Two Large Studies Demonstrate Complete Revascularization with Impella Heart Pumps Improves Ejection Fraction and Long-Term Patient Outcomes

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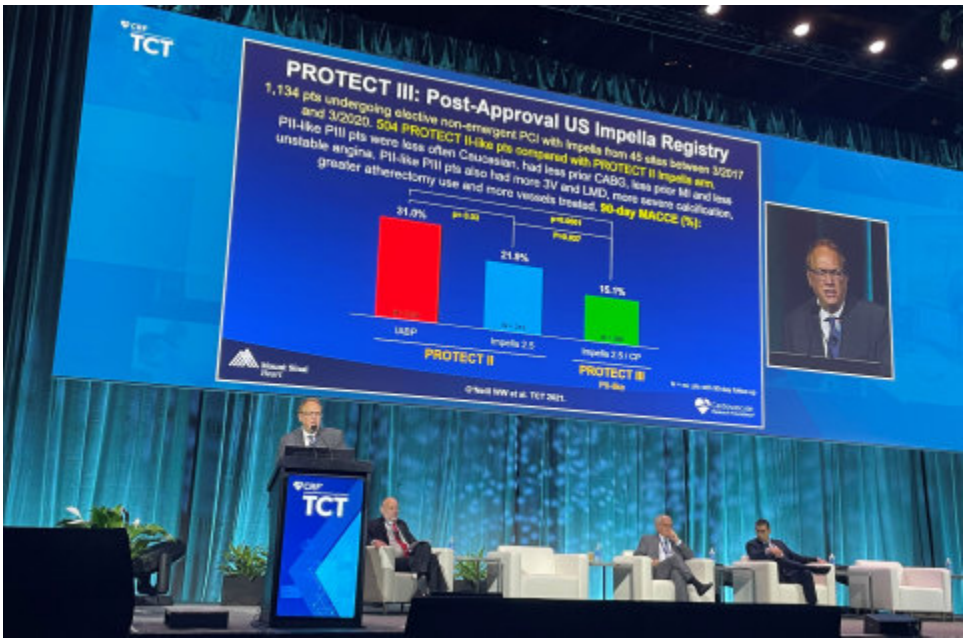
ORLANDO, Fla.--(BUSINESS WIRE)--Nov. 4, 2021-- The final results of the PROTECT III and Restore EF prospective studies demonstrate improved outcomes for high-risk PCI patients with the use of Impella heart pumps. The study results were reviewed this morning at Transcatheter Cardiovascular Therapeutics (TCT) 2021, the annual scientific symposium of the Cardiovascular Research Foundation, by Gregg Stone, MD, director of academic affairs for the Mount Sinai Health System in New York City. The presentation is available to watch on-demand at www.heartrecovery.com/tct-2021.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20211104005652/en/



Gregg Stone, MD, reviews the final results of the PROTECT III study in the Clinical Science Theater at TCT 2021 (Photo: Business Wire)

"The contemporary data from these two prospective studies provide evidence that the adoption of Impella best practices is improving safety and reducing MACCE in the high-risk PCI patient population," said Dr. Stone. "These best practices are being examined in a broader patient population as part of the ongoing PROTECT IV Randomized Controlled Trial of Impella in high-risk PCI, which hypothesizes that by providing hemodynamic stability during high-risk PCI, Impella will facilitate more optimal stent implantation and complete revascularization, and that will translate into improved early and late patient outcomes."

PROTECT III Final Results

The PROTECT III prospective study demonstrates improvement in 90-day clinical outcomes, completeness of revascularization, and safety, when compared to the PROTECT II Randomized Controlled Trial (RCT). The PROTECT II RCT found, when compared to intra-aortic balloon pump (IABP), Impella use led to a 29% relative risk reduction in MACCE at 90 days.

Study authors analyzed patients in PROTECT III who would have qualified for PROTECT II, known as "PII-like" patients, and compared them to PROTECT II patients. PROTECT III patients had improved 90-day MACCE rates, compared to PROTECT II patients (15.1% vs. 21.9%, p=0.037). This is a relative risk reduction of 31%. (*see figure 1*)

The study authors also note that PROTECT III patients, when compared to patients in PROTECT II:

- Were more complex, with more severe calcification, more rotational atherectomy and more vessels treated.
- Had more complete revascularization, with 78% less hypotension during support (2.2% vs. 10.2%, p=0.0004).
- Had improved in-hospital safety, with significantly fewer bleeding complications requiring transfusion (1.2% vs. 9.4%, p<0.001).

Restore EF Final Results

The Restore EF prospective study demonstrates the use of contemporary best practices with Impella in high-risk PCI significantly improves left ventricular ejection fraction (LVEF), heart failure symptoms, and anginal symptoms at 90-day follow-up in a wide variety of hospital settings including rural, urban, community and academic centers.

The study of 251 patients at 26 hospitals showed:

- Significant improvement in LVEF from baseline to 90-day follow-up (35% to 45% p<0.0001). LVEF improvement at 90 days is the study's primary endpoint. Restore EF is the latest study in a growing body of evidence demonstrating LVEF improvement with Impella-supported high-risk PCI. (*see figure 2*)
- Significant reduction of heart failure symptoms with 76% reduction in New York Heart Association (NYHA) classification III/IV at follow-up (62% to 15% p<0.001). (*see figure 3*)
- Significant reduction of anginal symptoms with 97% reduction in Canadian Cardiovascular Society (CCS) classification III/IV at follow-up (72% to 2% p<0.0001). (*see figure 3*)

Advancement in Technology and Best Practices

Since PROTECT II, Impella-supported high-risk PCI has evolved to include the more powerful Impella CP with SmartAssist heart pump, which was used in about two-thirds of the patients in the Restore EF and PROTECT III studies.

"Advancement in technology, along with best practice learnings and operator experience has led to improvements in patient outcomes in contemporary practice," said Jeff Moses, MD, the lead investigator of the PROTECT III study, director of interventional cardiovascular therapeutics and professor of medicine at Columbia University Medical Center in New York City, and director of advanced cardiac interventions at St. Francis Hospital and Heart Center in Roslyn, NY. "These two studies expand upon prior research and demonstrate a clinical benefit in today's broader patient population."

The PROTECT series of studies and the Restore EF study are sponsored by Abiomed (NASDAQ: ABMD) as part of its commitment to improving clinical outcomes.

ABOUT IMPELLA HEART PUMPS

The Impella 2.5® and Impella CP® devices are U.S. FDA approved to treat certain advanced heart failure patients undergoing elective and urgent percutaneous coronary interventions (PCI), such as stenting or balloon angioplasty, to reopen blocked coronary arteries.

The Impella 2.5, Impella CP, Impella CP with SmartAssist®, Impella 5.0®, Impella LD®, and Impella 5.5® with SmartAssist® are U.S. FDA approved to treat heart attack or cardiomyopathy patients in cardiogenic shock and have the unique ability to enable native heart recovery, allowing patients to return home with their own heart.

ABOUT ABIOMED

Based in Danvers, Massachusetts, USA, Abiomed, Inc. is a leading provider of medical devices that provide circulatory support and oxygenation. Our products are designed to enable the heart to rest by improving blood flow and/or provide sufficient oxygenation to those in respiratory failure. For additional information, please visit: www.abiomed.com.

FORWARD-LOOKING STATEMENTS

Any forward-looking statements are subject to risks and uncertainties such as those described in Abiomed's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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