

PRODUCT UPDATE

February 2019



For Best Outcomes in AMI Cardiogenic Shock, Place Impella 2.5® or Impella CP® Pre-PCI

What's New?

A preponderance of evidence from the FDA cVAD Study, Impella Quality Assurance Database and physician-initiated National Cardiogenic Shock Initiative support the recommendation that placing Impella 2.5 or Impella CP pre-PCI improves outcomes.

Physicians are strongly encouraged to place Impella 2.5 or Impella CP prior to performing a PCI on patients in cardiogenic shock.

Background

A critical mass of scientific research from five studies demonstrates that early implantation of Impella® leads to the best outcomes. The real-world data is summarized in *figure 1*.

Placing Impella prior to revascularization is a best practice identified through analyses of data in the IQ Database, validated in the cVAD study, and further validated by investigators leading the National Cardiogenic Shock Initiative.

Placement of Impella pre-PCI may allow for:

- Reperfusion of end organs prior to revascularization
- Hemodynamic support to the heart during revascularization
- The halting of progression of cardiogenic shock

Placement of Impella pre-PCI is included in multiple clinical protocols that demonstrate survival benefits, including the National Cardiogenic Shock Initiative, which demonstrates that when best practices are followed, including placement of Impella pre-PCI, cardiogenic shock survival increases from ~50% to 77%.

Summary

Physicians are strongly advised to place Impella 2.5 or Impella CP prior to revascularization.

See back for figures

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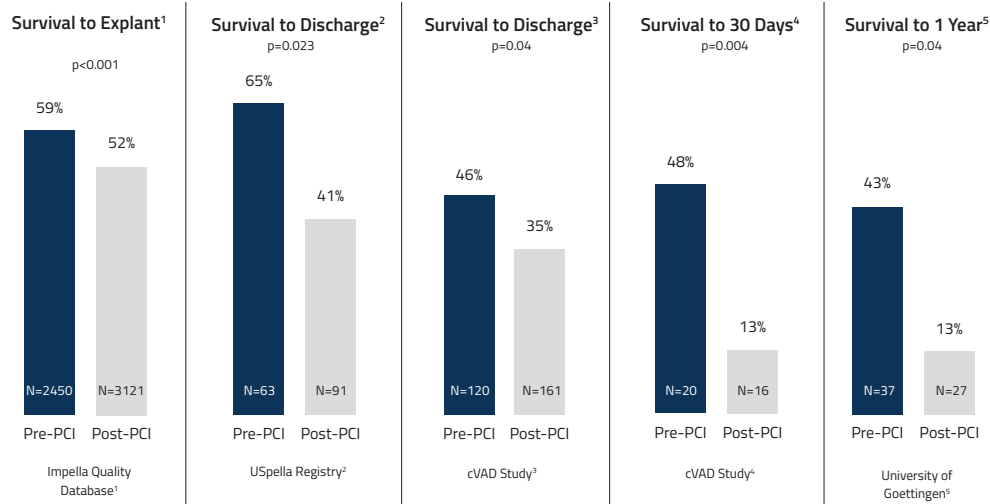


Figure 1: Unloading Pre-PCI Associated with Improved AMI-CGS Outcomes¹⁻⁵

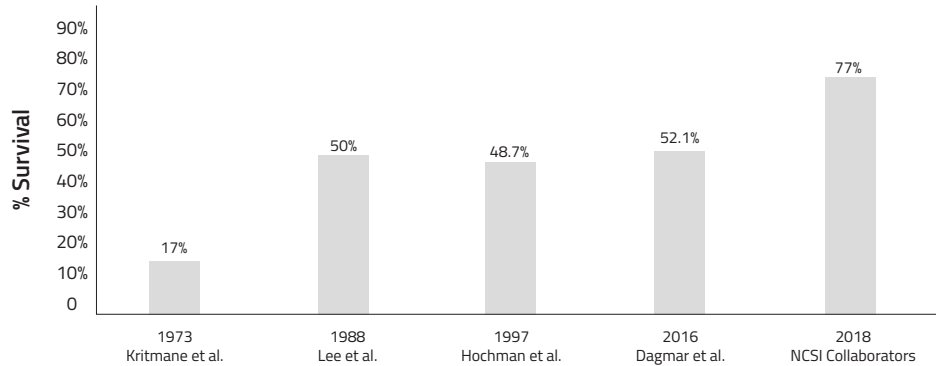


Figure 2: Historical Advancements in the Treatment of Cardiogenic Shock⁶

Variable	Estimate	Standard Error	Pr > Chi-Square	Odds Ratio Estimate	Lower 95% Confidence Limit for Odds Ratio	Upper 95% Confidence Limit for Odds Ratio
Age	-0.0184	0.00242	<.0001	0.982	0.977	0.986
Gender - Male	0.0362	0.0327	0.2678	1.075	0.946	1.222
PA catheter use	0.2538	0.0298	<.0001	1.661	1.478	1.867
Impella used Pre-PCI	0.1467	0.0291	<.0001	1.341	1.196	1.503
Impella CP use	0.1241	0.0341	0.0003	1.282	1.121	1.465

Figure 3: Predictors of Survival To Explant⁷

1. O'Neill, et al. Am Heart J. 2018 2. O'Neill, et al. J Int Cardiol. 2014 3. Basir, et al. Am J Cardiol. 2017 4. Meraj, et al. J Int Cardiol. 2017 5. Schroeter, et al. J Inv Cardiol. 2016 6. O'Neill, et al. TCT 2018 presentation 7. Analysis of outcomes for 15,259 US patients with acute myocardial infarction cardiogenic shock (AMICS) supported with the Impella device; O'Neill WW, Grines C, Schreiber T, Moses J, Maini B, Dixon SR, Ohman EM. Am Heart J. 2018 Apr 7;202:33-38. doi: 10.1016/j.ahj.2018.03.024.

For more information on this topic please see the meta-analysis:

Research Correspondence: Early Initiation of Impella in Acute Myocardial Infarction Complicated by Cardiogenic Shock Improves Survival, Flaherty, et al. JACC CI. 2017: 1803-06

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To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit: www.abiomed.com/important-safety-information

*This bulletin is intended for dissemination of technical information only.

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