

Case Study: Bi-VAD AB5000 for AMI Cardio- genic Shock Recovery

Patient Data

Indication for Use: AMI Cardiogenic Shock
Type of Support: Bi-VAD AB5000™ Ventricles
Age: 77 **Sex:** Female
Weight: 68 kg **Height:** 5'3" **BSA:** 1.70 m²
Blood type: O Negative

Surgical Data

Surgical Procedure: OPCAB x 3
AB5000 Bi-VAD Implant
CPB time: 73 minutes
Cross Clamp time: 0 minutes
Cannulation:
LVAD: 32 Fr. Intra-atrial groove
10 mm Hemashield™ graft to aorta
RVAD: 32 Fr. Mid-free wall
10 mm Hemashield graft to pulmonary artery

Patient Hemodynamics

	Pre-Implant	On-Support	Explant (PO Day #7)
CI:	1.4	2.6	2.4
EF:	<10%	—	>40%
SBP:	90	120	115
CVP:	18	13	10

Organ Function:

Liver: Total bilirubin >6.0 for 3 days before normalizing
Renal: Creatinine level increased to 3.6 before normalizing
Pulmonary: Extubated during support

Inotropic and Drug Support

Pre-implant: Levophed®, Vasopressin® and Dopamine
On-support: No inotropic support
Post-support: Milrinone
Other drug support: Amiodarone and Flolan®
IABP reinserted for 24 hours.

Anticoagulation

Blood products received in OR: 4 units of packed red blood cells (PRBC), 8 units of platelets, 20 units of cryoprecipitate

Anticoagulation post-op: Argatroban was started 24 hours after implant of AB5000 Ventricles. Activated Partial Thromboplastin Time (aPTT) remained between 70-90 seconds.

Implanting and Explanting Surgeon:

Dr. Louis Samuels, Lankenau Hospital, Wynnewood, PA

Clinical Consultant:

Maggie Flynn

History

On January 15, 2006, Rosemary Donaghue, a 77 year old mother and grandmother was admitted to Paoli Hospital with chest pain and shortness of breath.

A cardiac catheterization the next day showed three vessel disease with moderate to severe left ventricular dysfunction. Ms. Donahue was ruled-in for an inferior wall myocardial infarction (MI). She was transferred to Lankenau Hospital for a high risk coronary artery bypass graft (CABG) under the care of Dr. Goldman and Dr. Samuels.

Operative Summary

After successful transfer to Lankenau Hospital, Dr. Goldman performed an off-pump coronary artery bypass grafting (OPCABG) x 3 on January 18, 2006.

The patient was transferred to the cardiovascular intensive care unit (CVICU) in stable condition. Patient continued to do well and was soon extubated and out of bed (OOB).

On Post-operative (PO) Day#2, the patient became confused due to hypotension. Levophed and Milrinone were started with hemodynamic status remaining marginal. Her cardiac index (CI) was below 1.4 L/minute/m², urine output decreased, transesophageal echo (TEE) showed significant biventricular dysfunction. Dr. Louis Samuels was consulted and the patient was transferred to the operating room (OR) on intra-aortic balloon pump (IABP) and inotropic support for insertion of the Abiomed AB5000 Ventricular Assist Device (VAD).

The patient was placed emergently on cardiopulmonary bypass (CPB) for VAD implant. The bypass grafts were open. A 32 French atrial cannula was placed via the intra-atrial groove with the 10mm Hemashield® arterial cannula end-to-side anastomosed to the ascending aorta for left VAD support (LVAD). The right side was supported with a 32 French atrial cannula inserted into the free wall of the right atrium with the 10 mm Hemashield arterial cannula attached to the pulmonary artery (PA).

Total CPB time was 73 minutes with a cross clamp time of 0 minutes. The patient's hemodynamic status was restored with bi-ventricular flows at 4.5 L/minute. The patient was transferred back to the CVICU.

For additional information, please refer to the Instructions for Use (IFU) found at www.abiomed.com/products/ifus.cfm.



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Post-Operative Summary Continued

Post-Operative (PO) Day #1

The patient was admitted to the CVICU on Bi-VAD AB5000™ ventricle support. She was hemodynamically stable with good flows.

PO Day #2:

The patient remained stable with no evidence of bleeding from her chest tubes. Systolic blood pressure (SBP) was 115 and pulmonary artery pressures (PAP) decreased. Inotropic support was weaned and discontinued. IABP was removed. The patient was awake and following commands.

PO Day #8:

The patient was successfully extubated. She remained hemodynamically stable. Acute end-organ failure was improving. Flows were stable at 4.5 L/minute.

PO Day #10:

The patient was taken back to the OR after a TEE confirmed myocardial recovery. The AB5000 Ventricles were successfully explanted without any problems.

Ms. Donahue is now back home with her family and back in her garden. She is leading an active and productive life enjoying her children and grandchildren.

"This lovely lady was very fortunate to have benefited from Abiomed's technology—without it, she would have surely died," says Dr. Louis Samuels.



Mrs. Donahue at home in her garden.