For Immediate Release
March 4, 2020

Study of 21,848 High-Risk PCI Patients Demonstrates Lower Risk of Death and Complications in Patients who Receive PVADs (Impella)

Danvers, Mass., March 4, 2020 – A study of 21,848 non-emergent, high-risk patients who underwent percutaneous coronary intervention (PCI) with percutaneous ventricular assist devices (PVADs), including Impella, demonstrates the PVAD patients had a lower rate of mortality and complications than patients who underwent PCI with intra-aortic balloon pumps (IABPs). The study, by Al-khadra, et al., published in the February 15, 2020 print edition of *Catheterization & Cardiovascular Interventions*.

In the analysis, the PVAD cohort was significantly sicker than the IABP cohort. PVAD patients were older and had higher rates of hypertension, diabetes, hyperlipidemia, prior PCI, prior coronary artery bypass graft surgery, anemia, chronic lung disease, liver disease, renal failure, and peripheral vascular disease.

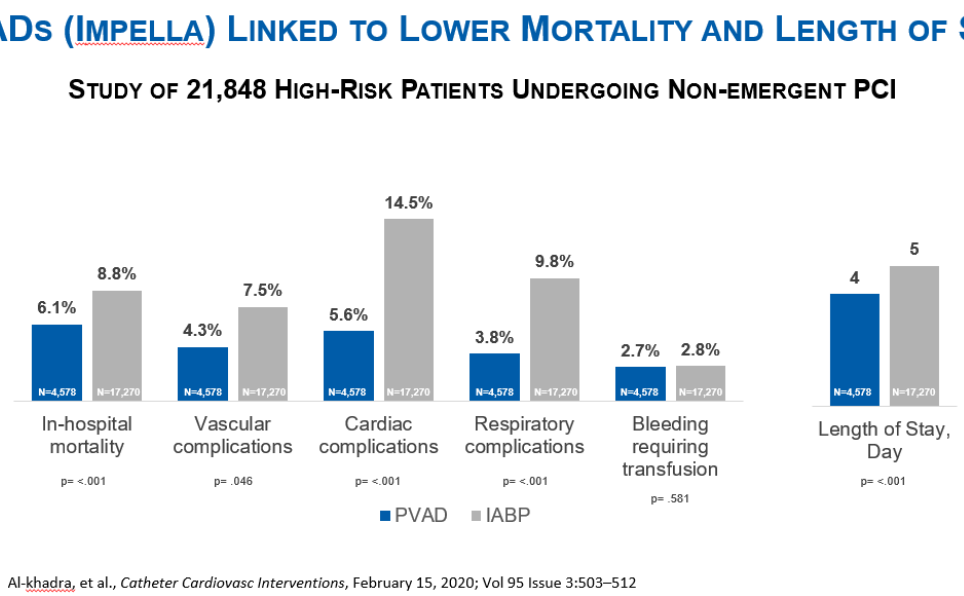
As detailed in figure 1, despite the higher rates of comorbidities, when investigators used multivariate logistic regression (n=21,848) they determined, compared to the IABP patients, PVAD patients were associated with:

- Lower in-hospital mortality (6.1% vs. 8.8%, p= <.001)
- Lower vascular complications (4.3% vs. 7.5%, p= .046)
- Lower cardiac complications (5.6% vs. 14.5%, p= <.001)
- Lower respiratory complications (3.8% vs. 9.8%, p= <.001)
- A similar rate of bleeding to IABP patients (2.7% vs. 2.8%, p= .581)

Furthermore, propensity score matching (n=1,926) demonstrated that, compared to the IABP patients, PVAD patients had:

- Lower in-hospital mortality (3.5% vs. 6.4%, p= <.012)
- Lower vascular complications (3.4% vs. 6.0%, p= .017)
- Lower cardiac complications (3.4% vs. 12.2%, p= <.001)
- Lower respiratory complications (2.6% vs. 6.1%, p= .001)
- A similar rate of bleeding to IABP patients (2.6% vs. 2.4%, p= .795)

Figure 1



Al-khadra, et al., *Catheter Cardiovasc Interventions*, February 15, 2020; Vol 95 Issue 3:503–512

Investigators obtained their data from the National Inpatient Sampling (NIS) database, the largest all-payer inpatient care database in the United States. NIS is developed through a partnership with the Agency for Healthcare Research and Quality (AHRQ) and contains data on approximately eight million Medicare and private payer hospital stays. The authors disclosed and described in detail the methods for the study population, patient and hospital characteristics and statistical analysis, including linear regression models and propensity score matching.

The study found PVADs, such as the Impella heart pump, had lower rates of mortality and lower rates of complications than the intra-aortic balloon pump.

"This analysis is another example of real-world data demonstrating improved outcomes for patients and reduced length of stay when PVADs are used," said Perwaiz Meraj, MD, one of the study's authors and director of interventional cardiology at Zucker School of Medicine at Hofstra/Northwell, Northwell Health in Manhasset, NY. "The use of best practices, techniques and technologies can enable safer, more complete revascularization that improves patient outcomes and quality of life."

The Al-khadra, et al. publication also noted that PVAD patients had a shorter length of stay than IABP patients (4 days vs. 5 days p= <.001). This finding is consistent with the PROTECT II randomized controlled trial (see figure 2) and multiple other peer-reviewed studies, including the Maini, et al. publication in *Expert Review of Pharmacoeconomics & Outcomes Research*. Maini et al. appraises the findings and conclusions of six publications and found PVADs, specifically

Impella 2.5, are associated with reduced hospital length of stay and are cost-effective when compared with IABP.

“High-risk PCI patients often pose a challenge to the interventionalist due to patient comorbidities which drive worse outcomes,” said Cindy Grines, MD, a study author and an interventional cardiologist and chief scientific officer at Northside Hospital Cardiovascular Institute in Atlanta. “This publication demonstrates the rationale for PVAD use during high-risk PCI. Left ventricular support maintains coronary perfusion during periods of transient hypotension during long or repeated inflations necessary to achieve complete revascularization.”

The Al-khadra et al. study was conducted independently by physician-investigators and not funded or reviewed by Abiomed. Study sites are Cleveland Clinic, Detroit Medical Center, Beth Israel Deaconess Medical Center/ Harvard Medical School, MedStar Washington Hospital Center, St. John Hospital and Medical Center, Emory University, Zucker School of Medicine at Hofstra Northwell Health, Henry Ford Health System, Keele University and Royal Stoke University Hospital.

The Impella heart pump is manufactured by Abiomed (NASDAQ: ABMD) and is the most studied mechanical circulatory support device in the history of the FDA with more than 14 years of FDA studies, real world clinical data on more than 140,000 patients, and more than 650 peer-reviewed publications.

Figure 2

PROTECT II FDA RCT 90 Day Safety Endpoints

	IABP (n=210)	Impella 2.5® (n=215)	p-value
Stroke	2.4%	0.9%	0.24
Vascular Complications[1]	1.9%	1.4%	0.68
Aortic Valve Damage	0%	0%	NA
Acute Renal Dysfunction	4.8%	4.2%	0.77
Volume of Contrast Administered	241ml	267ml	0.04

Source: O'Neill WW et al. Circulation. 2012 Oct 2:126(14):1717-27

1. Vascular complications from PROTECT II RCT = Cardiac, thoracic, or abdominal operation, or vascular operation for limb ischemia

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 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 Quarterly Report on Form 10-Q. 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.

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