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The RECOVER RIGHT™ trial: Use of the Impella RP percutaneous right ventricular assist device: An Hde study

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Background: Right Ventricular (RV) failure is a potentially lethal condition in medical and surgical patients with mortality > 50% in the most severe cases. Until now, medical and surgical management included inotropic support and extracorporeal mechanical circulatory assist devices. The RECOVER RIGHT™ trial was designed to investigate the role of a percutaneous RVAD in a subset of patients.

Methods: The RECOVER RIGHT™ is an FDA approved prospective, multicenter, single arm study that evaluates the safety and probable benefit of the Impella RP™ in patients with RVF refractory to medical treatment and deemed to require hemodynamic support. Two cohorts of patients were analyzed: Cohort A: Post Implantation from a durable LVAD and Cohort B: Post Cardiotomy or Post-MI Shock. Implantation inclusion criteria were as follows: Cardiac Index (CI) < 2.2 L/min/m2 despite one (or more) high dose inotrope and CVP > 15 mmHg or significant RV dysfunction on echocardiography. The primary endpoint was survival at 30 days or hospital discharge or next therapy. Secondary endpoints included hemodynamic improvement and decreased use of inotropes.

Results: 175 Patients were screened for eligibility and 30 patients were enrolled: Cohort A=18 pts, Cohort B=12 pts. The mean age was 59 years with 23 (77%) male gender. Successful implantation was achieved in 29 of the 30 cases (97%). The average duration of support was 1.5 days; the average flow was 3.2 L/min. Overall, 22 of 30 patients survived (73%). The survival of Cohorts A and B were 83% and 58% respectively. CI index improved in all cases while on support and following support; CVP decreased in all cases while on support and following support. Major Adverse Events were as follows: Pulmonary Embolism=0, Limb Ischemia=1 (3.3%), Neurologic event=1 (3.3%), Tricuspid and Pulmonic Valve dysfunction=1 (3.3%), Hemolysis=4 (13%), and Bleeding=18 (60%).

Conclusions: The RECOVER RIGHT™ is the first percutaneous RVAD FDA study. The use of the Impella RP device was:

- Reliably deliverable and safe
- Improved the hemodynamics
- Led to favorable outcomes

The Impella RP may play a pivotal role in the treatment of RVF.

Biography

Louis Samuels graduated Medical School from Hahnemann University (Philadelphia, PA) in 1987 and completed his Cardiothoracic Surgical training in 1995. He joined the faculty of Drexel University as the Surgical Director of Cardiac Transplantation. In 2001, Dr. Samuels and his team implanted the world's 5th totally implantable electric artificial heart (AbioCor™). In 2003, he joined the Main Line Health System as the Surgical Director of Heart Failure. In addition to cardiac transplantation and LVAD implantation, Dr. Samuels performs CABG and Valvular surgery. In 2012, Dr. Samuels became Professor of Surgery at Thomas Jefferson University School of Medicine. Dr. Samuels has authored over 100 peer reviewed manuscripts and serves as a reviewer for the Annals of Thoracic Surgery. In addition to participating in several clinical trials related to mechanical circulatory support, he continues to serve as a consultant and medical advisor to new technologies currently in trial.

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