Utilization and Outcomes of Impella vs IABP Among Patients with AMI Complicated by Cardiogenic Shock Undergoing PCI

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NCDR® NATIONAL CARDIOVASCULAR DATA REGISTRY

Center for Outcomes Research and Evaluation CORE

Funding Support

This work was supported in part by a Center of Excellence in Regulatory Science and Innovation (CERSI) grant to Yale University and Mayo Clinic from the US Food & Drug Administration (U01FD005938). Its contents are solely the responsibility of the authors and do not represent the official views of the Department of Heath and Human Services or the US Food and Drug Administration.

This research was supported by the American College of Cardiology's National Cardiovascular Data Registry (NCDR). The views expressed in this presentation represent those of the author(s) and do not necessarily represent the official views of the NCDR or its associated professional societies identified at CVQuality.ACC.org/NCDR

Background

- Cardiogenic shock occurs in about 10% of patients with acute MI and is associated with substantial morbidity and mortality.
- In addition to timely reperfusion and medical therapy, mechanical circulatory support (MCS) devices may be used to provide hemodynamic support, but guideline recommendations are limited
- Impella® devices provide greater hemodynamic support than IABP.[1]
- Impella® has been marketed in the U.S. since 2008, but with limited randomized clinical trial evidence in cardiogenic shock.
  - Only 2 RCTs enrolling 74 total patients have compared Impella® vs IABP.
  - No difference in 30-day mortality, but higher bleeding with Impella® use.[1,2]

[1]Seyfarth M, Sibbing D, Bauer I, et al. *J Am Coll Cardiol* 2008. [2]Ouweneel DM, Eriksen E, Sjauw KD, et al. *J Am Coll Cardiol* 2017.

Study Aims

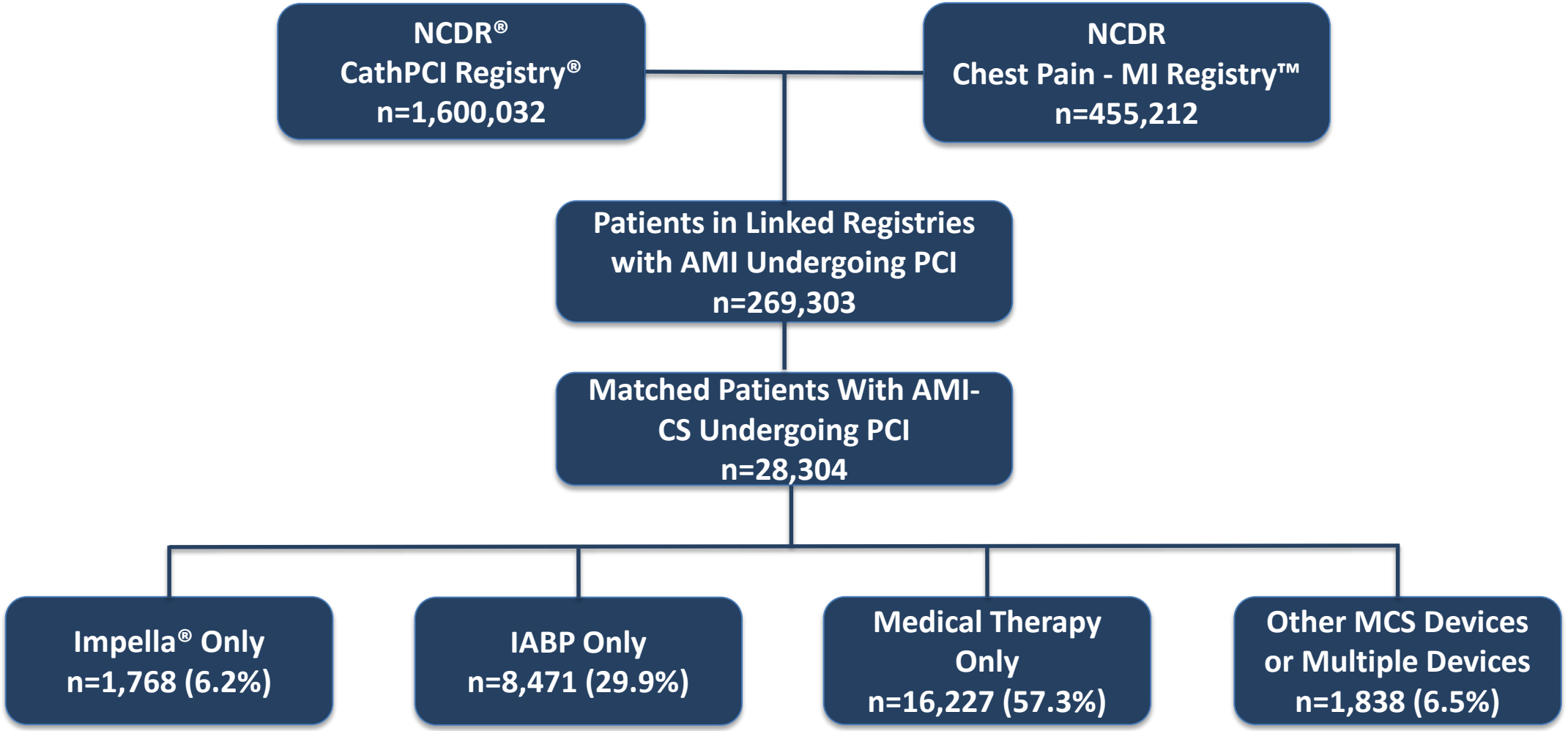
1) Assess MCS device utilization over time among patients with AMI complicated by cardiogenic shock (AMI-CS) undergoing PCI.

2) Apply propensity score matching to examine clinical outcomes among patients receiving Impella® or IABP
   A. Primary effectiveness outcome: in-hospital death
   B. Primary safety outcome: in-hospital major bleeding

Methods: Data Source

- **Identified patients with AMI-CS undergoing PCI between 10/1/2015 and 12/31/2017.**
  - **Linked cohort of the NCDR® CathPCI Registry® (>1500 US hospitals) and Chest Pain - MI Registry™ (>1000 US hospitals).**
  - **Standardized data elements: demographics, history, labs, procedural data**
  - **Robust data quality standards, including auditing.**
- **Cardiogenic shock: SBP < 90 mm Hg and/or cardiac index <2.2 L/min/m^2 for ≥ 30 minutes secondary to ventricular dysfunction, and/or requirement for inotropic, vasopressor, or MCS device therapy.**

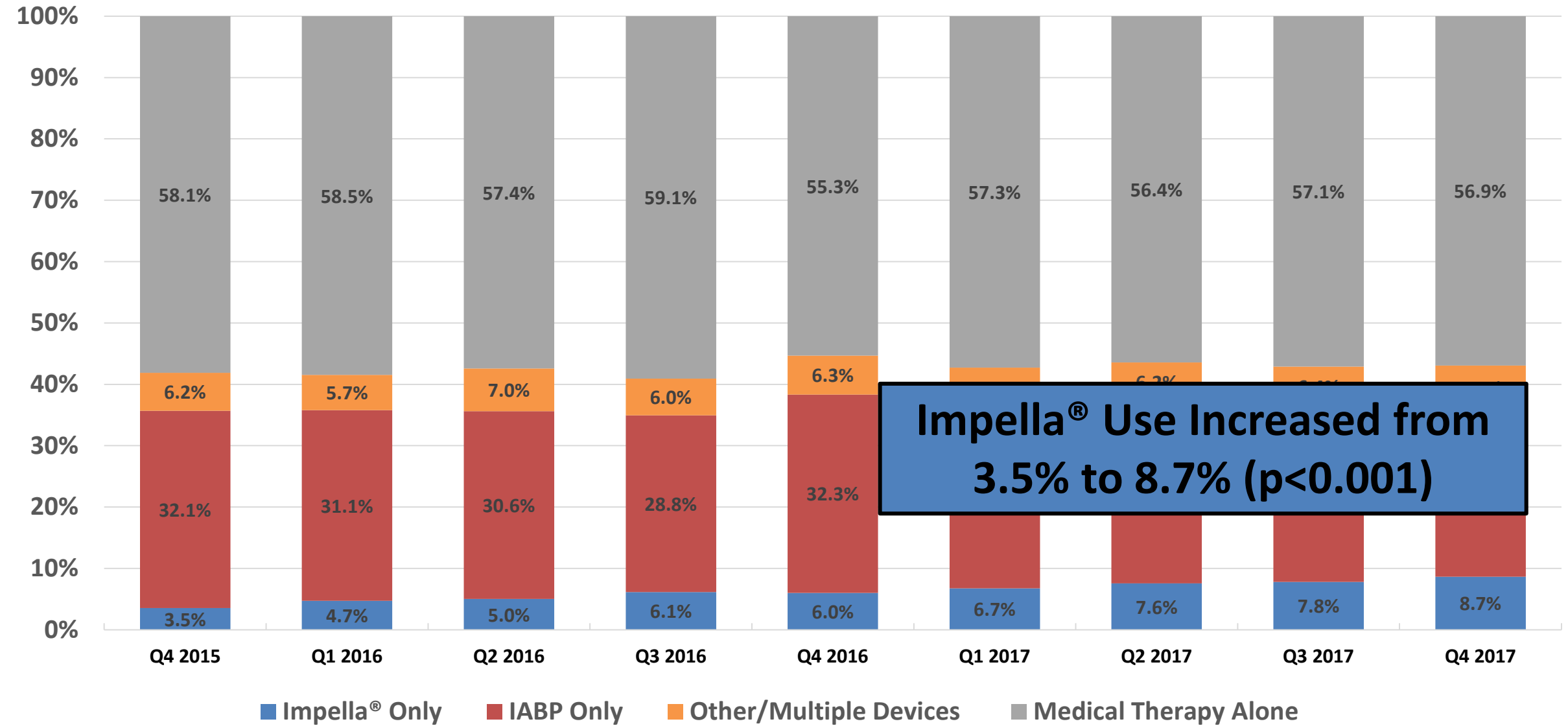
Methods: Cohort Construction



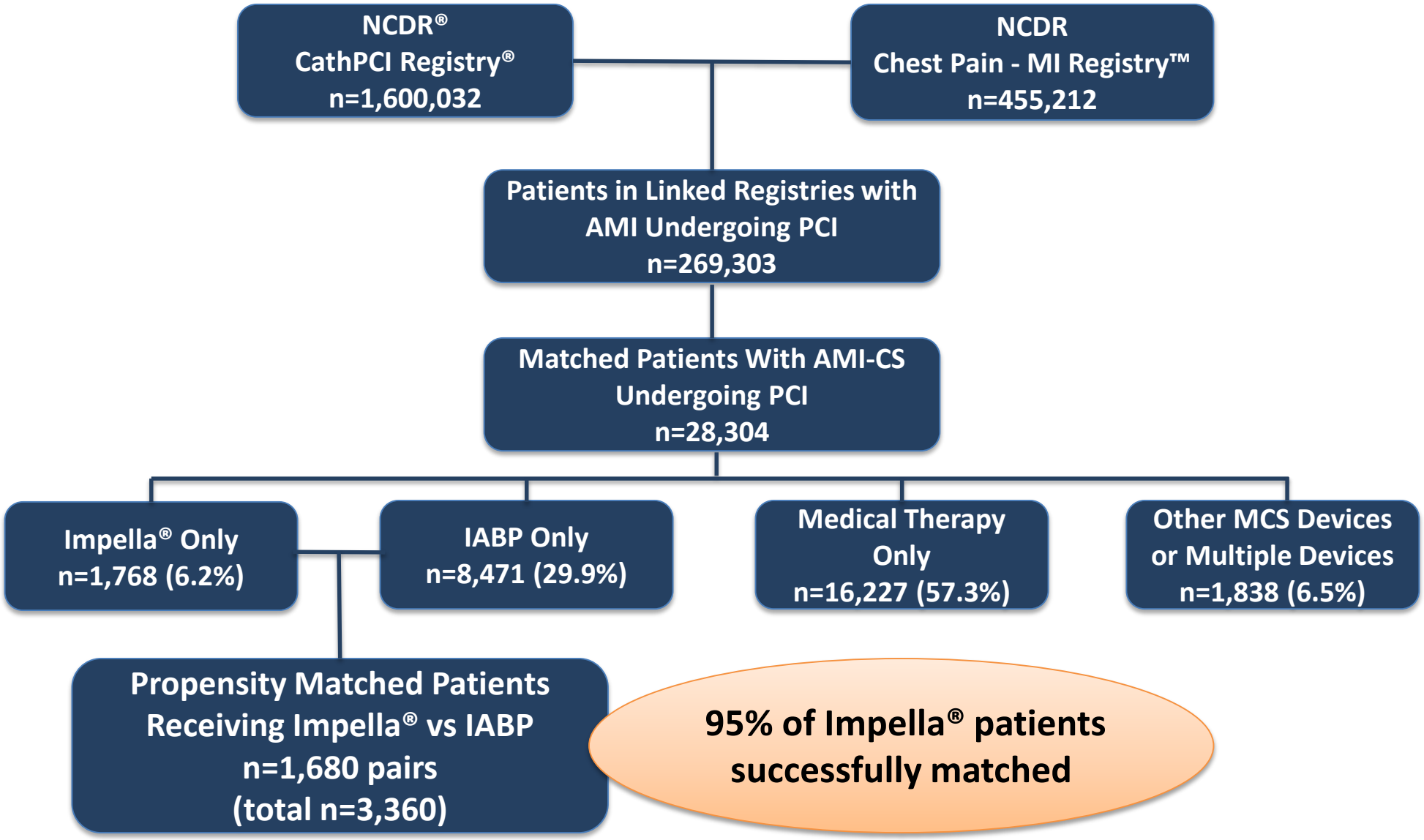
Characteristics of Patients with AMI-CS Undergoing PCI

Characteristic	Impella® Only (n=1,768)	IABP Only (n=8,471)	Medical Therapy Only (n=16,227)
Age, mean (SD) years	64.2 (12.0)	65.2 (12.4)	65.3 (12.8)
Male sex, %	71.3	69.2	64.8
Transferred from outside facility, %	27.3	23.8	24.8
Prior MI, %	22.3	20.7	22.0
Cerebrovascular disease, %	10.8	10.4	11.7
Peripheral artery disease, %	9.7	7.6	10.0
Diabetes, %	36.5	33.7	31.5
Cardiac arrest at first medical contact, %	25.4	24.3	23.4
STEMI, %	78.2	84.4	79.7
Anterior infarction, %	50.6	47.4	32.1
Left main and/or proximal LAD disease, %	62.6	54.7	33.5
Multivessel disease, %	66.2	63.5	48.6

MCS Device Utilization Over Time



Methods: Propensity Matching

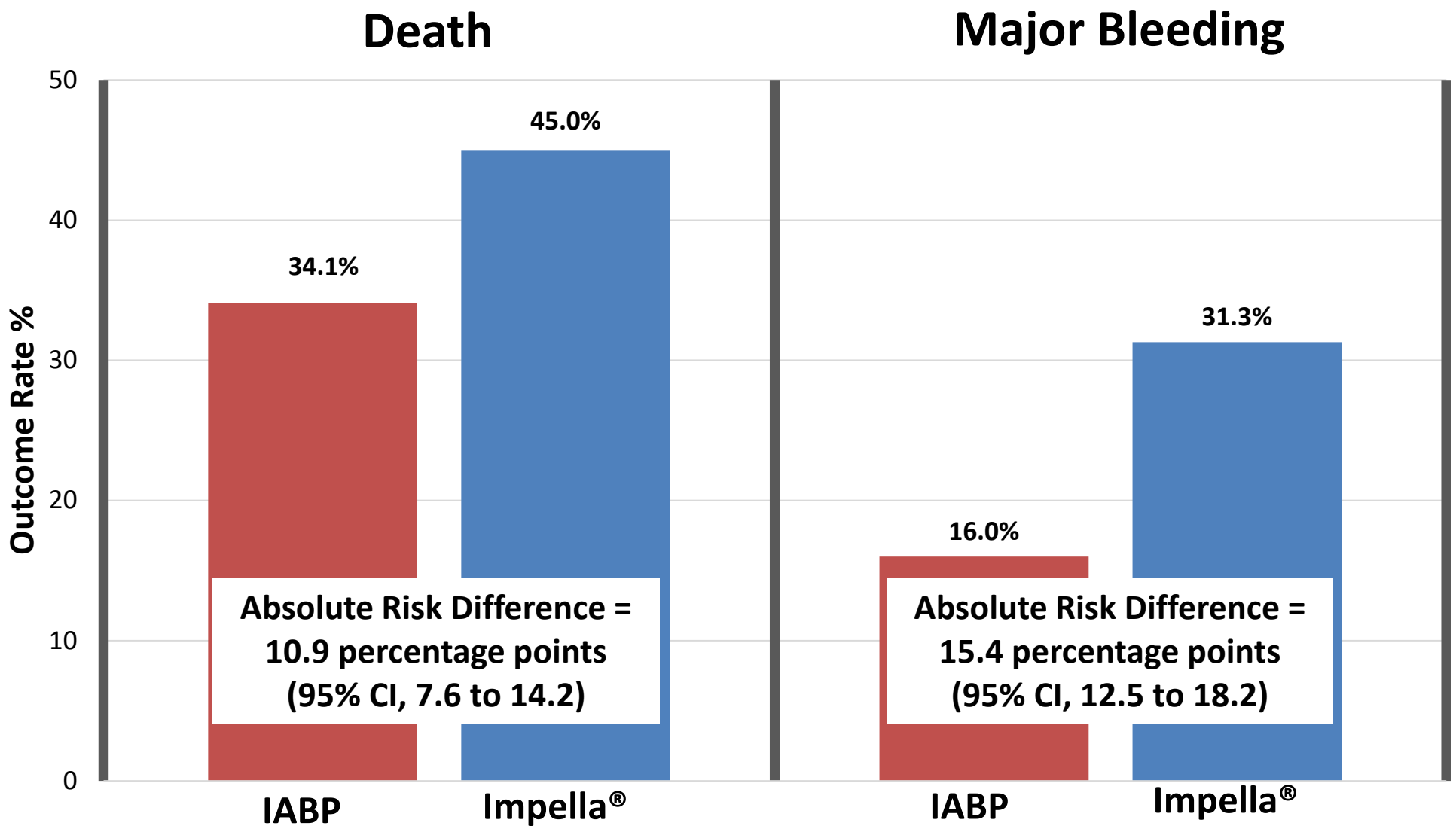


Characteristics of Propensity-Matched Cohort

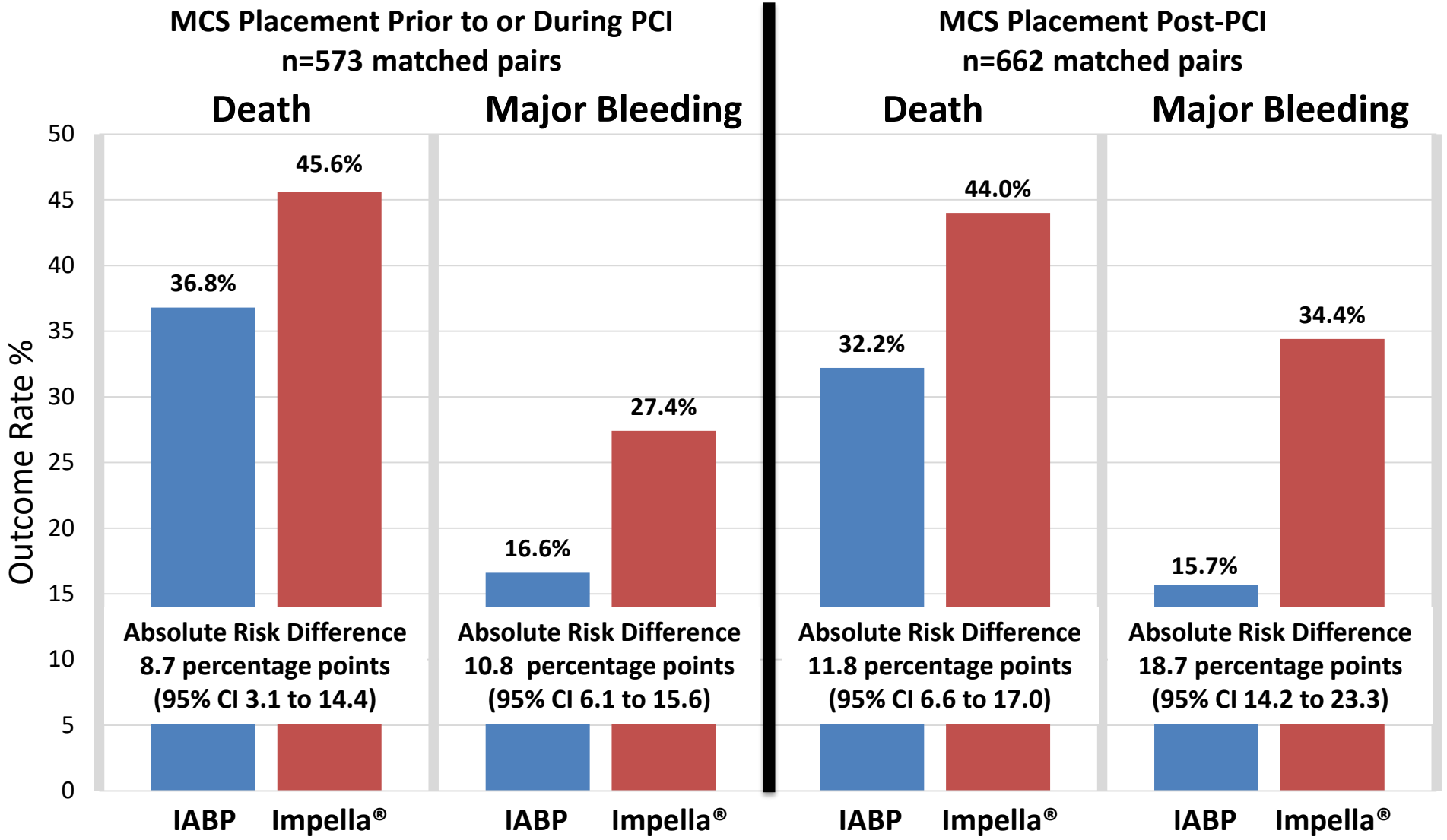
Characteristic	Impella® Only (n=1680)	IABP Only (n=1680)
Age, mean (SD) years	64.3 (11.9)	64.0 (11.9)
Male sex, %	71.1	71.3
Transferred from outside facility, %	27.4	26.8
Medical History, %		
Prior MI	22.9	22.7
Cerebrovascular disease	11.8	13.6
Peripheral artery disease	10.7	10.3
Diabetes	34.2	34.8
Clinical Characteristics, %		
Cardiac arrest at first medical contact	25.1	27.1
STEMI	78.8	79.0
Anterior infarction	50.4	52.3
Left main and/or proximal LAD disease	61.7	62.3
Multivessel disease	66.1	66.1

Standardized mean difference was <0.10 for all 75 variables used for propensity score matching: demographics, clinical history and presentation, infarct location, coronary anatomy, and clinical laboratory data

In-Hospital Clinical Outcomes



In-Hospital Outcomes, Stratified by Timing of Device Placement



Limitations

- **Residual confounding**
  - Robust propensity match: standardized difference <0.10 for all 75 variables.
  - 95% of patients treated with Impella®-only were successfully matched.
  - Results consistent across multiple sensitivity analyses (timing of device placement; hospitals using both IABP and Impella®; excluding transfers)
- **Clinical severity of AMI-CS patients in NCDR®**
  - Registry definition similar to trials.
  - High event rate consistent with contemporary clinical trials and registries.
- **Inability to distinguish different types of Impella® devices.**
  - Results primarily pertain to Impella® 2.5 and CP because 5.0 requires surgical cutdown, and patients receiving multiple devices were excluded.

Conclusions

This large, national, real-world study of patients with AMI-CS undergoing PCI demonstrates:

- **A significant 2.5-fold increase in the utilization of Impella® devices.**
- **Impella® was associated with significantly higher rates of in-hospital death and major bleeding compared to IABP.**

- **These data provide important insights into the performance of MCS devices in routine clinical practice, and outcomes in RCT settings may differ.**
- **Better evidence and guidance are needed regarding the optimal management of patients with AMI-CS as well as the role of MCS devices in general, and Impella® in particular.**