

# The Evolving Landscape of Impella® vs. IABP use in the United States

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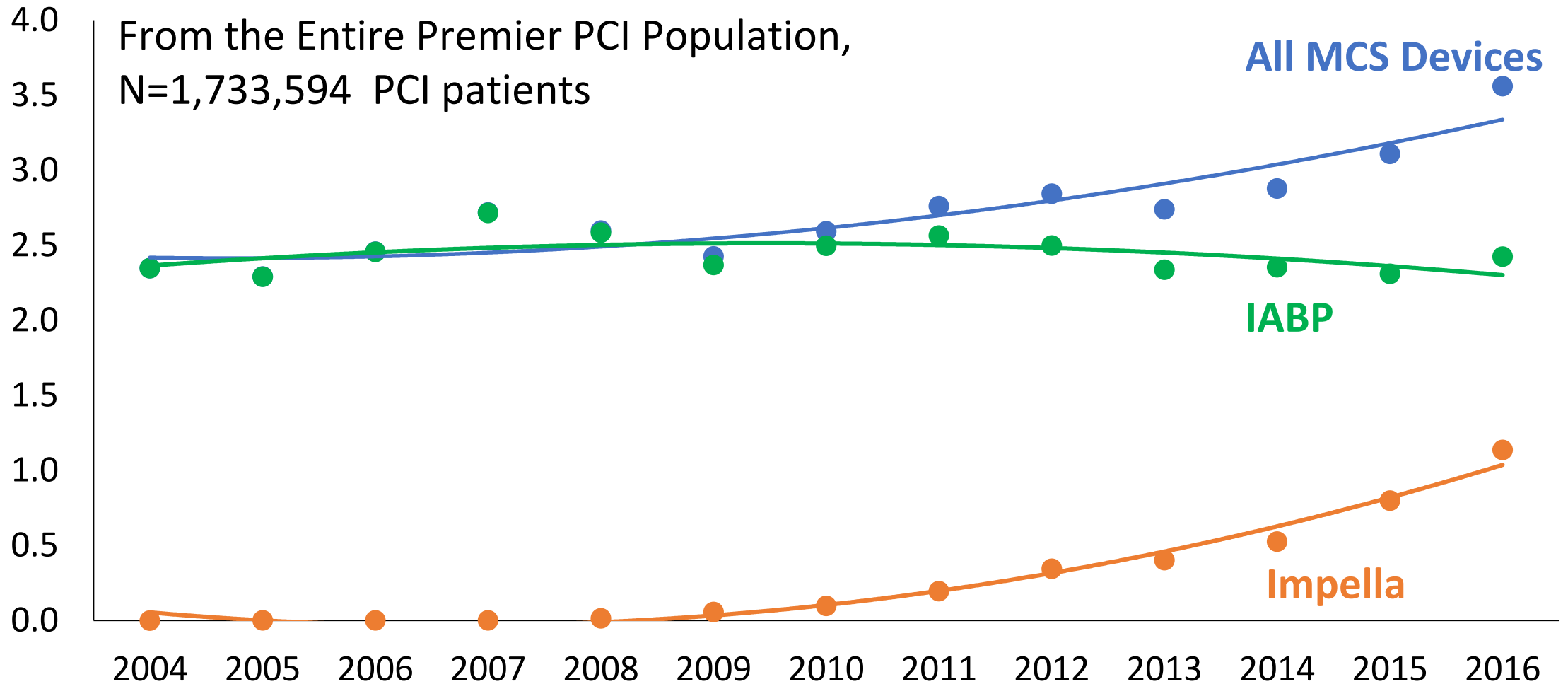
# Introduction

- Impella® was approved for mechanical circulatory support (MCS) in 2008, but large-scale, real-world outcomes and cost data on its use are lacking.
- Our objectives were to:
  - 1) Describe trends and variation in Impella® use across hospitals
  - 2) Compare outcomes (in-hospital mortality, bleeding, acute kidney injury (AKI) and stroke), hospitalization costs and length of stay
    - a) at the time-period level: in the pre-Impella® vs. Impella® era;
    - b) at the hospital level: across low- vs. high-Impella® use hospitals;
    - c) at the patient-level: by performing comparative effectiveness analysis

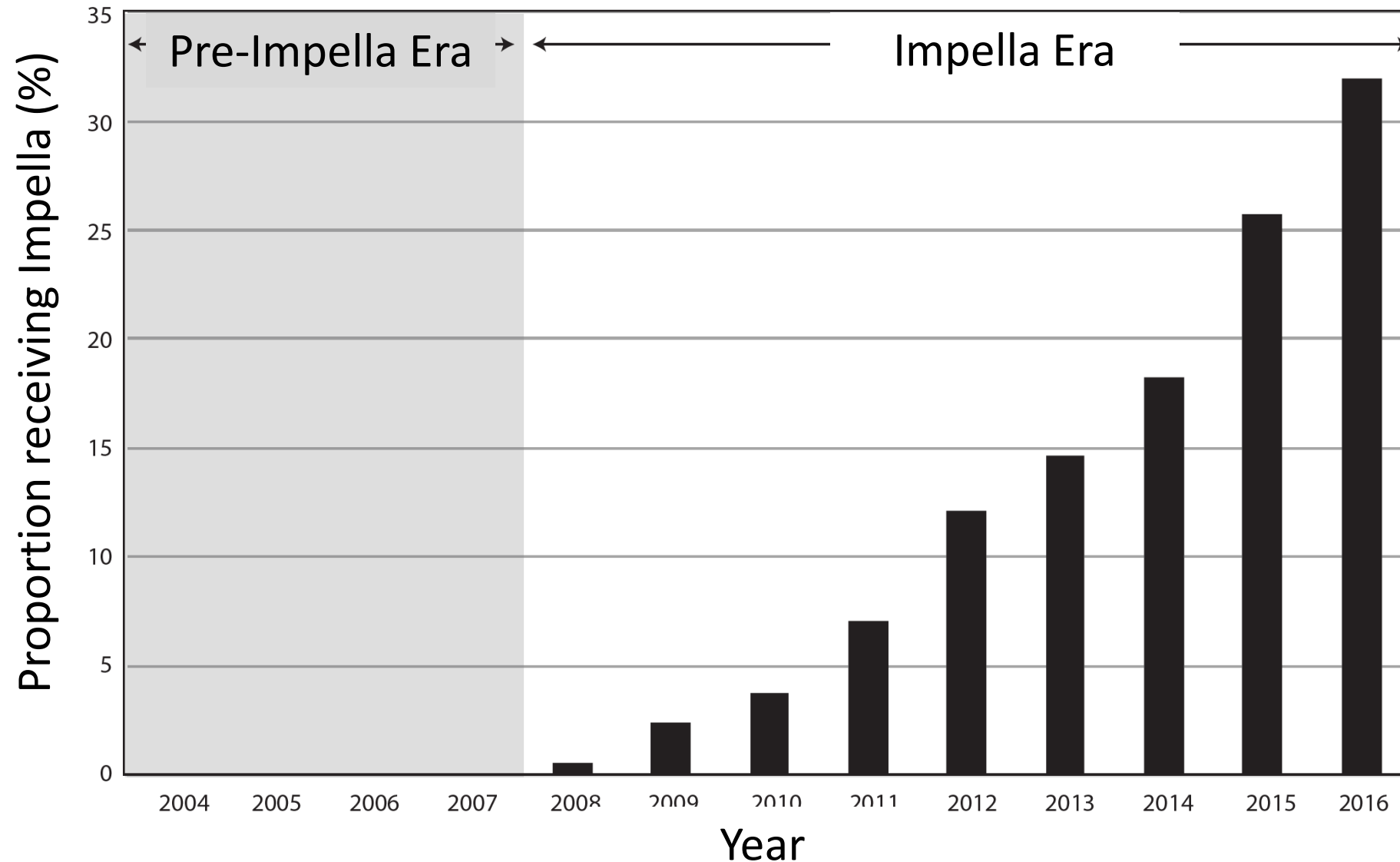
# Methods

- From the Premier Healthcare Database, we analyzed 48,306 patients undergoing PCI with MCS at 432 hospitals between 1/2004-12/2016.
- We analyzed the association of Impella<sup>®</sup> with outcomes and costs at three levels:
  - Time-period level
  - Hospital level
  - Patient level
- In all association analyses, we performed propensity adjustment and used hierarchical models to account for clustering of patients by hospitals.

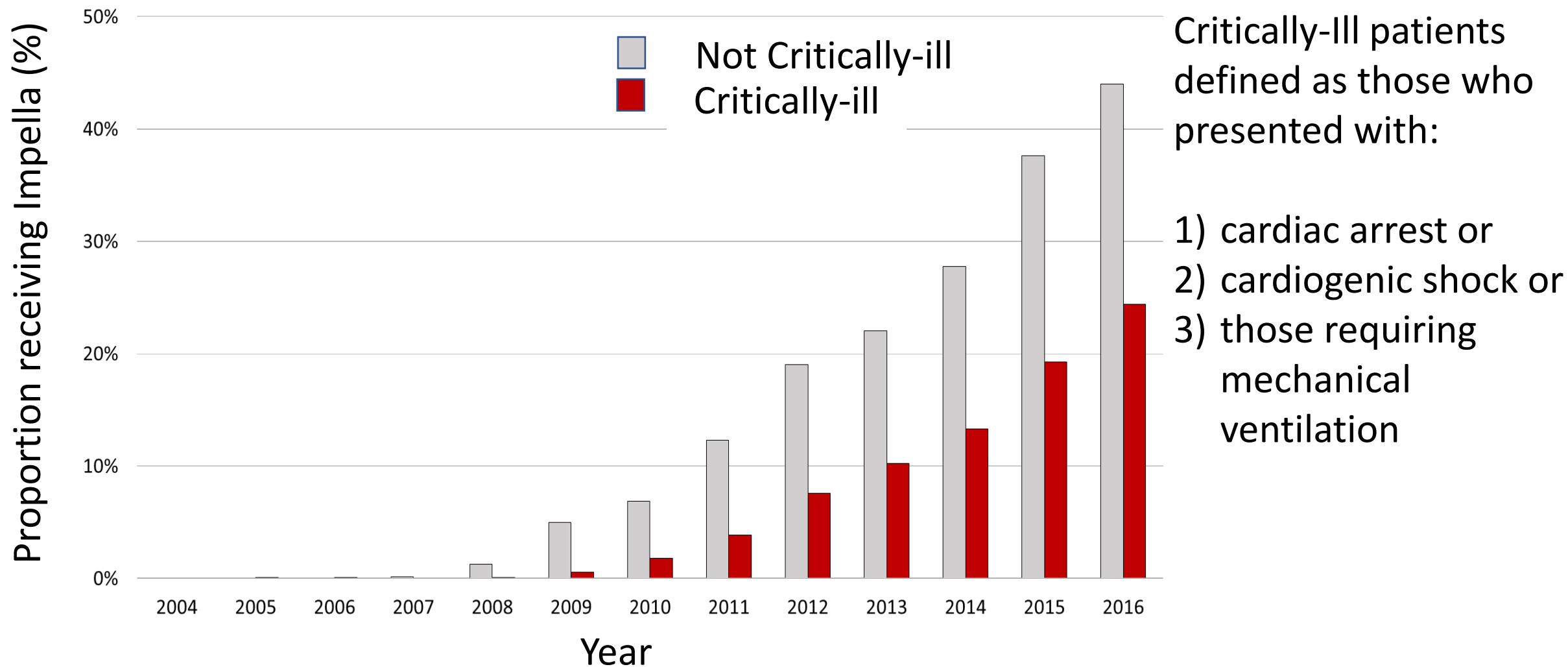
# Overall Practice Patterns of IABP, Impella® and MCS devices in PCI patients



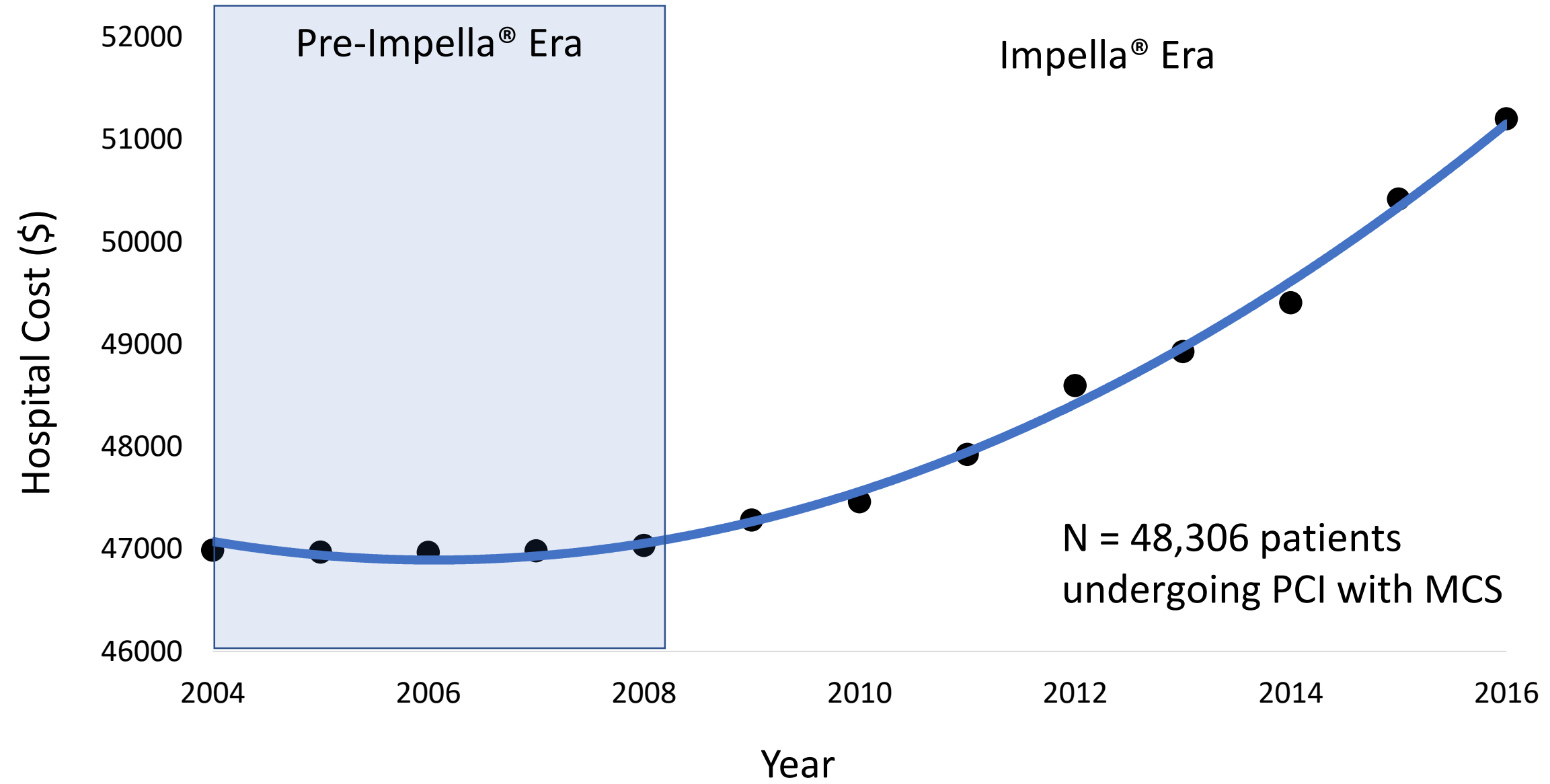
# Use of Impella® rapidly increased amongst PCI patients treated with MCS devices



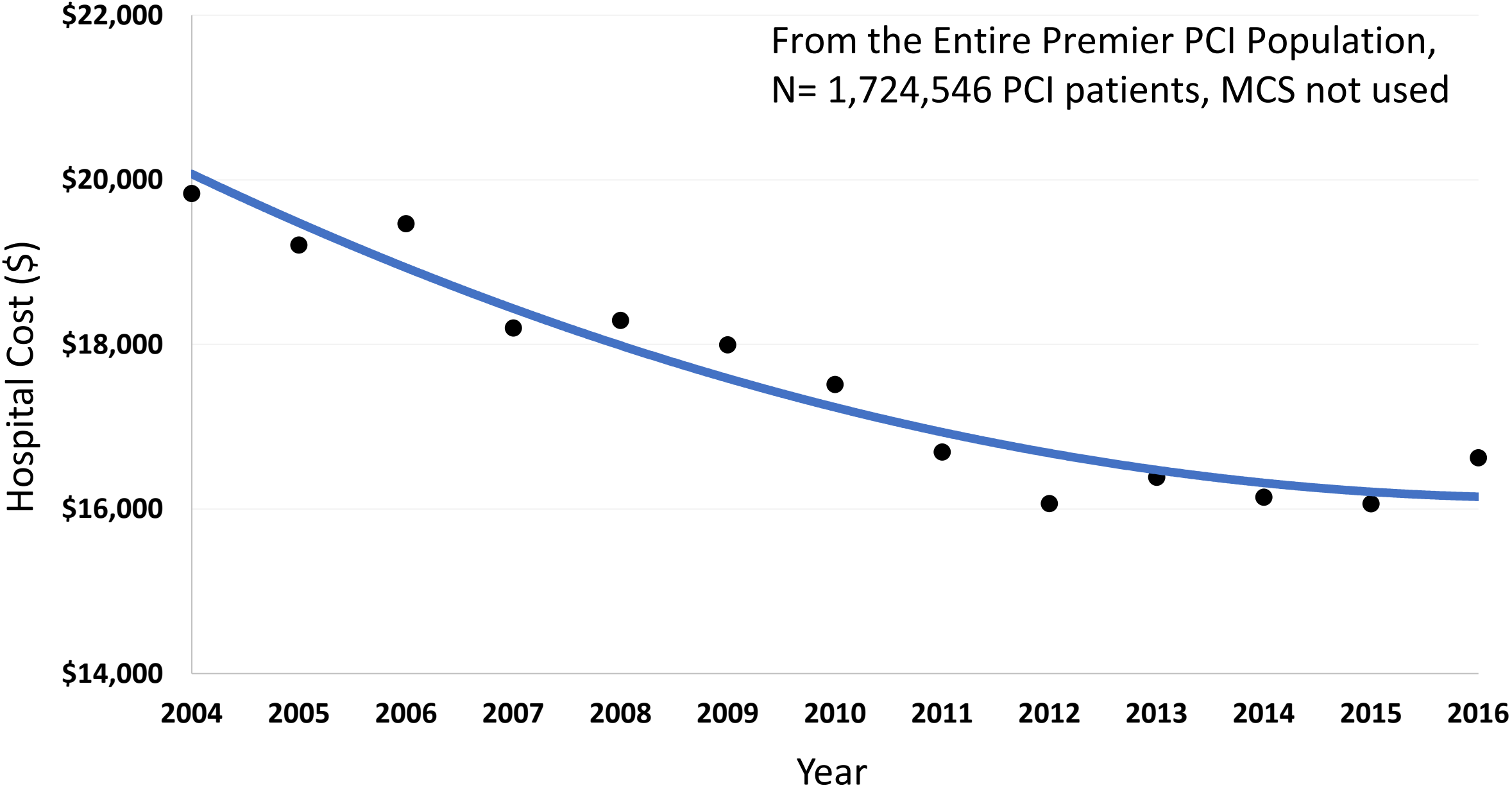
# Impella® was less likely to be used in critically-ill patients



# Increasing Cost Trend in MCS use PCI patients, in the Impella® Era

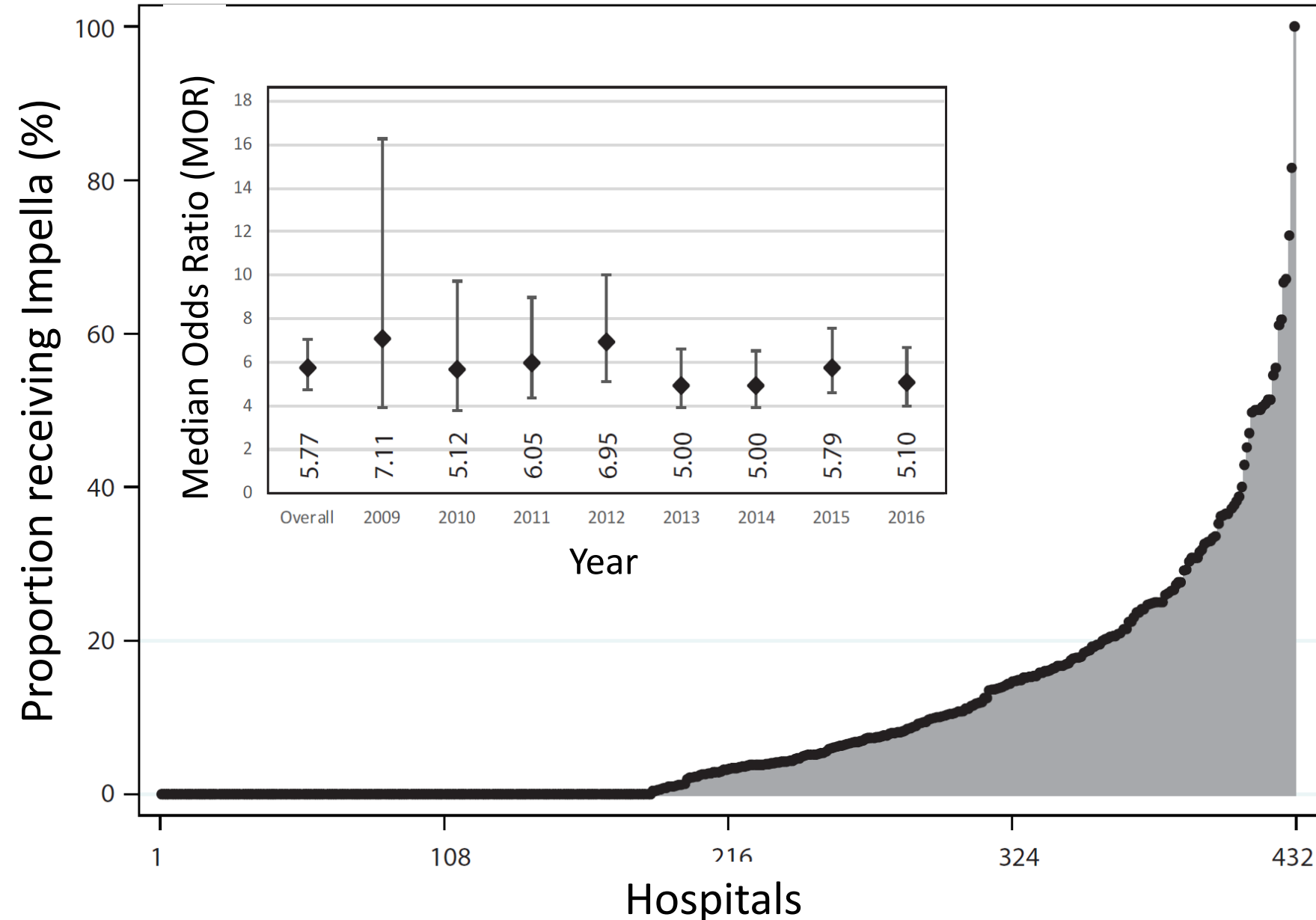


# Decreasing Cost Trend in non-MCS use PCI





# Large Variation in the Use of Impella®



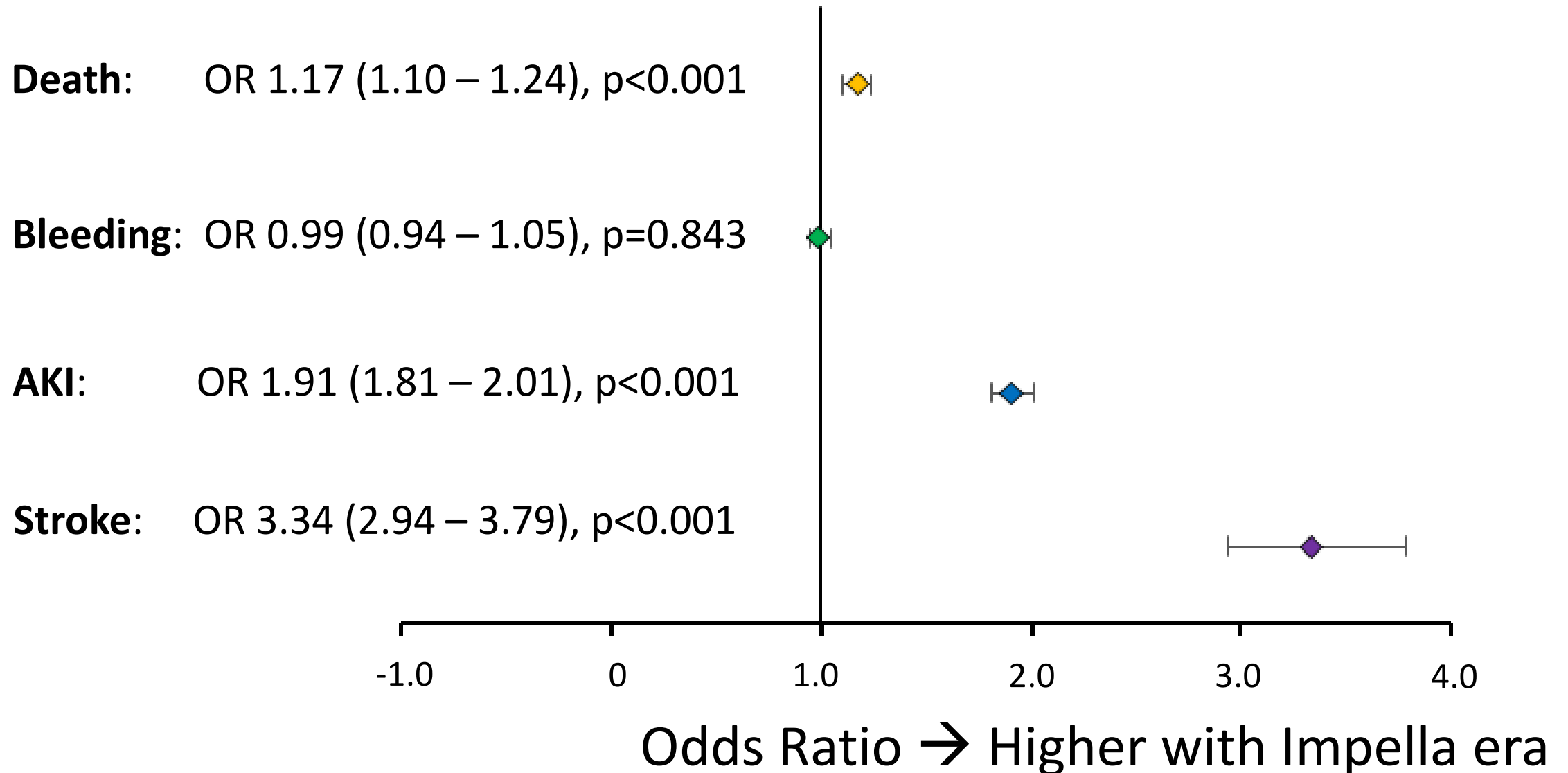
~ 6-fold variation  
in the likelihood  
of receiving  
Impella

# Large variation in outcomes among patients who received Impella® device

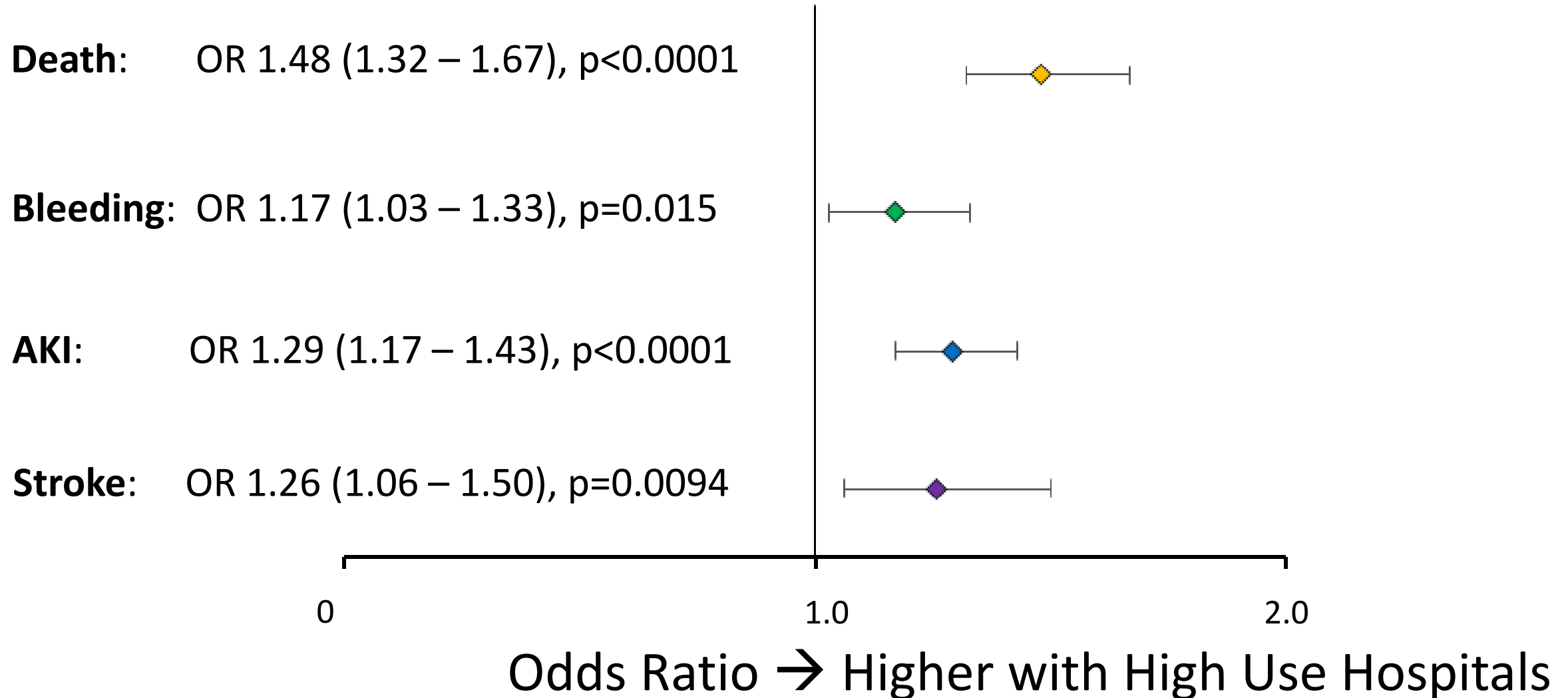
Outcome	Variation across hospitals (n = 4,782)
	Median Odds Ratio (MOR)
Death	1.71 (1.53 – 1.97)
Bleeding	2.62 (2.24 – 3.17)
AKI	1.53 (1.41 – 1.69)
Stroke	1.47 (1.27 – 1.86)
	Intraclass Correlation Coefficient (ICC, %)
Total LOS	5.18 (3.40 – 7.80)
ICU LOS	6.98 (4.67 – 10.31)
Total cost	17.80 (13.93 – 22.46)

- ~2.5-fold variation in Bleeding across hospitals
- ~1.5-fold variation in AKI, Stroke and Death across hospitals
- Less variation in LOS and Costs

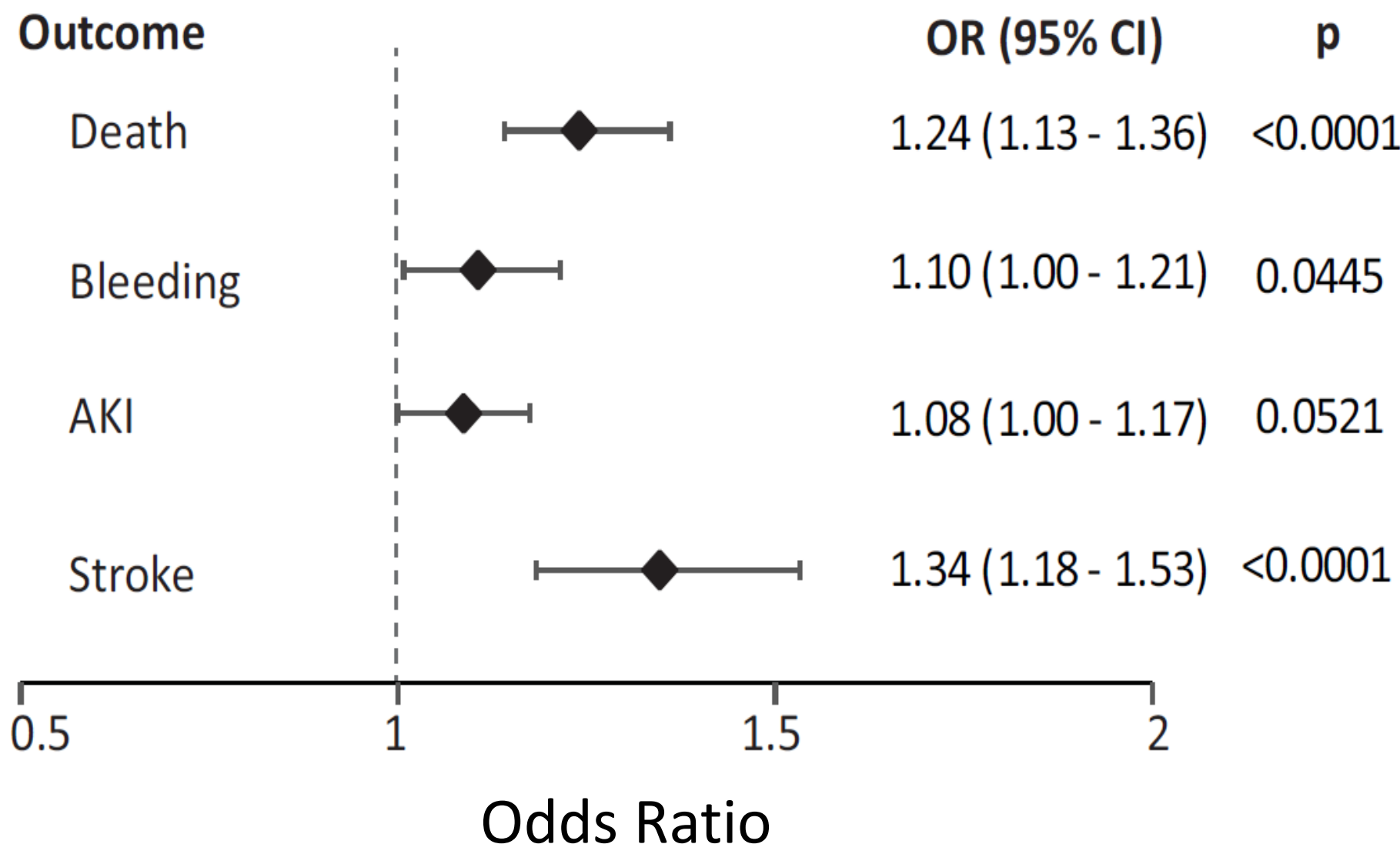
# Comparison of the pre-Impella® and Impella® era for outcomes (adjusted)



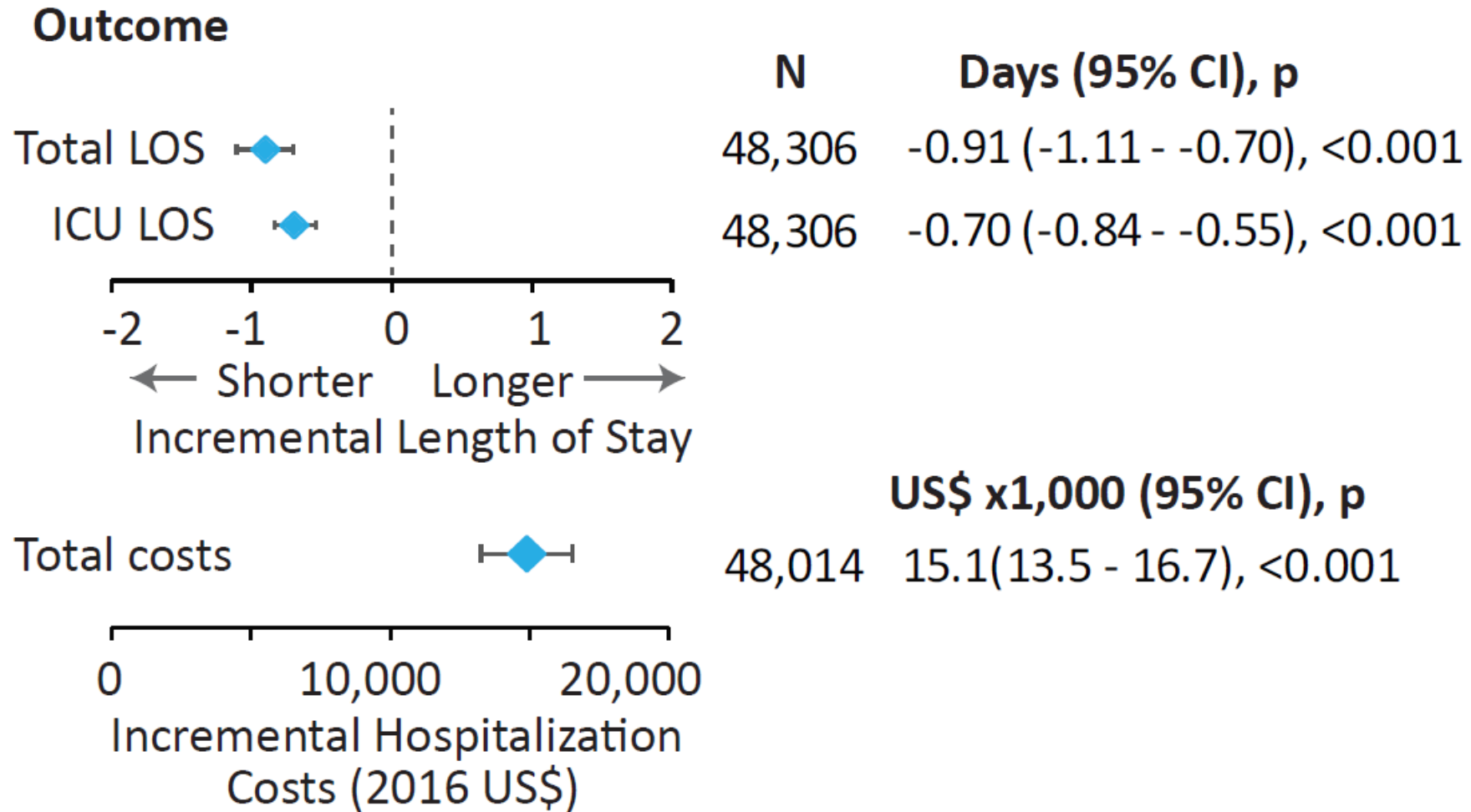
# Comparison of the Highest Quartile Impella® use Hospital vs. Lowest Quartile Impella® use Hospital for study outcomes (adjusted)



# Patient Level Comparative Effectiveness of Impella® vs. IABP (adjusted)

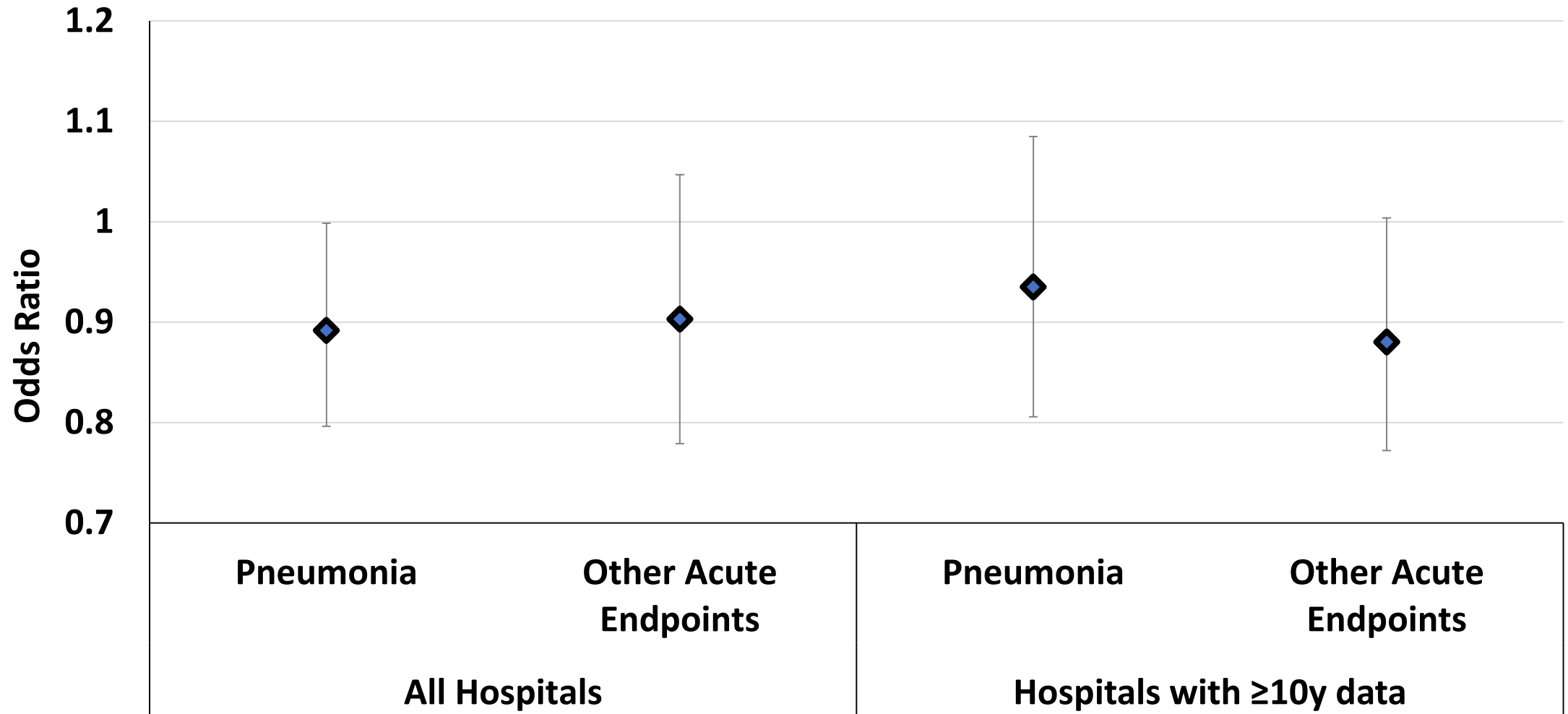


# Length of Stay and Hospital Costs (adjusted)



# Falsification Endpoint Analysis:

Association of Impella with adverse outcomes unlikely to be driven by unmeasured comorbid conditions or its use in sicker patients



Other Acute Endpoints include acute diarrhea, cellulitis, deep vein thrombosis, intestinal obstruction or osteomyelitis

# Limitations

- Observational study and cannot rule out unmeasured confounding or selection bias.
- The definition of cardiogenic shock and outcomes of death, bleeding, AKI and stroke are derived from ICD-9 codes and were not adjudicated.
- Angiographic details unavailable, unable to adjust for anatomic complexity.
- Costs are from the hospital perspective and limited to index hospitalization.
- The clinical reasoning behind selection of Impella<sup>®</sup> use cannot be ascertained.



# Conclusions

- Impella<sup>®</sup> is increasingly being used instead of IABP to support PCI in the United States.
- There exists a wide variation not only in the use of Impella<sup>®</sup> across hospitals but also in its associated outcomes across hospitals.
- The associated clinical outcomes did not show any substantial improvement, while costs of hospitalization rose.
  - Although unmeasured confounding cannot be ruled out, when analyzed by time periods, or at the level of hospitals or at the level of patients, Impella<sup>®</sup> use was associated with higher rates of adverse events and increased costs.
- **These data underscore the need for defining the appropriate use of MCS in patients undergoing PCI**

# Thank you

- Statisticians: Hemant Kulkarni and John House
- Co-authors: John A. Spertus MD MPH, Jephtha P. Curtis MD, Nihar Desai MD MPH, Frederick A. Masoudi MD MSc, Richard G. Bach MD, Christian McNeely MD, Firas Al-Badarin MD MSc, John A. House MS, Hemant Kulkarni MD, Sunil V. Rao MD
- Circulation Editors and Reviewers

