

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: 54 **Sex:** Male
Weight: 97.4 kg **BSA:** 2.12 m²

Surgical Data

Surgical Procedures: AB5000 Bi-VAD Implant, PFO closure, LVAD explanted, RVAD-assisted CABG x 1 LIMA to LAD, RVAD explanted

IABP prior to support: Yes

Cannulation:

LVAD: 32 Fr. to left ventricular apex
10 mm Hemashield™ graft to aorta
RVAD: 42 Fr. to mid-free wall
10 mm Hemashield graft to pulmonary artery

Patient Hemodynamics

| | Pre-Implant | On-Support | Explant (PO Day #20) |
|-----|-------------|------------|----------------------|
| CI: | <2.0 | 2.3 | 2.2 |
| EF: | 25% | — | 45-50% |

Organ Function:

Liver: Bilirubin, ALT: normal

Renal: Creatinine normal

Pulmonary: Pulmonary edema, nitric oxide used

Extubated on support: No

Inotropic and Drug Support

Pre-implant: Dobutamine @ 4 mcg/kg/min
Dopamine @ 6 mcg/kg/min

On-support: Milrinone @ .375 mcg/kg/min
Dopamine @ 3 mcg/kg/min

Anticoagulation Post Op

Full anticoagulation per cardio-pulmonary bypass (CPB) protocol, followed by full reversal with protamine. Heparin therapy started within 24 hours with PTTs maintained between 60-80 seconds.

Aprotinin used in OR

Blood products in OR: 1 unit packed red blood cells (PRBCs)

Tamponade x 1

No major bleeding issues

Implanting Surgeons:

Dr. Michael Argenziano

Dr. Yoshifumi Naka

Dr. Allan Stewart

Columbia University at New York Presbyterian, NY

Clinical Consultant:

Erin Marie McAuliffe

History

Phil Stauffer, a 54-year-old male, husband and father of two, was admitted to a community hospital for complaints of severe chest pain. The patient had an inferior and posterior-lateral wall infarction with a suspected diagnosis of triple vessel disease. A cardiac catheterization was performed with a stent placed in the Left Anterior Descending (LAD) Artery. The patient suffered a cardiac arrest x 2 during the procedure, but was resuscitated and subsequently stabilized with high-dose inotropic and intra-aortic balloon pump (IABP) support. Patient was transferred to Columbia University at New York Presbyterian Hospital.

The patient remained in the Coronary Care Unit (CCU) for the next 48 hours. A Transesophageal echo (TEE) was performed and showed left and right ventricular akinesis. A decision was made to take the patient to surgery for the placement of bi-ventricular AB5000™ support.

Operative Summary

The patient was taken to the Operating Room (OR) by Dr. Argenziano and Dr. Stewart and placed on bi-ventricular support. A 36 French malleable cannula was implanted in the apex of the left ventricle and a 10 mm Hemashield® graft was end-to-side anastomosed to the ascending aorta. A 42 French lighthouse tip cannula was placed in the mid free wall of the right atrium with a 10 mm Hemashield graft sewn to the pulmonary artery. Closure of a Patent Foramen Ovale (PFO) was also performed at this time. A TEE was used to confirm cannula placement and initial AB5000 flows were between 4.5 and 5.0 L/min on both sides, with total bypass time of 147 minutes. Closure of a Patent Foramen Ovale (PFO) was also performed at this time. There was minimal inotropic support required after implant.

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

Post-Operative (PO) Day #1

Patient was stabilized in the Intensive Care Unit (ICU) with bilateral flows between 4.6-5.3. Anticoagulation was started 24 hours post-operatively (PO) with porcine heparin. A heparin drip was started to keep the activated partial thromboplastin time (aPTT) between 60–80 seconds; a heparin bolus was not given.

PO Day #5

The patient's chest was re-explored due to a tamponade and a large clot was evacuated. A TEE was performed to evaluate left ventricular wall movement with some evidence of recovery. Low-dose inotropic support was initiated in anticipation of left ventricular assist device (LVAD) explant.

PO Day #6

Patient was taken to the OR for LVAD explant. A TEE showed recovery on the left side, but the right side remained hypokinetic. A decision was made to explant the left side only and give the right ventricle more time to recover. The LVAD was successfully explanted by Dr. Naka. The patient was placed on nitric oxide and diuresed over the next 14 days in an effort to assist with right-side recovery.

PO Day #14

The patient's right ventricular assist device (RVAD) flows were reduced to initiate the weaning process in order to evaluate recovery.

PO Day #20

The patient returned to the OR for explant of the RVAD AB5000 Ventricle and a decision was made at this point to perform a VAD-assisted Coronary Artery Bypass graft (CABG) x 1 with the Left Internal Mammary artery grafted to the Left Anterior Descending (LIMA to LAD) coronary artery off-bypass. The patient's flows were weaned with good hemodynamics and the RVAD was successfully explanted with a cardiac index (CI) of 2.2 and an ejection fraction (EF) of 45-50%.

PO Day #27

The patient was transferred to the Step Down Unit where he received physical therapy for muscle strengthening. After cardiac rehabilitation, he was discharged home to his loving family.



The Stauffer Family

"I am very grateful for ABIOMED and their device. It gave me a second chance of life with my family. I wish everyone could be as lucky,"
Phil Stauffer