

Case Study:

Impella® 2.5L Circulatory Support during Complex PCI in a Patient with Recent Acute Systolic Heart Failure and Residual Low Ejection Fraction

Mark A Grise, MD, Tyrone J. Collins, MD, and Samir N. Patel, MD
Ochsner Heart and Vascular Institute, New Orleans, LA

Introduction

A 77 year-old obese female with diabetes mellitus, hypertension, and dyslipidemia initially presented in the catheterization laboratory at Ochsner Heart and Vascular Institute, with signs of acute systolic heart failure. On angiography, the left ventricular ejection fraction was 25%, down from 60% as measured one year prior to the admission. Diagnostic angiography identified three-vessel coronary artery disease. Cardiac enzymes were positive including a peak troponin of 15. Four hours post angiography, the patient experienced asystolic arrest and was resuscitated by advanced cardiac life support. A cardiac surgery consult determined that the patient's low ejection fraction, recent history of cardiac arrest, and other co-morbidities made her an unacceptable candidate for surgical revascularization. She was subsequently maintained on mechanical ventilation, intravenous inotropic therapy, and Intra Aortic Balloon Pump (IABP) support in Cardiac Care Unit for several days before being successfully extubated and weaned from IABP support.

After stabilizing the patient, the decision was made to proceed with a percutaneous coronary intervention (PCI) supported with the Impella Recover LP 2.5 Percutaneous Cardiac Support System.

Device Description

The Impella 2.5 microaxial blood pump is percutaneously placed in the left ventricle to provide up to 2.5 liters per minute of non-pulsatile blood flow into the aorta. The pump configuration is unique in that it is inserted through a 13 Fr sheath placed in the femoral artery and the 9 Fr catheter body is passed across the aortic valve to position the inflow port within the left ventricle, while the outflow port and axial flow pump are positioned within the ascending aorta. The catheter is attached to the Impella control console, which provides continuous output and performance data on a display panel.

High-Risk PCI Procedure

Thirteen days following her asystolic arrest, the stabilized patient returned to the catheterization laboratory for an Impella-supported high risk PCI. The Impella 2.5 was inserted percutaneously via the left femoral artery and support was started on Performance Level 7 (P-7), with axial pump output flow of 2.0 – 2.1 liters per minute.

Baseline angiography identified a high-grade lesion (Figure 1) within the proximal LAD that was predilated and subsequently stented, with an excellent angiographic result (Figure 2). Attention then turned to the right coronary artery (RCA) which was severely

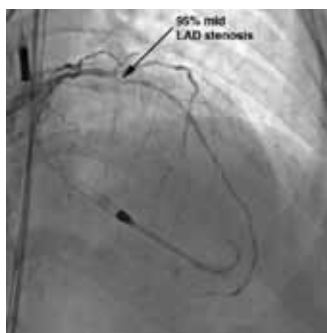


Figure 1. High-grade lesion of 95% mid-LAD stenosis



Figure 2. LAD post stent

diseased in both proximal and mid portions (Figure 3). Following placement of a 0.014" guidewire in the RCA, the patient developed complete heart block. The heart block lasted for over two minutes, during which time the Impella level was increased to Performance Level 9 with forward flows of 2.3 liters per minute.



The patient remained conscious during the episode of complete heart block. Although she had no pulsatile flow, her mean arterial blood pressure was maintained at 50 mm Hg by the Impella 2.5. With the return of sinus rhythm, atropine was administered and her heart rate and blood pressure quickly normalized. The proximal and mid RCA lesions were each subsequently stented with a drug-eluting stent (DES), without arrhythmia onset or sudden drop in blood pressure during the PCI. (Figure 4)

After completion of the PCI procedures, the patient was weaned from Impella circulatory support, the device was removed, and the access site closed with a suture-based closure device. The patient's clinical condition improved significantly over the next 24 hours and she was subsequently discharged.

Discussion

This patient with significant coronary artery disease and confounding cardiac dysfunction underwent a successful high-risk coronary intervention of the LAD coronary artery and RCA with placement of DES at each lesion. The entire procedure was performed with the support of the Impella Recover LP 2.5 system. Maintenance of near normal systemic blood pressure during the three PCI procedures kept the patient free from hemodynamic compromise and was especially important during the two-minute interval of cardiac arrest.

This case demonstrates the feasibility and ease of use of the Impella 2.5 device during high-risk complex percutaneous coronary interventions. The most striking aspect of this case was the support afforded the patient at the time of her heart block and the resulting asystole. Despite the asystolic episode, she remained completely lucid and appeared to suffer no deleterious effect from this event. On restoration of cardiac rhythm, the revascularization procedures were completed with excellent angiographic and physiologic outcomes recorded. Without the vital support provided by the Impella 2.5, the procedural outcome might have been appreciably worse.

"Impella gave me the confidence to continue with my planned intervention," said Dr. Mark Grise of the Ochsner Heart and Vascular Institute in New Orleans. "Despite the fact that this was our first case that we supported a patient with Impella, the patient remained stable and never exhibited any sign of distress. I am confident that the availability of the Impella will allow us to offer high-risk PCI to patients who would otherwise not have an acceptable treatment option. Not using Impella in high-risk patients would be like not wearing a seatbelt while riding in a car. It provides considerable safety to the procedure, especially any procedure in which complications are foreseeable due to existing complex anatomy or co-morbidities, as was the case in this procedure."

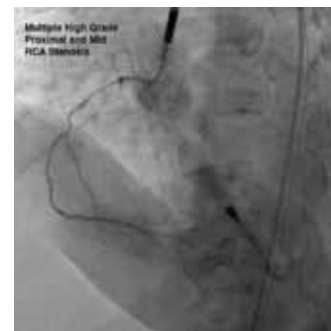


Figure 3. Multiple high-grade proximal and mid-RCA stenosis

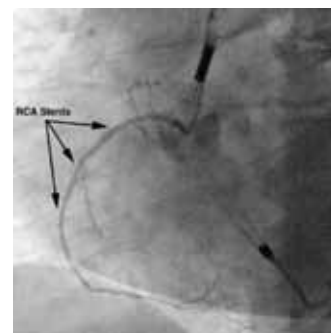


Figure 3. Post-stented RCA



Abiomed, Inc.
22 Cherry Hill Drive
Danvers, Massachusetts 01923 USA
Voice: 978-777-5410
Facsimile: 978-777-8411
Email: marketing@abiomed.com

Abiomed Europe GmbH
Neuenhofer Weg 3
52074 Aachen, Germany
Phone: +49 (241) 8860-0
Fax: +49 (241) 8860-111
Email: europe@abiomed.com

Abiomed Europe Hotline: +49 (0) 1805 ABIOMED (2246633)

ABIOMED is a trademark of Abiomed, Inc. and is registered in the U.S.A. and certain foreign countries. The ABIOMED logo and Recovering hearts. Saving lives. are trademarks of Abiomed, Inc. IMPELLA and RECOVER are trademarks of Abiomed Europe GmbH, a subsidiary of Abiomed, Inc. and are registered in the U.S.A. and certain foreign countries.

© 2008 ABIOMED, Inc. All rights reserved.