

Original Research

Initial Experience with the Impella Recover LP 2.5 Micro-Axial Pump in Patients Undergoing High-Risk Coronary Angioplasty

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Introduction: The Impella LP 2.5 device is a new percutaneous left ventricular assist device, an intravascular micro-axial blood pump designed for short term circulatory support in conditions characterized by profoundly reduced ventricular function. Percutaneous coronary intervention (PCI) is increasingly being used in patients who have severely compromised left ventricular contractility and complex coronary lesions, including multivessel disease.

Methods: Three patients (pts) underwent elective PCI with the use of the Impella system. All were very poor candidates for surgery because of severe comorbidities, with mean logistic EuroSCORE 39.3%. Echocardiography was used to rule out anatomical contraindications before implantation of the device. All pts had previous myocardial infarctions and impaired left ventricular (LV) function with LV ejection fraction <25-30%. We evaluated the effects of the pump on cardiac output, mean pulmonary wedge pressure and mean blood pressure, using right heart catheterization. We also assessed hemoglobin, cardiac enzymes (CK, CKMB and troponin), creatinine and NT-proBNP levels before and the day after the intervention.

Results: The procedure was uncomplicated, without any acute, device-related adverse events during LV support. The Impella was used for a mean time of 9.3 hours (range 2 to 24 hours) and was removed immediately after the intervention in all but one patient. The device did not induce or increase aortic valve regurgitation. Two pts needed pharmacologic inotropic support during the procedure. Mean blood pressure increased in all 3 pts without pulmonary wedge pressure reduction, presumably due to a combination of pump function and PCI-induced ischemia. The mean drop in hemoglobin levels was 1.7 g/dl. The mean increase in creatinine levels due to contrast was 1 mg/dl. NT-proBNP showed a variable response. Two pts remained stable at follow up and one expired one month later due to worsening heart failure.

Conclusions: The growing heart failure population and the benefit of revascularization in patients with severe LV dysfunction have led to an increase in the number of mechanically assisted percutaneous coronary interventions. Circulatory support with the Impella LP 2.5 pump during high risk PCI is feasible, but larger studies are required to demonstrate its efficacy in these severely compromised and vulnerable patients.

Percutaneous coronary intervention (PCI) has been increasingly applied to patients with severely depressed left ventricular function and complex coronary lesions. The availability of hemodynamic support devices offers a promising option to reduce PCI-related complications in high risk procedures.¹⁻⁹ A number of techniques have been proposed for circula-

tory support during high-risk PCI, but no single approach has achieved wide acceptance so far. The most frequently used left ventricular (LV) support device is the intra-aortic counterpulsation balloon, which can deliver a cardiac output of 0.5 L/min.⁸ We report on 3 patients with severely compromised LV systolic function and complex coronary lesions including multivessel dis-

ease, who underwent PCI with the use of a new left ventricular assist device, the Impella Recover LP 2.5 system. (Abiomed Europe GmbH, Aachen, Germany).

Methods

The Impella Recover LP 2.5 system is a novel percutaneous LV unloading assist device, consisting of a miniaturized rotary blood pump that is placed across the aortic valve, where it aspirates blood from the LV cavity and expels it into the ascending aorta.^{9,10} The device can be introduced percutaneously through a 13 F femoral sheath (Figure 1). It is connected distally to a portable mobile console, on which invasive pressure, recorded from the catheter, is displayed together with the actual rotational speed of the pump (revolutions per minute, rpm), thus providing information about the correct positioning and functioning of the device. The driving console allows 9 gradations in speed from 2000 to 50,000 rpm and the pump has been designed to deliver an output of up to 2.5 L/min.^{10,11} It can be safely left in place for up to 5 days.

We report 3 cases of patients with severe LV impairment who underwent elective high-risk PCI with the use of the Impella Recover LP 2.5 system for the first time in Greece. All patients were very poor candidates for surgery, as was determined after a joint meeting with our cardiothoracic surgeons. Based on the patients' characteristics, their EuroSCORE was calculated and all of them had been previously rejected for cardiac surgery. Before implantation, echocardiograms were obtained in all patients to exclude LV thrombi or anatomical contraindications – e.g. ventricular septal defect, aortic valve disease (stenosis and/or regurgitation or an artificial valve) – as suggested by Catena et al.⁹ All patients had a LV ejection fraction <25-30%. Vascular accessibility was documented angiographically at the beginning of the procedure.

First case

A 63-year-old man (body surface area [BSA] 1.75 m²), with a prior history of inferior/lateral myocardial infarction, several hospitalizations due to congestive

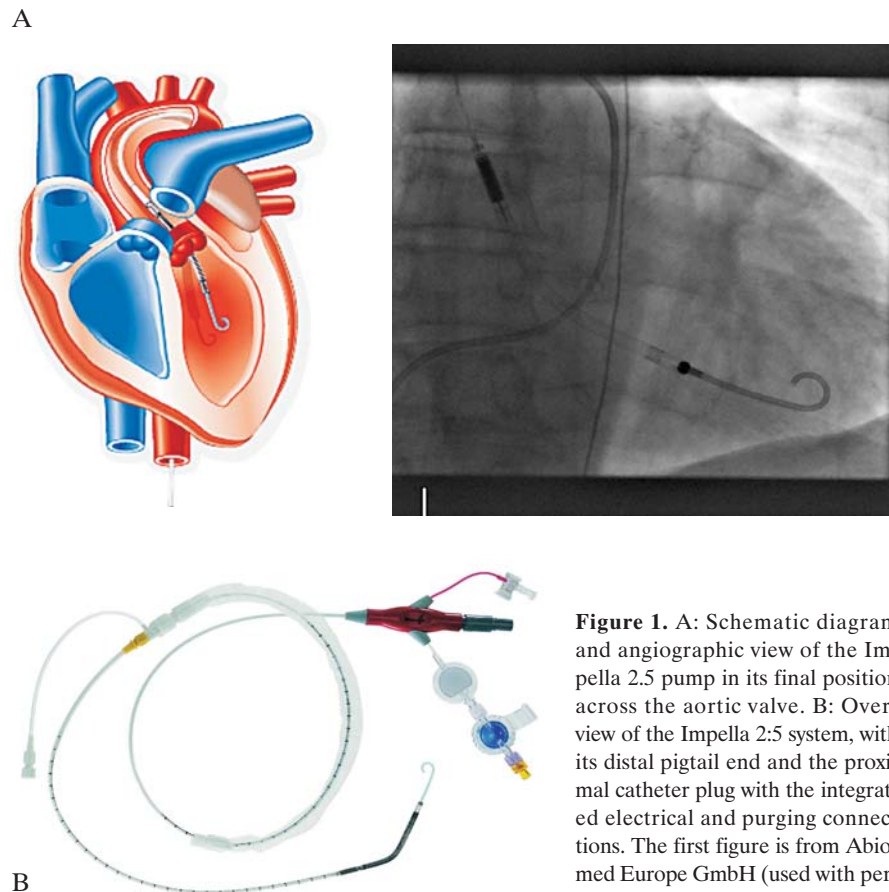


Figure 1. A: Schematic diagram and angiographic view of the Impella 2.5 pump in its final position across the aortic valve. B: Overview of the Impella 2.5 system, with its distal pigtail end and the proximal catheter plug with the integrated electrical and purging connections. The first figure is from Abiomed Europe GmbH (used with permission).

heart failure and worsening unstable angina, was referred to our hospital for revascularization. He had a prior history of diabetes mellitus, systemic hypertension, mild renal failure and an episode of cerebrovascular ischemic stroke. His coronary angiography, 4 months previously, had revealed total occlusion of the left circumflex (LCX) and right coronary (RCA) arteries and significant narrowing in the mid and distal left anterior descending artery (LAD). A stress single photon emission computed tomography (SPECT) examination showed viable myocardium with a reversible perfusion defect in the LV anterior wall and myocardial scars in the inferior and lateral walls. Echocardiography showed LV dilatation, akinesia of the anterior and inferior walls, apical dyskinesia, and impaired LV and right ventricular (RV) function, without significant valve regurgitation or thrombus. His perioperative surgical EuroSCORE logistic was 37.7%. Thus, we decided to perform a PCI in the last remaining patent vessel, the LAD.

Two 6 F sheaths were placed in the right femoral artery (RFA) and right femoral vein (RFV). Once accessibility through both femoral arteries was confirmed, a 13 F sheath was placed in the left femoral artery (LFA). Via a diagnostic Judkins right catheter (JR4) a dedicated exchange 0.014" guidewire was placed in the left ventricle. After purging the Impella pump with heparinized glucose 25% solution and a test run, the pump was positioned over the wire across the aortic valve under angiographic guidance. In this patient the correct implantation of the Impella 2.5 LP device required 20 minutes, owing to technical difficulties in advancing the catheter over the very flexible guidewire. During this stage the patient had significant femoral bleeding and became hemodynamically and electrically unstable, requiring elective intubation and inotropic support with dopamine, dobutamine and xylocaine. After initial stabilization, we confirmed the correct position of the pump and increased its function to the maximum speed of 50,000 rpm. The mean blood pressure increased from 62 mmHg to 85 mmHg. A 6 F guiding catheter (JL4) was introduced via the RFA to the LAD. The lesions of the mid and distal LAD were predilated and the distal, mid, and proximal LAD were subsequently stented with a good angiographic result.

The patient was transferred to the coronary care unit (CCU) and remained intubated with the Impella 2.5 LP device for LV support for 24 hours. The next day the device was removed and manual compression was used to achieve uneventful hemostasis.

There was a significant decrease in the hemoglobin level from 10.4 g/dl to 8.9 g/dl, necessitating blood transfusion. There was no marked cardiac enzyme elevation the day after the procedure (max CK 235 mU/ml, CKMB 5.5 ng/ml, CTNI 0.59 ng/ml) and no increase in serum creatinine levels (max value 2.0 mg/dl). The amount of non-ionic contrast used was 330 ml.

The patient was discharged four days later in stable condition and four months later he reported a great reduction of angina with only mild episodes of dyspnea.

Second case

A 53-year-old man (BSA 1.72 m²) with end-stage heart failure was admitted to our hospital for evaluation for heart transplantation. His prior medical history reported an extensive anterior myocardial infarction five years ago. That same year he underwent coronary artery bypass surgery with 2 arterial grafts: left internal mammary artery (LIMA) to the LAD, and right internal mammary artery (RIMA) to the posterior descending artery (PDA). The previous week he had had an acute coronary syndrome causing cardiogenic shock and a need for LV support with an intra-aortic balloon pump (IABP). His coronary angiogram revealed diffuse three-vessel disease, total occlusion of the LAD, RCA and RIMA, significant multiple stenoses to LCX/OM1 and a subtotal lesion in the anastomosis of LIMA to LAD, which was judged to be the culprit lesion for his recent ischemic episode. Left ventriculography showed LV enlargement, with an ejection fraction (EF) <15%.

Echocardiography showed LV dilatation, LVEF 15-20%, moderate to severe mitral regurgitation (3⁺/4) and impaired RV contractility, without thrombus formation in the LV cavity or structural complications from the recent infarction. Several tests, such as dobutamine stress echo, magnetic resonance imaging (MRI) and SPECT with reinjection, revealed viable myocardium in the anteroapical wall of the LV with preserved thickening. Because of the recent hemodynamic instability, and considering the poor prognosis (EuroSCORE logistic 55.2%), we decided to perform a high-risk elective PCI to the anastomotic lesion of LIMA to LAD through the LIMA, assisted by the Impella 2.5 LP device.

After positioning a 6 F sheath in the RFA and another 6 F in the LFA in order to document accessibility, we observed severe spasm in both femoral arteries, especially the LFA, that resolved gradually under intra-arterial infusion of nitrates. Following the intro-

duction of the 13 F sheath to the LFA, the Impella pump was implanted, passing through the peripheral atherosclerotic artery without problems. The patient was stabilized hemodynamically with a low dose of inotropic agents (dopamine, dobutamine). A 6 F guiding IMA catheter was placed into the LIMA and the anastomotic lesion to the LAD was twice predilated and subsequently stented with a quite satisfactory angiographic result.

Before and after the intervention right heart catheterization was performed to observe pressure changes due to LV unload with the Impella Recover LP 2.5 device. Mean blood pressure before pump support was 66 mmHg and increased to 77 mmHg after the procedure, with stable pump flow at 2.3 L/min. Cardiac output decreased from 2.7 L/min to 2.3 L/min, with a reduction in cardiac index from 1.5 L/min/m² to 1.32 L/min/m². Mean pulmonary wedge pressure increased from 36 mmHg to 52 mmHg.

The patient was subsequently transferred to the CCU. The Impella was taken out two hours later because of limb pain and ischemia, which immediately resolved after removal of the pump. Manual compression for about 30 minutes was used for hemostasis with no significant device-related local complications.

There was a severe decrease in hemoglobin level, from 12.3 g/dl to 10.4 g/dl, necessitating blood transfusion. There was no cardiac enzyme elevation (max CK 122 mU/ml, CKMB 0.4 ng/ml, CTNI 0.25 ng/ml) the day after the procedure, but there was a remarkable increase in serum creatinine levels (from 1.6 to 4.3 mg/dl) on the third day, due to contrast mediated nephropathy. The amount of non-ionic contrast used was 290 ml. The baseline N-terminal pro-brain natriuretic peptide (NT-proBNP) level was 4690 pg/ml and the next day it was 6186 pg/ml.

Despite the angiographic success, the patient remained severely ill and hemodynamically unstable; a week later he again needed IABP support. He refused transplantation and he was transferred to the referring hospital, where he expired one month after the intervention from worsening heart failure.

Third case

The third case concerns a 50-year-old male (BSA 1.8 m²) with congestive heart failure, who had had an acute anterior myocardial infarction 2 years previously with a low LVEF. He had recently been treated for acute pulmonary edema and was receiving levosimendan monthly. He was hypertensive and an ex-smoker. Six months

earlier, coronary angiography had indicated severe three-vessel disease with a 95% LAD stenosis, and 80% stenosis in the proximal LCX and proximal RCA. Dobutamine stress echo revealed viability in the anterior and lateral wall and scar in the inferior and posterior wall. The surgical risk score according to EuroSCORE was 25.2%. The patient was a very poor candidate for surgical revascularization and he wished to have a percutaneous revascularization procedure, so he was scheduled for elective high-risk PCI to the LAD, assisted by the Impella Recover LP 2.5 system.

Echocardiography showed LV dilatation, LV ejection fraction 30%, moderate mitral regurgitation (1-2⁺/4), without intracavitary thrombus.

The same procedure as previously reported was used for the implantation of the pump, with no difficulties in positioning and stability through the aortic valve. The proximal segment of the LAD was predilated and stented with two drug-eluting stents.

Before and after the intervention right heart catheterization and pressure measurement were performed. Mean blood pressure before pump support was 80 mmHg and increased to 109 mmHg at the end of the procedure, with a stable pump flow of 2.5 L/min. Cardiac output increased from 5.9 L/min to 6.6 L/min. Mean pulmonary artery pressure increased from 29 mmHg to 39 mmHg. Mean pulmonary wedge pressure increased from 21 mmHg to 25 mmHg. The patient remained hemodynamically stable during PCI and there was no need for further inotropic support. The Impella pump was removed 3 hours later and hemostasis was obtained with manual compression for 20 minutes.

There was a small reduction in hemoglobin level from 11.9 g/dl to 10.9 g/dl and no need for blood transfusion. There was no cardiac enzyme elevation (max CK 65 mU/ml, CKMB 0.4 ng/ml, CTNI 0.12 ng/ml) the day after the procedure, whereas a mild increase in serum creatinine levels (from baseline 1.8 mg/dl to max value 2.1 mg/dl) was seen on the third day. The amount of non-ionic contrast used was 350 ml. NT-proBNP at the end of PCI was 1332 pg/ml and three days later, the day the patient was discharged from hospital, it was 533 pg/ml.

In the scheduled follow up 4 months later the patient reported an improvement of his symptoms and no need for hospitalization or repeat inotropic support.

Discussion

All patients who were selected to undergo Impella-assisted, high-risk PCI were very poor surgical candi-

dates and provided written informed consent before the procedure. Based on their EuroSCORE, the mean predicted mortality was 39.3%. In previous studies patients had similar baseline characteristics⁹ and perioperative risk. In all patients the device was implanted before the procedure to provide support in case of sudden ischemia and hemodynamic deterioration. There was a need for pharmacologic support in 2 of our cases, allowing for less expeditious maneuvers and less patient discomfort during balloon inflations, despite their very poor LV function.

Although the device has been designed to contribute up to 2.5 L/min of cardiac output at peak performance, we observed an output increase only in the third patient, whereas the cardiac output decreased in our second patient, as previously described by Meyns et al.¹¹ Positioning the Impella can be quite demanding and may affect the efficiency of the pump, although the console gives guidance for proper repositioning when needed. The worsening of hemodynamics noted in two patients, despite the use of the Impella, was attributed to the very high-risk baseline characteristics and suggests that the procedural risk would have been prohibitive without the implementation of a left ventricular assist device.

It should be emphasized that the hemodynamic response to the Impella can be quite variable between patients, depending on their clinical status and baseline hemodynamics. As described recently, placement of the Impella pump during high risk PCI frequently results in LV volume overload and occasionally, in patients with acute hemodynamic compromise such as during the acute phase of ischemia, in a significant elevation of LV end-diastolic pressure.¹² We also observed these changes in our second and third patients. Causes of this phenomenon may include peri-cannular leak around the Impella catheter or deep placement of the device, causing turbulent vortices at the level of the aortic leaflets that prevent proper coaptation.¹²

There was an increase in mean blood pressure in all 3 patients. There was an adverse effect on filling pressures, with an increase in mean pulmonary capillary wedge pressure from 27 to 40 mmHg. Our findings indicate that, despite placement of the Impella, substantial hemodynamic compromise may occur as a result of volume overload and periprocedural ischemia. Similar results as regards hemodynamic parameters were observed by Valgimigli et al.¹² There was no significant increase in aortic regurgitation or any new onset in any case, based on pre- and post-procedural echocardiographic assessment.

Only one patient, who had peripheral arterial disease, experienced limb ischemia and reported pain after the implantation. Closure of the puncture site was performed with manual compression in all 3 patients with uneventful hemostasis.

All patients received 70 IU/kg heparin to achieve an activated clotting time >250 seconds prior to pump implantation, and also heparin via the pump's lubrication system (glucose 25%). Hemoglobin levels were assessed before and after the procedure. The first patient had a perioperative femoral bleeding complication through the 13 F sheath. The mean decrease in hemoglobin level was 1.7 g/dl and 2 of the 3 patients required red blood cell transfusion because of substantial blood loss during the procedure. We did not observe the occurrence of hemolysis in our patients. These changes are similar to the ones reported by Henriques et al.¹⁰ Mean creatinine levels increased from 1.8 to 2.8 mg/dl with a mean amount of contrast medium of 323 ml.¹⁴ Periprocedural cardiac enzyme elevation was not clinically relevant in any patient, considering the EuroSCORE estimated risk.

Levels of NT-proBNP, whose production and secretion is linked to LV wall stretch, were measured in 2 patients. There was a significant reduction in the third patient and an increase in the second patient. Interpretation of these results is limited, because it can be affected by the coronary intervention itself and by the different stage of congestive heart failure.

Although implantation of the Impella 2.5 device appears to be feasible and safe, its insertion requires more care, time, effort and well trained personnel. After placement into the LV across the aortic valve, we observed no significant complications, and only small repositioning corrections were performed. The mean duration of the LV support was 9.3 hours (range from 2 to 24 hours), similar to results reported previously.¹⁰⁻¹²

Conclusions

Our experience gives new input for future trials to assess the effect of the Impella Recover LP 2.5 assist device on outcome in this group of patients, but multicenter randomized clinical trials are needed to clearly define the role of this device in providing satisfactory circulatory support.

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