ABIOMED Case Report

Impella® Circulatory Support System

ABIOMED®
Recovering hearts. Saving lives.

Impella® 2.5 in Last Remaining Patent Vessel

Interview with William O'Neill, M.D.
William Beaumont Hospital

Introduction

A 64 year old gentleman was referred to William Beaumont hospital in May, 2006 for evaluation of cardiac transplantation. He was known to have a long history of ischemic cardiomyopathy with severely depressed left ventricular function. Three months prior to admission he was found to have an ejection fraction of 15%. His native right coronary artery, left anterior descending artery, and first obtuse marginal branch were totally occluded. The native left main and left circumflex arteries both had severe stenosis and heavy calcification. The left circumflex had minor collateral circulation to the right coronary. His saphenous vein graft (SVG) to OM1 was patent but the SVG to RCA and the native left subclavian artery, that fed the left internal mammary artery graft to the LAD and diagonal branch, were both occluded.

The patient returned to William Beaumont hospital in July with New York Heart Association (NYHA) class III heart failure. His weakened state along with chronic renal impairment, anemia, hypertension, carotid disease, and peripheral vascular disease made him a poor surgical candidate and he was admitted for an elective PCI with Impella 2.5 support.

Device Description

The Impella 2.5 is a percutaneously placed transaortic circulatory support device which provides up to 2.5 L/minute of flow from the left ventricle directly into the ascending aorta. The 12Fr. device is mounted on a 9Fr. catheter and which is connected to the Impella mobile console.

Clinical Summary

The patient was taken to the cardiac catheterization lab where the Impella 2.5 was inserted via the right femoral artery without complications. Percutaneous Coronary Intervention (PCI) was performed via the left femoral artery. The patient had a successful rotablation, Percutaneous Translumenal Coronary Angioplasty (PTCA) and stent to both the left main and left circumflex arteries. There was also rotablation and PTCA performed on the diagonal branch of the LAD. Impella support was carried on throughout the entire procedure. Gradual weaning of Impella was done over twenty minutes without incident the patient was extubated with stable hemodynamics despite prolonged left main intervention.

The patient was discharged to home three days after his procedure. Follow up examinations were performed at 30 and 90 days. He was free of symptoms and his activity level was much improved.

Discussion

This clinical case demonstrates the feasibility of a minimally invasive circulatory support device, the Impella 2.5, in a patient with severe recurrent coronary disease and impaired ventricular function. The patient's diastolic blood pressure and mean blood pressure were maintained in a normal range despite prolonged inflations during balloon and stent deployment. Avoidance of crossing into the so called "Ischemic Threshold" implies avoiding the cascade of prolonged ischemia and hemodynamic compromise. This intervention has now allowed 26 months of minimal symptoms and greatly enhanced activity without the cardiac transplantation for which he was originally referred.

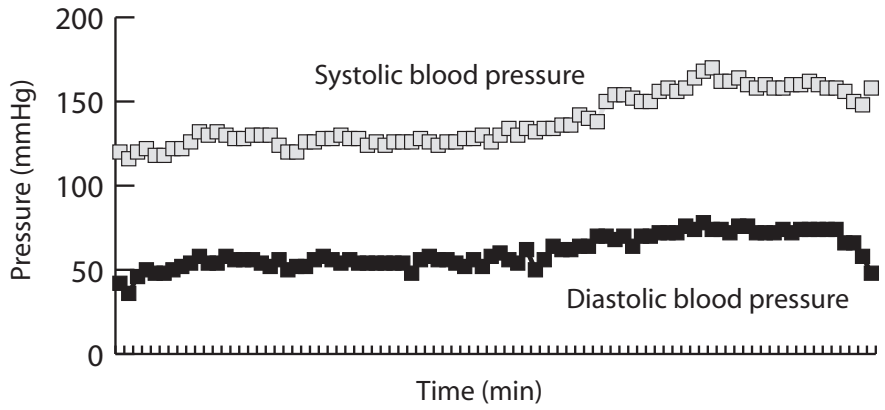
Patient Data	
Device Use	Impella 2.5
Indication	Hemodynamic support during High Risk PCI
Gender	Male
Weight	87.4 kg
Height	180 cm
BSA	2.09
Age	64
New York Heart Association (NYHA)	Class III heart failure

Cath Lab Findings	
Right Coronary Artery	100% occluded
Left Coronary Artery	Sub totally occluded
Left Anterior Descending and Circumflex Arteries	LAD 100% occluded Severe proximal stenosis in the circumflex that gave off signifying heavily calcified distal branches w/ right angle bend in its mid portion
Bypass Grafts	The patent graft to the obtuse marginal with no distal disease

Intervention	
Diagonal	MRA 1.5 Burr, Balloon
Distal Left Main and proximal Circumflex	MRA 1.77 Burr, Balloon, Stent

Hemodynamics	Pre	30 days post discharge
EF %	15%	20 – 25%
AOP	117/93	142/76
CVP	9	N/A

Maintenance of diastolic Blood Pressure throughout procedure



Impella Support	
Impella support duration	90 minutes
Average flow	2.2 LPM

ABIOMED®
Recovering hearts. Saving lives.™

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)

HCS-P105-0208-1
October 2008