-to-treat population did not differ between the assessed groups (Impella 35.1% vs. IABP 40.1%; P =0.277). At 90 days, there was an insignificant trend towards a lower major adverse event rate for Impella (P = 0.066). At this time, in the per-protocol population, the difference gained significance (P = 0.023). This led to a presumption that the difference would be more visible in the long-term. The patient cohort evaluated in the PROTECT II trial was similar to the one in BCIS-1 [9]. Given that in the BCIS-1 study the use of elective IABP insertion before high-risk PCI was not supported, it would seem intuitive to expect that the superior haemodynamic support provided by the Impella would offer no supplementary impact on adverse outcomes. Analysing the trends of mechanical circulatory support usage in the US in 2008, Impella was implemented in 2.5% of all PCIs with mechanical circulatory support (MCS), and after 2008, its use tended to increase up to 31.9% in 2016, while IABP application remained stable [30].

In their research, including 48 306 patients treated with PCI and MCS, Amin et al. demonstrated consistency of their results with prior research. In a study from the National Inpatient Sample, a substantial increase was also found for the use of pLVADs in recent years, with a greater risk of mortality and higher associated cost, indicating consistency across different populations. In another study, it was suggested that contrary to the belief that Impella was being used in sicker

patients, it was actually implemented in lower risk patients (more likely to be elective, and less likely to experience shock or have STEMI than IABP patients), a finding also noted in our study [31]. However, in our research, Euroscore II values did not differ between the IABP and Impella groups, and patients from the first group had significantly better LVEF. This seems to be justified because, as it is well-known, the pressure generated by the left ventricle is required for the efficient work of IABP, and too low cardiac output may result in minimal improvement regarding the haemodynamics of coronary and systemic circulation, or even its absence. Similarly to the results of our analysis, in the report based on the U.S. registry, it has been demonstrated that patients from the Impella group experienced multi-vessel disease more frequently, they had more bifurcation lesions, chronic total occlusions and were related to a greater frequency of intravascular litothrypsy and rotational atherectomy use. In contrast to our study, those patients were older (67.85 vs. 64.62 years) [30]. It was also highlighted that the usage of Impella was related to greater mortality, acute kidney injury and stroke, evaluated via multivariable regression analysis [30].

Revising previously published studies on the Impella pump, a relatively low number of patients was included in the trials: 86 [8], 225 [4], 144 [5] and 175 [6]. In the study published by Burzotta et al. [8], it was reported that MACCE rate during the mean 14 months of follow-up was 24%, while overall mortality totalled 10.5%. A similar statement may be assumed in the case of our research, because both registers were maintained in a similar manner, although the group of patients examined by our team was much smaller. Burzotta el al. also analysed periprocedural bleeding-related complications, although they occurred less often when compared to our study (12% BARC 1–3), while in our sub-group of patients treated with Impella, this value exceeded 40% (BARC 1–3), and was significantly greater when compared to the IABP sub-group (13.6%) or the whole BARC 1.

Analysing the results of the current study, it may be concluded that the greater frequency of bleeding-related complications in the group of Impella patients is a consequence of larger vascular access sizes, different methods of artery closure and higher doses of anticoagulants. Certainly, the rotational mechanism supporting the work of the left ventricle of the heart is also important, as it causes haemolysis, anemisation and may also have impact on impaired coagulation. A number of cases and analyzes involving the use of the axillary and subclavian vascular access in patients requiring pLVAD, both in acute and stable patients, are described [32, 33]. Based on the published research results, it seems that upper limb accesses are a promising alternative and may be associated with fewer complications, and in some cases may

be the only possible method of percutaneous treatment with pLVAD in advanced arteriosclerosis. lower limbs (e.g. in the case of Lerish's syndrome).

CONCLUSIONS

The use of pLVAD devices in patients undergoing complex, high-risk PCIs, with reduced LVEF, is a treatment option for patients disqualified for surgery by cardiac surgeons. The results of percutaneous treatment in this group of patients differ depending on the type of the implemented left ventricular support, remaining at a comparable and acceptable level in relation to the results of studies published by other authors. The differences in treatment outcomes between the group of patients treated with Impella and the group of patients who underwent IABP certainly result, to a significant extent, from the baseline characteristics of patients and their procedure-related risks.

Limitations

Undoubtedly, the presented results are preliminary. The study group is limited to a small size, and strong conclusions cannot be drawn. In addition, by observing the patients included in the study, we found certain bias in the selection of patients, i.e. those from the Impella group were characterised by significantly lower LVEF, demonstrating a very significant relationship with long-term prognosis, despite the fact that the estimated periprocedural mortality risk was similar in both groups.

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REFERENCES

1. Chieffo A, Dudek D, Hassager C, et al. Joint EAPCI/ACVC expert consensus document on percutaneous ventricular assist devices. Eur Heart J Acute Cardivasc Care. 2021; 10(5): 570–583, doi: 10.1093/ehjacc/zuab015, indexed in Pubmed: 34057173.
2. Chieffo A, Burzotta F, Pappalardo F, et al. Clinical expert consensus document on the use of percutaneous left ventricular assist support devices during complex high-risk indicated PCI: Italian Society of Interventional Cardiology Working Group Endorsed by Spanish and Portuguese Interventional Cardiology Societies. Int J Cardiol. 2019; 293: 84–90, doi: 10.1016/j.ijcard.2019.05.065, indexed in Pubmed: 31174920.

3. Dixon SR, Henriques JPS, Mauri L, et al. A prospective feasibility trial investigating the use of the Impella 2.5 system in patients undergoing high-risk percutaneous coronary intervention (The PROTECT I Trial): initial U.S. experience. JACC Cardiovasc Interv. 2009; 2(2): 91–96, doi: 10.1016/j.jcin.2008.11.005, indexed in Pubmed: 19463408.
4. O'Neill WW, Kleiman NS, Moses J, et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study. Circulation. 2012; 126(14): 1717–1727, doi: 10.1161/CIRCULATIONAHA.112.098194, indexed in Pubmed: 22935569.
5. Sjauw KD, Konorza T, Erbel R, et al. Supported high-risk percutaneous coronary intervention with the Impella 2.5 device the Europella registry. J Am Coll Cardiol. 2009; 54(25): 2430–2434, doi: 10.1016/j.jacc.2009.09.018, indexed in Pubmed: 20082934.
6. Maini B, Naidu SS, Mulukutla S, et al. Real-world use of the Impella 2.5 circulatory support system in complex high-risk percutaneous coronary intervention: the USpella Registry. Catheter Cardiovasc Interv. 2012; 80(5): 717–725, doi: 10.1002/ccd.23403, indexed in Pubmed: 22105829.
7. Baumann S, Werner N, Ibrahim K, et al. Indication and short-term clinical outcomes of high-risk percutaneous coronary intervention with microaxial Impella® pump: results from the German Impella® registry. Clin Res Cardiol. 2018; 107(8): 653–657, doi: 10.1007/s00392-018-1230-6, indexed in Pubmed: 29520699.
8. Burzotta F, Russo G, Ribichini F, et al. Long-term outcomes of extent of revascularization in complex high risk and indicated patients undergoing impella-protected percutaneous coronary intervention: report from the Roma-Verona registry. J Interv Cardiol. 2019; 2019: 5243913, doi: 10.1155/2019/5243913, indexed in Pubmed: 31772533.
9. Perera D, Stables R, Thomas M, et al. Elective intra-aortic balloon counterpulsation during high-risk percutaneous coronary intervention: a randomized controlled trial. JAMA. 2010; 304(8): 867–874, doi: 10.1001/jama.2010.1190, indexed in Pubmed: 20736470.
10. Becher T, Baumann S, Eder F, et al. Comparison of peri and post-procedural complications in patients undergoing revascularisation of coronary artery multivessel disease by coronary artery bypass grafting or protected percutaneous coronary

intervention with the Impella 2.5 device. Eur Heart J Acute Cardiovasc Care. 2019; 8(4): 360–368, doi: 10.1177/2048872617717687, indexed in Pubmed: 28660768.

11. Neumann FJ, Sousa-Uva M, Ahlsson A, et al. 2018 ESC/EACTS Guidelines on myocardial revascularization. Eur Heart J. 2019; 40(2): 87–165, doi: 10.1093/eurheartj/ehy394, indexed in Pubmed: 30165437.
12. Knuuti J, Wijns W, Saraste A, et al. 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes. Eur Heart J. 2020; 41(3): 407–477, doi: 10.1093/eurheartj/ehz425, indexed in Pubmed: 31504439.
13. Nashef SA, Roques F, Michel P, et al. European system for cardiac operative risk evaluation (EuroSCORE). Eur J Cardiothorac Surg. 1999; 16(1): 9–13, doi: 10.1016/s1010-7940(99)00134-7, indexed in Pubmed: 10456395.
14. Fried LP, Tangen CM, Walston J, et al. Frailty in older adults: evidence for a phenotype. J Gerontol A Biol Sci Med Sci. 2001; 56(3): M146–M156, doi: 10.1093/gerona/56.3.m146, indexed in Pubmed: 11253156.
15. Sianos G, Morel MA, Kappetein AP, et al. The SYNTAX Score: an angiographic tool grading the complexity of coronary artery disease. EuroIntervention. 2005; 1(2): 219–227, indexed in Pubmed: 19758907.
16. Mehran R, Rao SV, Bhatt DL, et al. Standardized bleeding definitions for cardiovascular clinical trials: a consensus report from the Bleeding Academic Research Consortium. Circulation. 2011; 123(23): 2736–2747, doi: 10.1161/CIRCULATIONAHA.110.009449, indexed in Pubmed: 21670242.
17. Clauss RH, Birtwell WC, Albertal G, et al. Assisted circulation. I. The arterial counterpulsator. J Thorac Cardiovasc Surg. 1961; 41: 447–458, indexed in Pubmed: 13693965.
18. Kantrowitz A. Experimental augmentation of coronary flow by retardation of the arterial pressure pulse. Surgery. 1953; 34(4): 678–687, indexed in Pubmed: 13102153.
19. Curtis JP, Rathore SS, Wang Y, et al. Use and effectiveness of intra-aortic balloon pumps among patients undergoing high risk percutaneous coronary intervention: insights from the National Cardiovascular Data Registry. Circ Cardiovasc Qual Outcomes. 2012; 5(1): 21–30, doi: 10.1161/CIRCOUTCOMES.110.960385, indexed in Pubmed: 22147887.
20. Mishra S, Chu WW, Torguson R, et al. Role of prophylactic intra-aortic balloon pump in high-risk patients undergoing percutaneous coronary intervention. Am J Cardiol.

2006; 98(5): 608–612, doi: 10.1016/j.amjcard.2006.03.036, indexed in Pubmed: 16923445.

21. Brodie BR, Stuckey TD, Hansen C, et al. Intra-aortic balloon counterpulsation before primary percutaneous transluminal coronary angioplasty reduces catheterization laboratory events in high-risk patients with acute myocardial infarction. Am J Cardiol. 1999; 84(1): 18–23, doi: 10.1016/s0002-9149(99)00185-x, indexed in Pubmed: 10404845.
22. Briguori C, Sarais C, Pagnotta P, et al. Elective versus provisional intra-aortic balloon pumping in high-risk percutaneous transluminal coronary angioplasty. Am Heart J. 2003; 145(4): 700–707, doi: 10.1067/mhj.2003.14, indexed in Pubmed: 12679768.
23. Urban PM, Freedman RJ, Ohman EM, et al. In-hospital mortality associated with the use of intra-aortic balloon counterpulsation. Am J Cardiol. 2004; 94(2): 181–185, doi: 10.1016/j.amjcard.2004.03.058, indexed in Pubmed: 15246896.
24. Stone GW, Ohman EM, Miller MF, et al. Contemporary utilization and outcomes of intra-aortic balloon counterpulsation in acute myocardial infarction: the benchmark registry. J Am Coll Cardiol. 2003; 41(11): 1940–1945, doi: 10.1016/s0735-1097(03)00400-5, indexed in Pubmed: 12798561.
25. Zeymer U, Bauer T, Hamm C, et al. Use and impact of intra-aortic balloon pump on mortality in patients with acute myocardial infarction complicated by cardiogenic shock: results of the Euro Heart Survey on PCI. EuroIntervention. 2011; 7(4): 437–441, doi: 10.4244/EIJV7I4A72, indexed in Pubmed: 21764661.
26. Romeo F, Acconcia MC, Sergi D, et al. Lack of intra-aortic balloon pump effectiveness in high-risk percutaneous coronary interventions without cardiogenic shock: a comprehensive meta-analysis of randomised trials and observational studies. Int J Cardiol. 2013; 167(5): 1783–1793, doi: 10.1016/j.ijcard.2012.12.027, indexed in Pubmed: 23295041.
27. Califf RM, Phillips HR, Hindman MC, et al. Prognostic value of a coronary artery jeopardy score. J Am Coll Cardiol. 1985; 5(5): 1055–1063, doi: 10.1016/s0735-1097(85)80005-x, indexed in Pubmed: 3989116.
28. Perera D, Stables R, Clayton T, et al. Long-term mortality data from the balloon pump-assisted coronary intervention study (BCIS-1): a randomized, controlled trial of elective balloon counterpulsation during high-risk percutaneous coronary intervention. Circulation. 2013; 127(2): 207–212, doi: 10.1161/CIRCULATIONAHA.112.132209, indexed in Pubmed: 23224207.

29. Remmelink M, Sjauw KD, Henriques JPS, et al. Effects of mechanical left ventricular unloading by Impella on left ventricular dynamics in high-risk and primary percutaneous coronary intervention patients. Catheter Cardiovasc Interv. 2010; 75(2): 187–194, doi: 10.1002/ccd.22263, indexed in Pubmed: 19941329.
30. Amin AP, Rao SV, Bach RG, et al. The evolving landscape of Impella use in the United States among patients undergoing percutaneous coronary intervention with mechanical circulatory support. Circulation. 2020; 141(4): 273–284, doi: 10.1161/CIRCULATIONAHA.119.044007, indexed in Pubmed: 31735078.
31. Khera R, Cram P, Lu X, et al. Trends in the use of percutaneous ventricular assist devices: analysis of national inpatient sample data, 2007 through 2012. JAMA Intern Med. 2015; 175(6): 941–950, doi: 10.1001/jamainternmed.2014.7856, indexed in Pubmed: 25822170.
32. Schultz J, Duval S, Shaffer A, et al. Axillary or subclavian Impella 5.0 support in cardiogenic shock: a systematic review and meta-analysis. ASAIO J. 2022; 68(2): 233–238, doi: 10.1097/MAT.0000000000001452, indexed in Pubmed: 35089264.
33. Tycińska A, Grygier M, Biegus J, et al. Mechanical circulatory support. An expert opinion of the Association of Intensive Cardiac Care and the Association of Cardiovascular Interventions of the Polish Cardiac Society. Kardiol Pol. 2021; 79(12): 1399–1410, doi: 10.33963/KP.a2021.0169, indexed in Pubmed: 34861044.

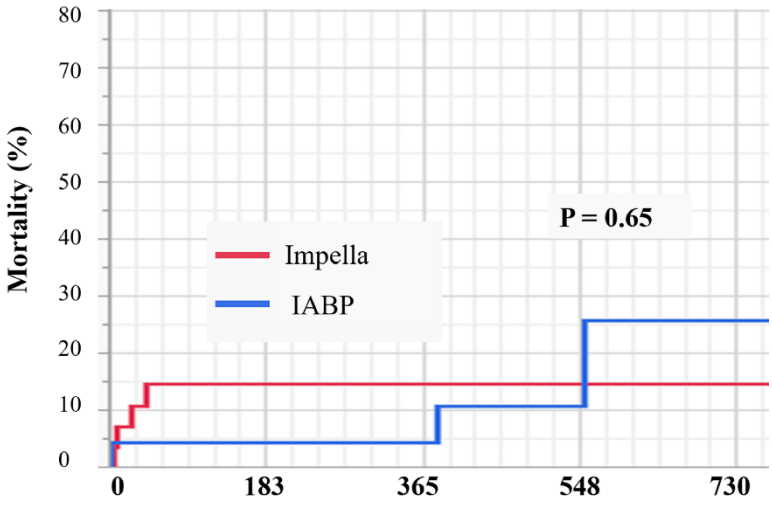
Table 1. Clinical outcomes

		Impella n = 28	IABP n = 22	Total n = 50	*P*-value
Hospitalisation duration, days		12.5 (6.3–18.8)	8 (4–15.8)	10.50 (5.8–18)	0.21
Vascular access complications (LVAD)					
BARC (bleeding) class	0	11 (39.3%)	18 (81.8%)	29 (58%)	0.006
	1	7 (25%)	3 (13.6%)	10 (20%)	
	2	3 (10.7%)	0 (0%)	3 (6%)	
	3a	3 (10.7%)	0 (0%)	3 (6%)	

	3b	4 (14.3%)	1 (4.6%)	5 (10%)	
Invasive treatment of puncture-site complications					
Surgical		1 (3.6%)	0 (0%)	1 (2.1%)	1
Thrombin		1 (3.6%)	0 (0%)	1 (2.1%)	1
Need for blood transfusion					
No blood transfusion		26 (92.8)	21 (95.4%)	47 (94%)	0.57
One unit		1 (3.6%)	1 (4.6%)	2 (4%)	
Two units		1 (3.6%)	0 (0%)	1 (2%)	
Clinical complications					
In-hospital death		1 (3.7%)	1 (4.6%)	2 (4.1%)	1
Follow-up duration		154 (58–281.3)	447.5 (70.8–585.3)	224 (72–456)	0.04
Death		4 (14.3%)	3 (13.6%)	7 (14%)	1
MI		0 (0%)	0 (0%)	0 (0%)	—
Stroke		1 (3.6%)	0 (0%)	1 (2%)	1
Re-PCI		1 (3.6%)	0 (0%)	1 (2%)	1
TLR		1 (3.6%)	0 (0%)	1 (2%)	1
TVR		1 (3.6%)	0 (0%)	1 (2%)	1
MACE		5 (17.9%)	3 (13.6%)	8 (16%)	1

Data are presented as median (interquartile range [IQR]) for continuous variables and counts (percentages) for nominal variables

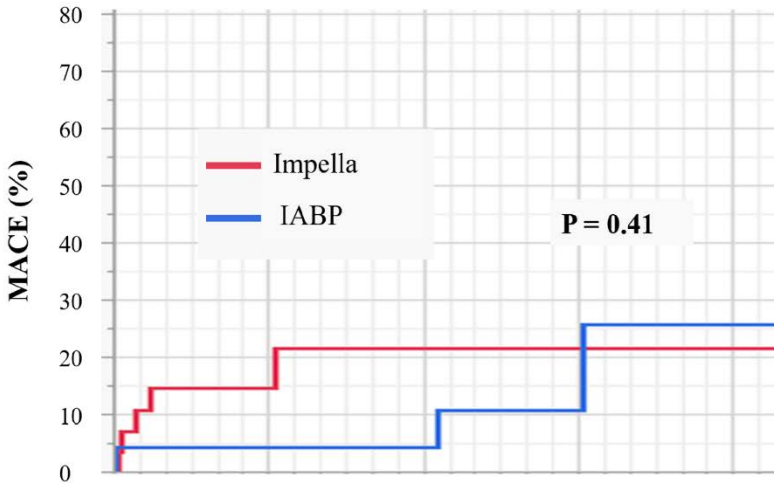
Abbreviations: BARC, Bleeding Academic Research Consortium; IABP, intra-aortic balloon pump; LVAD, left ventricle assist device; MACE, major adverse cardiovascular events; MI, myocardial infarction; PCI, percutaneous coronary intervention; TVR, target vessel revascularisation; TLR, target lesion revascularisation



Follow-up, days		0	183	365	548	730
Overall	At risk	50	27	20	9	6
	Cumulative number of events	1	5	5	6	7
Impella	At risk	28	12	5	3	2
	Cumulative number of events	0	4	4	4	4
IABP	At risk	22	15	15	6	4
	Cumulative number of events	1	1	1	2	3

Figure 1. Kaplan–Meier estimates comparing overall survival between patients treated with complex and high-risk PCI with Impella and IABP support

Abbreviations: see Table 1



Follow-up, days		0	183	365	548	730
Overall	At risk	50	27	20	9	6
	Cumulative number of events	1	5	6	7	8
Impella	At risk	28	12	5	3	2
	Cumulative number of events	0	4	5	5	5
IABP	At risk	22	15	15	6	4
	Cumulative number of events	1	1	1	2	3

Figure 2. Kaplan–Meier estimates comparing MACE occurrence between patients treated with complex and high-risk PCI with Impella and IABP support

Abbreviations: see Table 1