High-risk percutaneous coronary intervention with Impella CP hemodynamic support. A case series and method presentation

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Introduction

Advanced age and additional co-morbidities in patients suffering from coronary artery disease (CAD), with complex coronary lesions including multi-vessel and unprotected left main (ULM), preclude surgical revascularization due to high perioperative morbidity and mortality. For such patients, percutaneous coronary intervention (PCI) may be the only alternative, even if there is a significant technical challenge and procedural risk.

Percutaneous hemodynamic support may be favorable during high-risk PCI [1–3]. Intra-aortic balloon pump (IABP) counter-pulsation is the most commonly used approach. Its benefit of improving long-term survival after high-risk PCI was confirmed in a recent meta-analysis [4]. However, IABP only modestly increases cardiac output and coronary blood flow, and may provide insufficient circulatory support when a hemodynamic collapse occurs [2, 3]. The Impella CP axial flow pump (ABIOMED Inc., Danvers MA, USA) is another percutaneous device, which offers more effective hemodynamic support compared to IABP [5, 6].

We describe five cases of patients who underwent complex PCI supported by the Impella CP, which is a novel approach in Poland [7].

Cases report

Demographic, clinical and procedural data are summarized in Table I. All patients were men with mean age of 78.8 ±8.2 years and mean left ventricular ejection fraction (LVEF) of 29.4 ±13.4%. Baseline coronary lesions' localization in angiography and final PCI results in two illustrative patients are shown in Figure 1. High risk was determined based on clinical presentation with myocardial infarction (MI) (4 patients), impaired LV function, advanced age, significant co-morbidities, chronic heart failure symptoms and complex lesions with unprotected distal left main and multi-vessel disease. The PCI was performed in AUTO mode and all patients received drug-eluting stent (DES), after rotablation in 1 patient. Impella CP was removed in all patients immediately after PCI and the femoral artery was closed with two Perclose ProGlide (Abbott Vascular, CA, USA) devices. Clinical status has improved in all patients and there were no deaths during 30-day follow-up.

Circulatory support with the Impella CP

The Impella CP Circulatory Support System is a 14 Fr size micro-axial blood pump, mounted on a 9 Fr catheter, which aspirates the blood from the LV cavity and expels it to the ascending aorta [8]. With its maximal speed of 46,000 revolutions per minute (rpm), the device enhances the blood flow from the LV to the aorta by a maximum of 3.3 to 3.5 l/min in clinical conditions. In contrast to the IABP, the Impella works independently of cardiac rhythm [3]. The single-use components of the Impella CP system include the Impella CP catheter, 0.018 inch 260 cm placement guidewire, connector cable, purge cassette and introducer kit containing a 14 Fr peel-away introducer, 8–10–12 Fr dilators and 0.035-inch stiff guidewire for access. The catheter is inserted percutaneously, usually into the femoral artery through a 14 Fr vascular sheath, and can be held in place up to 5 days (6 h in US), according to the manufacturer's recommendation.

The main mechanism of action of the Impella CP is unloading of the LV. As a result, the Impella CP reduces

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Table I. Demographic, clinical and procedural data

Parameter	Case 1 (Figures 1 A, B)	Case 2	Case 3	Case 4 (Figures 1 C, D)	Case 5
Age [years], sex	86, male	82, male	86, male	69, male	71, male
Diagnosis	NSTEMI	NSTEMI	NSTEMI	NSTEMI	UA
EF (%)	42–45	35–38	37	15	15
Other risk factors	DM, CRD	CHF III, CRD	CHF III/IV, pleural effusion, chronic cerebral ischemia, stenosis in the left carotid	CHF III/IV, CRD, anemia, recurrent VT with resuscitation, significant MR	CHF III, VT, ICD,
Ischemic ST depression in the ECG (leads)	I, II, III, V3–V6	I, aVL, V4–V6	I, aVL, V5–V6	Ventricular pacing	Atrial pacing, LBBB
Coronary angiography (localization of critical lesions)	Distal ULM and bifurcation of LAD/D1, chronic occlusion of RCA	Distal ULM and 3 VD, chronic occlusion of RCA. Severe protrusion of under-expanded Cx DES to LM	Distal ULM, LAD, Cx, RCA, massive calcifications	Distal ULM, LAD, chronic occlusion of RCA	Distal ULM, proximal LAD
Procedure details	PCI of distal LM and LAD/D1 bifurcation	PCI of distal LM	Rotablation of distal LM and LAD (formerly two-staged PCI of RCA with 5 DES)	PCI of LAD and distal LM (formerly staged recanalization of RCA with implantation of 3 DES)	PCI of distal LM, LCx and LAD
Number of DES	5	2 (1 self-expanding)	3	4 (1 self-expanding)	3
Impella removal	Immediately after PCI	Immediately after PCI	Immediately after PCI	Immediately after PCI	Immediately after PCI
Complications	Transient worsening of renal function	Small hematoma (Impella entry), gout attack	Small hematoma (guiding catheter entry)	None	None
Duration of hospitalization after PCI [days]	11	4	4	21	4

CHF – congestive heart failure, CRD – chronic renal disease, ICD – implantable cardioverter-defibrillator, Cx – circumflex, D – diagonal, DES – drug-eluting stent, DM – diabetes mellitus, LAD – left anterior descending, LM – left main, MR – mitral regurgitation, RCA – right coronary artery, VD – vessel disease, VT – ventricular tachycardia, EF – ejection fraction.

end-diastolic pressure and wall tension, thus reducing LV work and myocardial oxygen demand [9]. Moreover, the Impella CP decreasing the pulmonary capillary pressure reduces right ventricular afterload, and increasing the aortic pressure increases coronary perfusion. Forward flow through the pump decreases with increasing ventricular-aortic gradient; thus the highest pump flow and motor current occur during systole when the gradient is minimal. This makes characteristic motor current fluctuations during the cardiac cycle. This phasic flow pattern is reported as maximum and minimum flows. It is also used for Impella CP positioning and flow calculation. The flow through the pump is preload dependent and may be decreased in case of low LV pressure, small LV cavity or impaired right ventricular function [8].

Proper positioning of the catheter requires positioning of its inlet about 3.5 cm below the annulus of the aortic valve (3 cm in a small LV) and in the middle of the LV cavity. It is important to keep the catheter away from the mitral valve leaflets, chordae and papillary muscles. Moreover, coiling in the LV cavity must be avoided. The catheter outlet should be placed in the ascending aorta, well above the aortic valve [8].

The Automated Impella Controller (AIC) provides an interface for controlling the function of the Impella CP catheter, fluid purge and backup power during transportation (at least 60 min when fully charged). At the beginning, after the catheter insertion and careful positioning assessment, the pump is started in AUTO mode, which automatically increases the flow rate over 30 s. After this period of time it is necessary to check waveforms on the AIC and the position of the catheter, which has a tendency to be drawn into the ventricle. In AUTO mode the motor speed of the Impella CP is set to achieve the maximum possible flow without causing suction. After 3 h of operation the controller automatically switches to P-level mode, which can be set from P-1 to P-8 (0–1.7 l/min to 3.0–3.3 l/min). It is important to remember that a setting of P-0 or P-1 will result in retrograde flow when the Impella CP catheter is placed across the aortic valve. While on the Impella CP support, a patient's blood flow inherently loses its pulsatile nature, which may cause

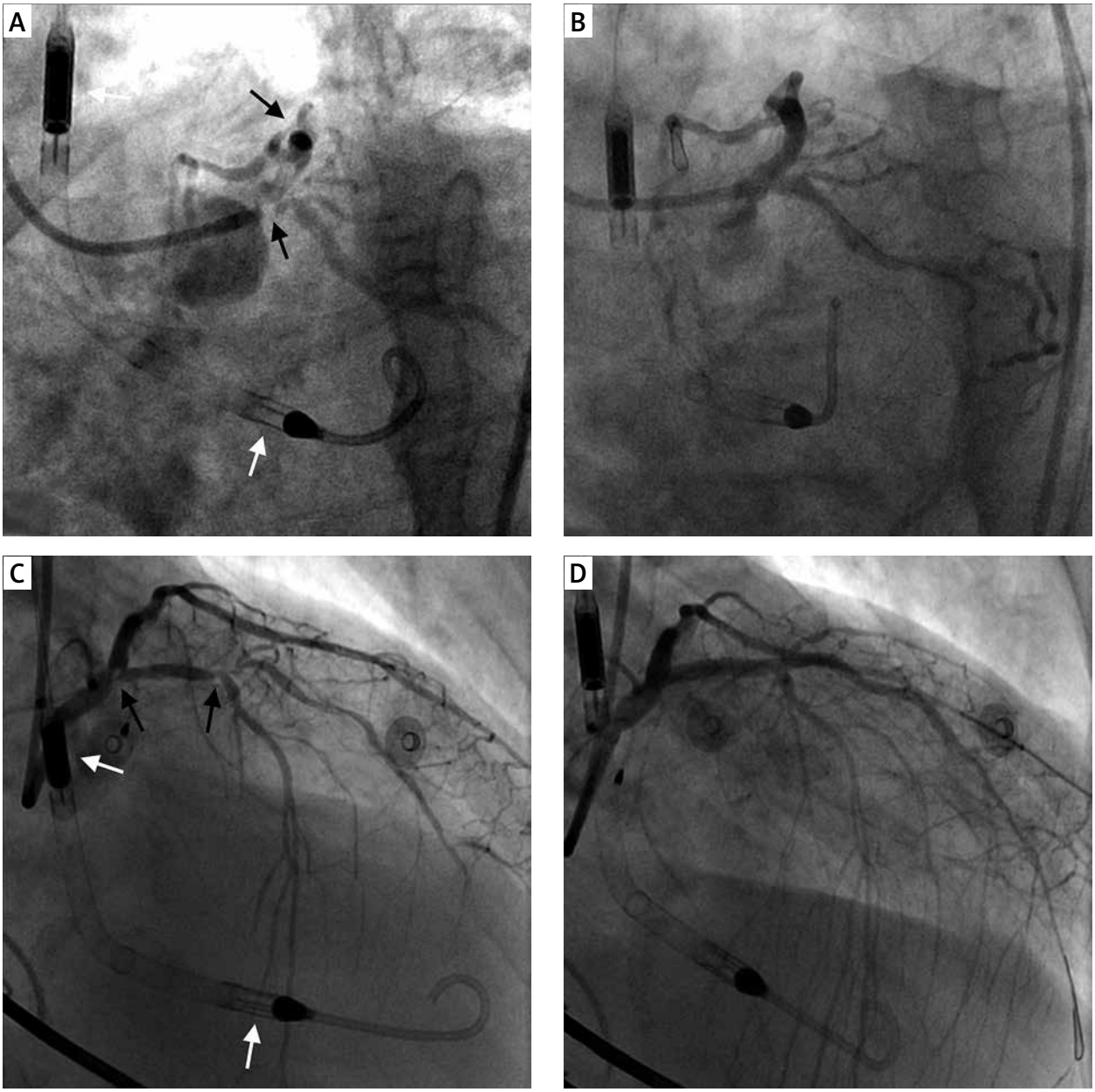

Figure 1. Angiography of the left coronary arteries before and after PCI of two illustrative patients (treated lesions – black arrows) with the Impella CP in the LV (lower white arrows) and rotary pump in the aorta (upper white arrows)

a patient's pulsatility to drop or disappear completely. As a result, a drastic drop or a "zero" value calculated for SpO_2 can be observed, regardless of the true arterial oxygen saturation, adequate mean blood pressure, skin color and arterial blood gas analysis. Reducing Impella CP support, and administering IV fluids to increase blood volume, and/or small doses of ephedrine or phenylephrine, can return pulsatility [8].

During Impella CP support systemic anticoagulation and anticoagulation added to the purge fluid are required. The systemic anticoagulation should prolong activating clotting time (ACT) to 160–180 s (or > 250 s during PCI) or activated partial thrombin-time (aPTT) adjusted to achieve an ACT target. Because the purge fluid – whether 5% or 20% dextrose – contains 50 IU/ml of heparin, it is important to remember that the patient will also receive a higher rate of infusion of heparin. In the case of heparin-induced thrombocytopenia (HIT), a systemic delivery of an alternative anticoagulant is required, but the Impella CP catheter has not been tested with any alternative anticoagulants in the purge solution [8].

The Impella CP Circulatory Support System is intended for partial circulatory support (e.g. in cardiogenic shock or high-risk PCI). It is important to make a care-

ful clinical assessment before the decision of using the Impeller CP. Performing cardiac echocardiography is advised to exclude thrombus in the LV cavity, which may result in the Impella CP pump stopping. In such circumstances there is also a risk of systemic embolization with LV Impella CP placement, usually due to catheter manipulation in the LV cavity. Severe aortic regurgitation (≥ 2) is a relative contraindication due to increased aortic pressure, which can lead to increase of the aortic regurgitation and LV dilatation. Known or suspected unrepaired abdominal aortic aneurysm, significant descending aorta aneurysm or dissection of the aorta requires special care. Patients with aortic stenosis (orifice area ≤ 1.5 cm^2) or other abnormal valve performance may be compromised by the use of the Impeller CP. Mechanical aortic valve or heart constrictive devices are contraindications to Impella CP support [8]. Peripheral vascular disease is a relative contraindication, making impossible insertion of a large diameter sheath, even after iliac artery dilatation with a balloon (self-experience). In such cases it is advised to select alternative access depending on the clinical situation. The Impella CP can be removed immediately after successful high-risk PCI. Percutaneous closure devices, such as Perclose ProGlide (Abbott Vascular, CA, USA), can be used, but for long-term implants should be avoided due to infection risk.

If extending cardiac support is necessary after PCI, it is important to disable the AUTO feature and switch to the P-level mode with the highest support (P8), and to disable suction control. The purge system should be transferred to "standard configuration". It is also very important to verify the Impella CP catheter position after installation of the patient in the Intensive Care Unit. The potential complications associated with improper positioning of the catheter include placing the catheter inlet in the ascending aorta, advancing the catheter too far into the LV, and placing the catheter in the papillary muscle. The mentioned inappropriate positions can be well visualized in trans-thoracic cardiac echocardiography (TTE) in the parasternal long-axis projection. The ideal position of the inlet in the LV is approximately 3.5 cm from the aortic valve. To correct the position of the Impella CP a careful manipulation of the catheter should be done during continuous TTE guidance. The volume status and right ventricular function should also be assessed in TTE. In case of any suspicion of Impella CP displacement, control echocardiography should be performed [8].

Short weaning trials can be performed during observation of LV recovery in echocardiography. If the hemodynamics are stable and only small doses of inotropic support are required, the decision of the final weaning can be made. The support level is gradually decreased over 4–6 h until support is at 1–1.5 l/min. In stable patients the catheter is pulled out into the descending aorta, and after discontinuation of systematic unfractionated heparin the ACT should fall to ≤ 150 s. After 30 min, the AIC can be turned off and the catheter can be removed. A 30–40 min manual compression is almost always sufficient, but direct surgical closure may also be considered [8].

The most common complications are related to the access site (bleeding, infection, limb ischemia) and/or involve stroke, hemolysis, suction episodes and inadequate hemodynamic support.

Discussion

A decision to use hemodynamic support in our patients was especially difficult, due to the lack of a universal definition of high-risk PCI, and was determined by both the degree of complexity of the coronary artery disease and clinical co-morbidities, such as LV dysfunction, advanced age, diabetes, renal dysfunction and prior procedural history. According to one definition, high-risk PCI is the treatment of an unstable patient with an ejection fraction of less than 25% or the target vessel supplying more than half of the myocardium [10]. However, the LVEF cut-off value may vary from 25% to 40%, depending on the expert's opinion [2, 3]. Complex procedures usually require long procedural times and challenging techniques, such as rotational atherectomy, and are more prone to acute vessel occlusion, low-flow or distal embolization and myocardial necrosis. It was demonstrated that partial circulatory support with the Impella CP has been associated with more extensive use of rotational atherectomy and a periprocedural increase of cardiac biomarkers indicative of myocardial injury [5]. The Impella system has been shown to be effective and safe both in high-risk PCI and MI complicated by cardiogenic shock (CS). The ISAR-SHOCK trial randomized 26 patients with MI and CS to IABP or the Impella 2.5. The primary end point (cardiac index change 30 min after implantation) was higher in the Impella group (0.49 ±0.46 vs. 0.11 ±0.31 l/min/m^2; p = 0.02), but 30-day survival was identical (46.2%) in both groups. No device-related technical failure, major bleeding or ischemia during support was observed. There was only one case of acute limb ischemia requiring surgery in the Impella arm [11]. The PROTECT I trial enrolled 20 stable patients who underwent high-risk PCI. All patients had severely impaired left ventricular function with EF < 35% and underwent PCI of the ULM or last patent coronary artery with Impella 2.5 support. Successful implantation and freedom from hemodynamic compromise during PCI (primary efficacy endpoint) were observed in all patients. In 30 days follow-up two patients died and two had a periprocedural MI [12]. The Europella registry evaluated 144 stable patients undergoing high-risk PCI of the ULM, last patent artery or multi-vessel disease with Impella 2.5 support. Mortality was 5.5% at 30 days (9 patients). Major bleeding requiring transfusion or surgery occurred in 9 patients. There was one stroke and one case of hemolysis requiring transfusion [13]. Another

large registry that proved the clinical effectiveness of the Impella 2.5 is USPELLA. It is recruiting patients undergoing high-risk elective or urgent PCI and patients with MI complicated by CS. The interim analysis, including data of 352 patients, showed a low major adverse cardiovascular event rate (8%) and high survival rate (96%) in the 30-day follow-up (O'Neill WW, TCT 2010). The PROTECT II trial was the first prospective randomized controlled trial comparing the Impella 2.5 versus IABP in patients undergoing non-emergent high-risk PCI [5]. In the available data of 452 patients randomized before premature discontinuation of the study, the composite primary end point (all-cause death, MI, stroke or transient ischemic attack, any repeat revascularization, need for a cardiac or vascular operation, acute renal insufficiency, severe intra-procedural hypotension, cardiopulmonary resuscitation, ventricular tachycardia requiring cardioversion, aortic insufficiency or angiographic failure of PCI) was observed in 35.1% of the Impella group and in 40.1% of the IABP group (p = 0.277) at 30 days in the intention-to-treat (ITT) population. A non-significantly lower major adverse event rate was observed in the Impella 2.5 supported patients compared with IABP in the ITT population (respectively 40.6% vs. 49.3%, p = 0.066) at 90 days. This difference reached statistical significance at 90 days in the per protocol population (respectively 40.0% vs. 51.0%, p = 0.023). In hemodynamic analysis the Impella 2.5 provided stronger support than IABP (p = 0.001).

Conclusions

Hemodynamic support with the Impella CP device in our high-risk elderly patients was effective, safe and easily removable. With the Impella CP device we were able to perform complex PCI with a good angiographic result and without intra-procedural complications. It appears to be a feasible strategy in patients undergoing high-risk PCI.

Conflict of interest

The authors declare no conflict of interest.

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