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.

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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.

Figure 1: Unloading Pre-PCI Associated with Improved AMI-CGS Outcomes

- **Variable**
  - Age
  - Gender - Male
  - PA catheter use
  - Impella used Pre-PCI
  - Impella CP use

- **Estimate**
  - Age: -0.0184
  - Gender - Male: 0.0362
  - PA catheter use: 0.2538
  - Impella used Pre-PCI: 0.1467
  - Impella CP use: 0.1241

- **Standard Error**
  - Age: 0.00242
  - Gender - Male: 0.0327
  - PA catheter use: 0.0298
  - Impella used Pre-PCI: 0.0291
  - Impella CP use: 0.0341

- **Pr > Chi-Square**
  - Age <.0001
  - Gender - Male: 0.2678
  - PA catheter use <.0001
  - Impella used Pre-PCI <.0001
  - Impella CP use <.0001

- **Odds Ratio Estimate**
  - Age: 0.982
  - Gender - Male: 1.075
  - PA catheter use: 1.661
  - Impella used Pre-PCI: 1.341
  - Impella CP use: 1.282

- **Lower 95% Confidence Limit for Odds Ratio**
  - Age: 0.977
  - Gender - Male: 0.946
  - PA catheter use: 1.478
  - Impella used Pre-PCI: 1.196
  - Impella CP use: 1.121

- **Upper 95% Confidence Limit for Odds Ratio**
  - Age: 0.986
  - Gender - Male: 1.222
  - PA catheter use: 1.867
  - Impella used Pre-PCI: 1.503
  - Impella CP use: 1.465

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