# Circulatory support with Impella CP device during high-risk percutaneous coronary interventions: initial experience in Poland

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## Introduction

Coronary revascularization is an important part of the treatment of patients with coronary artery disease. However, a significant proportion of patients are characterized by high-risk features. Many of these patients are referred for high-risk percutaneous coronary interventions (PCIs) due to the extremely high risk of surgery. To support such procedures and to facilitate the care of high-risk patients, percutaneous left ventricular assist devices (pLVAD) were developed. Due to confounding data and downgraded guidelines for use of the intra-aortic balloon pump (IABP), especially in cardiogenic shock caused by myocardial infarction (MI), there is currently growing interest in pLVAD [1, 2]. The use of pLVAD during high-risk PCI in Europe varies from country to country mainly due to different reimbursement policies.

## Aim

Due to growing interest in pLVAD support during high-risk PCIs in Poland and Europe, we aim to present our initial experience with the Impella CP system during high-risk PCIs.

## Material and methods

The study is a prospective registry of all patients treated with the Impella CP (ABIOMED Inc., Danvers, MA, USA) in Poland. Data are collected based on a dedicated questionnaire. The registry is currently conducted in six high-volume PCI centers. All procedures are performed with highly experienced operators and are fully supported by company (distributor in Poland) staff either on site for elective procedures or with phone support for emergency usage. Also two types of training courses are provided for physicians, nurses and technicians: one for staff performing the procedure with the Impella and the second for staff taking care of patients after the procedure. This is important for the first cases when this new technology is implemented.

The results are presented as the number of patients or mean ± standard deviation where applicable.

## Results

A total of 10 patients were treated with Impella CP support from April 2013 to August 2015 (four in 2013/14 and six in 2015). In all cases except one, the Impella CP was used during high-risk elective PCI, and the present

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analysis is focused on those nine patients. In this one excluded case, the Impella CP was used due to an acute MI complicated with cardiogenic shock. Baseline characteristics of enrolled patients are summarized in Table I. All patients were men with a mean age of 73 ±11 years and mean left ventricular ejection fraction of 32 ±8%. The baseline risk profile of enrolled patients was rather high, with previous revascularization, previous MI and chronic kidney disease in half of the patients. In the majority of cases the left main coronary artery was the target vessel for PCI (Table I). All patients received drug-eluting stents during PCI. In all cases the device was implanted under the supervision of the company representative on site. In all cases the femoral access with a 14 F Oscor introducer and Abiomed 0.018 guidewire was used. In two cases the Impella CP was implanted with surgeon support and in seven with the wire insertion method. The Automated Impella Controller was used in all patients with Autoflow and P-level configuration in 5 and 4 patients respectively. In all cases support with the Impella CP was continued until the end of the procedure. Surgical closure was used in four patients and an arterial closure device in 5 patients (four with Perclose ProGlide (Abbott Vascular, CA, USA), one with AngioSeal (St. Jude Medical, MN, USA)). Thirty-day outcomes of patients treated for high-risk elective PCI were good, with no death during follow-up. Only in 1 patient was a small hematoma at the site of device insertion noted.

## Discussion

In our initial series we found the use of the Impella CP during high-risk PCI to be feasible and safe.

Patients with extensive coronary artery disease, depressed left ventricular ejection fraction, hemodynamic instability and multiple comorbidities are at high risk for coronary revascularization procedures. During recent years due to population aging in Europe there is a growing number of such high-risk elderly patients who are candidates for revascularization. Coronary artery bypass grafting with full revascularization seems to be a preferred option, but often due to high surgical risk such patients are referred for percutaneous revascularization [3, 4]. In such a case the benefit of percutaneous revascularization is expected; however, the risk of periprocedural events is very high. Therefore there is a strong clinical need of periprocedural support. Formerly, IABP was used as a PCI support mainly for patients with MI and/or cardiogenic shock. It was used less often during elective high-risk procedures. However, according to current data the value of IABP is questionable [1, 2]. To overcome the limitations of IABP and to reduce the risk of PCIs in such patients, the strategy of procedural support with pLVAD technology was proposed. The Impella technology is an axial flow, rotary pump built on a 9 Fr catheter. For PCI support, the device is deployed via femoral access

**Table I.** Summary of enrolled cases

| Patient | Indication | Age [years] | Gender | AH | DM | PCI | CABG | MI | CKD | PVD | LVEF (%) | Target vessel(s) | Stent | Support | Configuration | Access | Insertion method | Closure method | Access site complications | 30-day outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | HRPCI | 61 | Male | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 40 | LM | DES | On site | Autoflow | Femoral | Wired | Perclose | No | Survived |
| 2 | HRPCI | 66 | Male | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 30 | LM | DES | On site | Autoflow | Femoral | Wired | Surgical | No | Survived |
| 3 | HRPCI | 86 | Male | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 42 | LM, LAD, Cx | DES | On site | Autoflow | Femoral | Wired | Angioseal | No | Survived |
| 4 | HRPCI | 75 | Male | 1 | 0 | 0 | 1 | 0 | 1 | 0 | 34 | LAD | DES | On site | P-Level | Femoral | Wired | Perclose | No | Survived |
| 5 | HRPCI | 71 | Male | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 15 | LM | DES | On site | P-Level | Femoral | Wired | Surgical | No | Unknown** |
| 6 | HRPCI | 82 | Male | 0 | 0 | 1 | 0 | 1 | 1 | 0 | 35 | LM, LAD | DES | On site | Autoflow | Femoral | Wired | Perclose | Hematoma | Survived |
| 7 | HRPCI | 58 | Male | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 27 | LAD | DES | On site | P-Level | Femoral | Surgical | Surgical | No | Survived |
| 8 | HRPCI | 86 | Male | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 37 | LM, LAD, Cx | DES | On site | Autoflow | Femoral | Wired | Perclose | Hematoma* | Survived |
| 9 | HRPCI | 69 | Male | 1 | 1 | 0 | 0 | 1 | 1 | 1 | 29 | LM, LAD | DES | On site | P-Level | Femoral | Surgical | Surgical | No | Survived |

*AH – arterial hypertension, CABG – previous coronary artery bypass grafting, CKD – chronic kidney disease, Cx – circumflex coronary artery, DES – drug-eluting stent, DM – diabetes mellitus, HRPCI – high-risk percutaneous coronary intervention, LAD – left anterior descending coronary artery, LM – left main coronary artery, LVEF – left ventricular ejection fraction, MI – previous myocardial infarction, PCI – previous percutaneous coronary intervention, PVD – peripheral vascular disease. *Not related to Impella CP implantation; **survived in-hospital stay, no data on 30-day follow-up.*

in a retrograde way across the aortic valve. In our series of patients the Impella CP with higher blood flow was used. The Impella CP theoretically provides nonpulsatile forward blood flow of up to 4.0 l/min (max speed 46 000 rpm) which is independent of cardiac rhythm. However, there is native heart pulsatile flow creating pulsatility of blood flow through the device. That is why the motor current maximum is reached during systole and is associated with higher flows and higher pump speeds. So pump flow is the highest during systole and lowest during diastole [5]. In our series of cases in five patients the "Autoflow" and in four the "P-level" pump configuration was used. Autoflow is a fully automated program in which the device provides maximal support for the particular patient, and there is no need for operator intervention. This may be a reasonable option for initial cases. P-level configuration is a manual mode in which a support level from P0 to P9 may be selected, but some experience is necessary to use such a protocol. This mode is also useful for device removal, especially for cardiogenic shock patients when support should be gradually reduced (like in IABP) before termination. Importantly, the device is designed for a fully percutaneous femoral approach with no need of surgical preparation. However, in the presented results surgical vascular access was used in 2 cases in one study center, but it was according to the local policy for new device introduction rather than a systemic approach. In 4 cases surgical vessel closure was performed for the same reason. For high-risk PCI support, vascular access and vascular closure after Impella usage may be used fully percutaneously by an operator who is experienced in this technology. For initial cases, surgical back-up may be a reasonable option. In Poland, the first procedure of percutaneous Impella support (Impella 2.5 device) was performed in the Institute of Cardiology in Krakow (K. Żmudka, T. Pawelec) in 2007. In the PROTECT II study, Impella technology was shown to be associated with improved clinical outcome at 90 days as compared to IABP in patients undergoing high-risk PCI [6]. In a sub-analysis of PROTECT II the benefit of Impella (compared to IABP) was observed in patients with three-vessel coronary artery disease and impaired left ventricular function [7]. The PROTECT II study was based on the Impella 2.5 device. In the Europella Registry on high-risk patients with a logistic EuroSCORE of about 15%, the 30-day death rate was 5.5%, the vascular complication rate was 4%, and device malfunction was not observed, showing Impella 2.5 periprocedural support to be safe and feasible [8]. Similarly, in the USpella registry the overall angiographic success was 99%, the survival rate was 96% at 30 days and 88% at 12 months, and in 3.4% of patients transfusion was required due to access site bleeding [9]. Despite the higher risk of the patients included in the USpella registry as compared to those enrolled in the randomized trial (PROTECT II), clinical outcomes of registry "real-life" patients appeared to be favorable [10]. Operator's experience seems to be important for patient outcomes when using Impella support during high-risk PCI. In the prespecified subgroup analysis of the PROTECT II study in which the outcomes were evaluated after excluding the first Impella and IABP patients at each site, a trend toward higher rates of major adverse cardiovascular events at 30 days was observed for the subgroup of the first versus the remaining Impella 2.5 patients. Importantly, after exclusion of the first patient in each group, the major adverse cardiovascular event rate for the Impella 2.5 was significantly lower compared to IABP at 90 days (38% vs. 50%; $p = 0.029$) [11]. This may suggest the presence of a learning curve associated with the use of the Impella 2.5. So it may be better to perform the first cases with the supervision of an experienced proctor. This fact also raises a question about the hub-spoke concept for PCI procedures with Impella support. It may be reasonable to establish reference centers to increase the team experience and improve the results by cumulating the usage of the device in a limited number of centers. It should be underlined that such a scenario is possible in planned PCI procedures but probably not in patients with cardiogenic shock, who are also a target population for pLVAD support [12].

The presented strategy describes the so-called "protected PCI". In such an approach, complex PCI procedures in high-risk patients may be performed with a full range of devices and techniques due to the stable hemodynamic status driven by the pLVAD support. This may improve patients' outcome. However, the penetration of pLVAD is dependent on the reimbursement policy. In Poland this procedure is currently not reimbursed, and it is fully covered by hospital funds. Impella usage during high-risk PCI is reimbursed in many European countries and the USA.

It is worth mentioning that besides LV support it is also possible to provide right ventricle support with the Impella RP system. It may be used in patients with cardiogenic shock due to RV failure and may be helpful either in isolation or in combination with the Impella CP for patients with shock [13].

Based on previous studies as well as on the presented experience, the Impella CP seems to be feasible and safe as circulatory support during high-risk PCI procedures.

## Conflict of interest

The authors declare no conflict of interest.

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