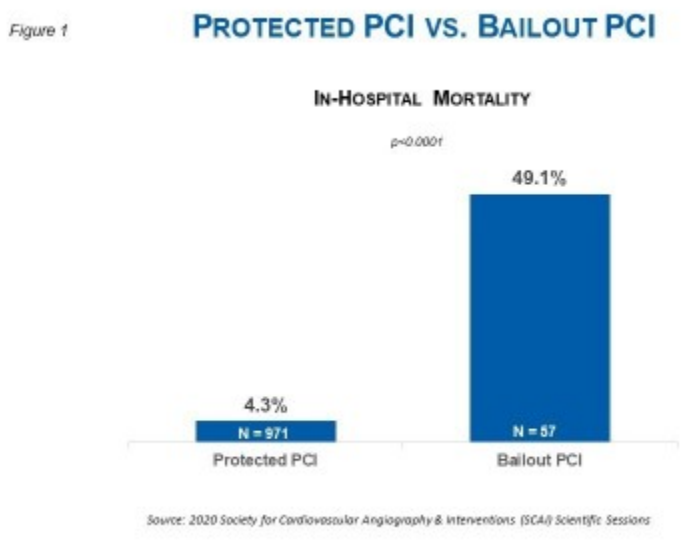
PROTECT III Study Shows Placing Impella Prior to High-Risk PCI is Associated with Lower Mortality Compared to Bailout PCI

May 19, 2020

Women Disproportionately Impacted with Bailout

DANVERS, Mass.--(BUSINESS WIRE)--May 19, 2020-- Data from more than 1,000 patients presented during the virtual 2020 Society for Cardiovascular Angiography & Interventions (SCAI) Scientific Sessions demonstrates Impella reduced in-hospital mortality when placed before a non-emergent percutaneous coronary intervention (PCI) is performed. As detailed in the online presentation, the research found, in the setting of high-risk PCI, when Impella is placed pre-PCI, it is associated with a ten times reduction of in-hospital mortality, compared to when Impella is placed during bailout PCI (see figure 1). Bailout PCI is defined as when a physician starts an elective or urgent PCI without planning to use Impella support, then initiates Impella support during the procedure when the patient becomes hemodynamically unstable.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200519005627/en/



(Graphic: Business Wire)

The data presented is from an adjunct study of PROTECT III, the ongoing, prospective FDA post-approval study for Impella in high-risk PCI. The research is authored by William O'Neill, MD, medical director of the Center for Structural Heart Disease at Henry Ford Hospital and Jeffrey W. Moses, MD, director of interventional cardiovascular therapeutics and professor of medicine at Columbia University Medical Center.

The study's authors write, "Support with Impella in hemodynamically stable patients undergoing non-emergent PCI, also termed Protected PCI, is now a well-established indication in a selective patient population at high risk for hemodynamic collapse during PCI. However some physicians may eschew preventive hemodynamic support and prefer a bailout strategy should hemodynamic collapse occur." The study aimed to quantify the risk of such a bailout strategy.

The study analyzed 1,028 patients supported with Impella 2.5 or Impella CP (971 in Protected PCI group and 57 in bailout group). In the bailout group, females were more prevalent (50.9% vs. 27.2%, p=0.0002), the median baseline left ventricular ejection fraction was significantly higher (40% vs 30%, p<0.0001), heart failure was less prevalent (42.1% vs 56.9%, p=0.039), and left main disease was less prevalent (40.0% vs 56.1%, p=0.03). In summary, the bailout group had a higher percentage of women, the patients were younger, and had a higher ejection fraction with less heart failure. Despite these differences the study found:

- In-hospital mortality was significantly higher in the bailout group compared to the Protected PCI group, respectively (49.1% vs. 4.3%, p<0.0001). The difference in mortality was significant across patients experiencing hemodynamic collapse secondary to refractory hypotension or coronary perforation/dissection.

"Failure to prospectively identify patients who may experience hemodynamic collapse during non-emergent PCI leads to excessive in-hospital mortality. This data shows that Impella support prior to initiation of the PCI can reduce this risk," said Dr. O'Neill.

"Many of these patients requiring bailout Impella are younger women with healthier ejection fractions, so they are often overlooked for mechanical support," said Cindy Grines, MD, chief scientific officer of Northside Hospital Cardiovascular Institute in Atlanta. "However, these women may not tolerate prolonged ischemia during PCI. These data show that we need to recognize women as a vulnerable population and consider support in advance."

The use of Impella can also allow for a high-risk patient to receive a more complete revascularization, as detailed in the 2020 SCAI Position Statement on Optimal Percutaneous Coronary Interventional Therapy for Complex Coronary Artery Disease. The SCAI guidelines, which published on Thursday, note, "Observational studies demonstrate improved procedural cardiovascular hemodynamics and more complete revascularization in the presence of MCS (mechanical circulatory support) devices despite higher-risk patient profiles."

ABOUT IMPELLA HEART PUMPS

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

Impella CP, Impella CP with SmartAssist®, Impella 5.0®, Impella LD®, and Impella 5.5™ with Smart Assist® are U.S. FDA approved heart pumps used 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. The Impella RP® is U.S. FDA approved to treat right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. Impella is the most studied mechanical circulatory support device in the history of the FDA with more than 10 years of FDA studies, real world clinical data on more than 140,000 patients and more than 650 peer-reviewed publications.

In Europe, the Impella 2.5, Impella CP and Impella CP with SmartAssist are CE marked for treatment of high-risk PCI and AMI cardiogenic shock patients for up to 5 days. Impella 5.0 and Impella LD are CE marked to treat heart attack or cardiomyopathy patients in cardiogenic shock for up to 10 days. The Impella 5.5™ with Smart Assist® is CE marked to treat heart attack or cardiomyopathy patients in cardiogenic shock for up to 30 days. The Impella RP is CE marked to treat right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, open-heart surgery, or refractory ventricular arrhythmia.

To learn more about the Impella platform of heart pumps, including their approved indications and important safety and risk information associated with the use of the devices, please visit www.impella.com.

ABOUT ABIOMED

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

FORWARD-LOOKING STATEMENTS

This release contains forward-looking statements, including statements regarding development of Abiomed's existing and new products, the company's progress toward commercial growth, and future opportunities and expected regulatory approvals. The company's actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including uncertainties associated with the scope, scale and duration of the impact of the COVID-19 pandemic, development, testing and related regulatory approvals, including the potential for future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, technological change, government regulation, litigation matters, future capital needs and uncertainty of additional financing, and other risks and challenges detailed in the company's filings with the Securities and Exchange Commission, including the most recently filed Annual Report on Form 10-K and the filings subsequently filed with or furnished to the SEC. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. The company undertakes no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200519005627/en/

****For further information please contact:**
Tom Langford
Director of Communication
978-882-8408
tlangford@abiomed.com

Source: Abiomed, Inc.