



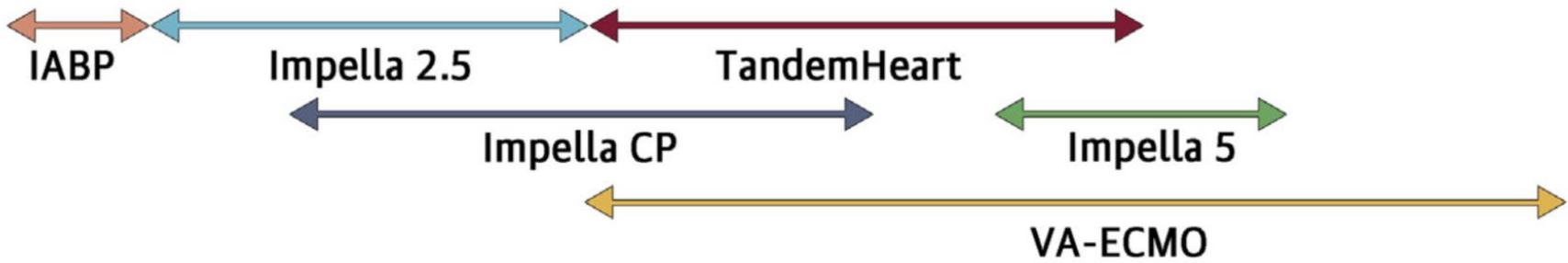
Commentary: Mechanical Circulatory Support for Percutaneous Coronary Intervention

Ranya Sweis, MD, MS
Northwestern University
Chicago, IL USA



IABP IMPELLA TANDEMHEART VA-ECMO

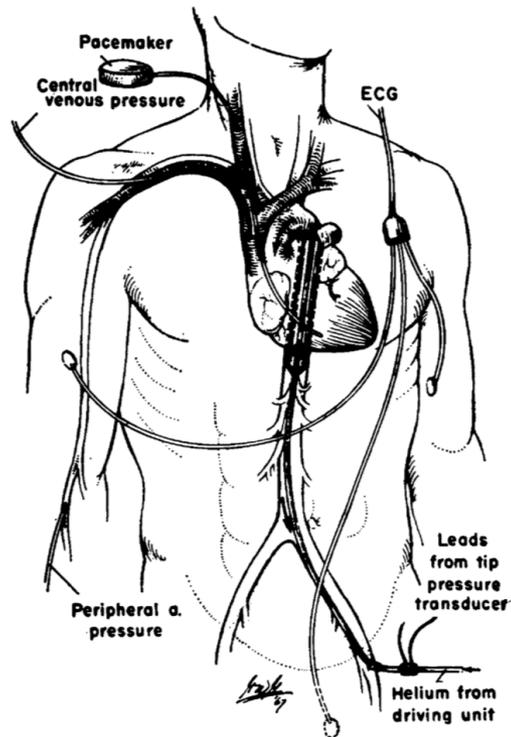
0 - 1 L 1 - 2 L 2 - 3 L 3 - 4 L 4 - 5 L 5 - 7 L



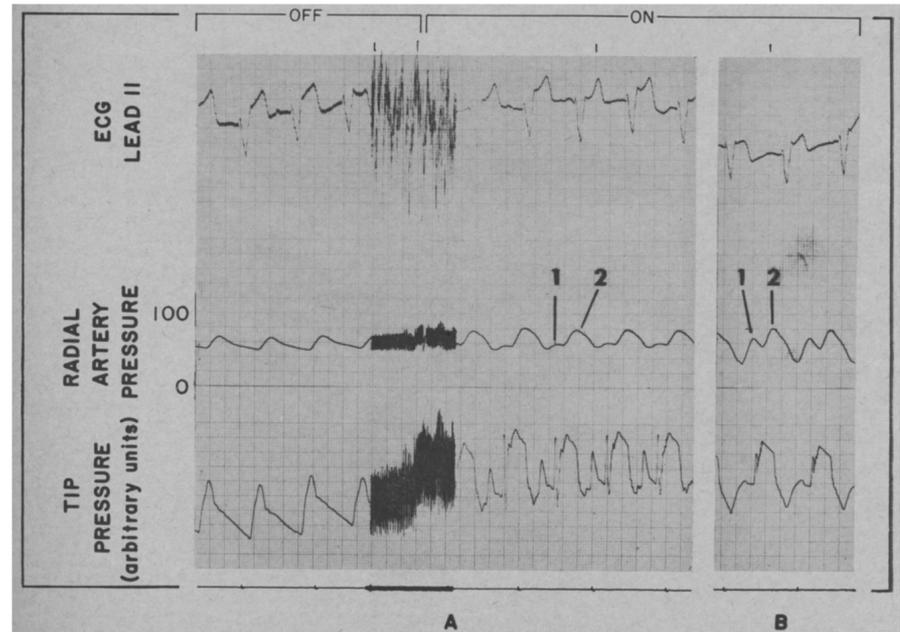
January 8, 1968

Initial Clinical Experience With Intraaortic Balloon Pumping in Cardiogenic Shock

Adrian Kantrowitz, MD; Steinar Tjønneland, MD; Paul S. Freed, MS; et al



2. Schematic representation of balloon pumping setup. Balloon shown in position for pumping.



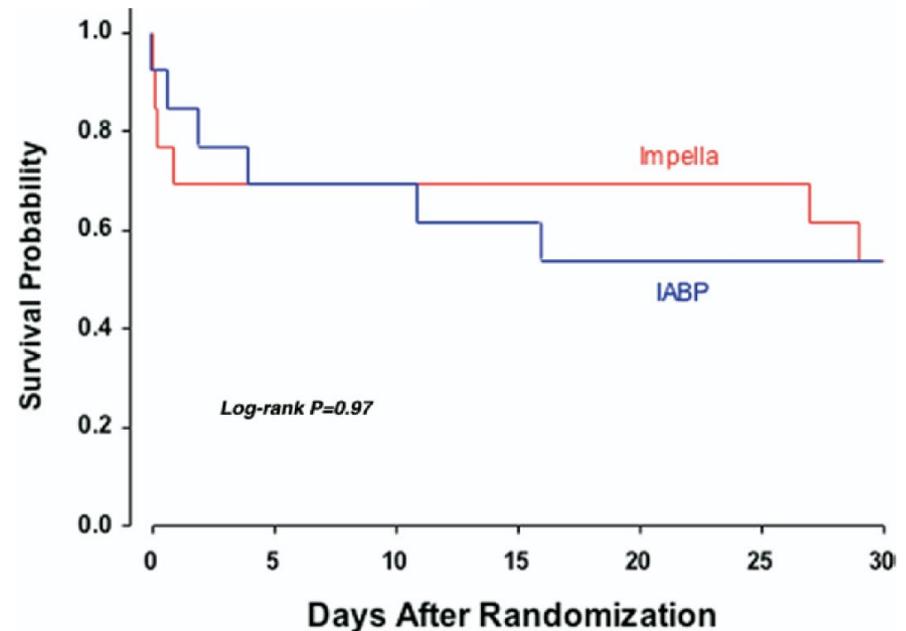
5. Electrocardiogram (ECG), right radial artery pressure, and central aortic pressure from pressure transducer (case 1). A, Recorded during initiation of balloon pumping. B, Recorded 15 minutes later. Component of radial artery pressure curve due to natural heart (1). Component due to balloon pumping (2).

A Randomized Clinical Trial to Evaluate the Safety and Efficacy of a Percutaneous Left Ventricular Assist Device Versus Intra-Aortic Balloon Pumping for Treatment of Cardiogenic Shock Caused by Myocardial Infarction

Melchior Seyfarth, MD,*† Dirk Sibbing, MD,* Iris Bauer, MS,* Georg Fröhlich, MD,† Lorenz Bott-Flügel, MD,† Robert Byrne, MB, MRCPI,* Josef Dirschinger, MD,† Adnan Kastrati, MD,* Albert Schömig, MD*†

Munich, Germany

- ISAR SHOCK: Feasibility and safety study
- 25 MI with shock patients randomized to IABP vs. Impella 2.5
- Increased cardiac index after 30 minutes with Impella
- Improved lactate levels
- Similar 30 day mortality

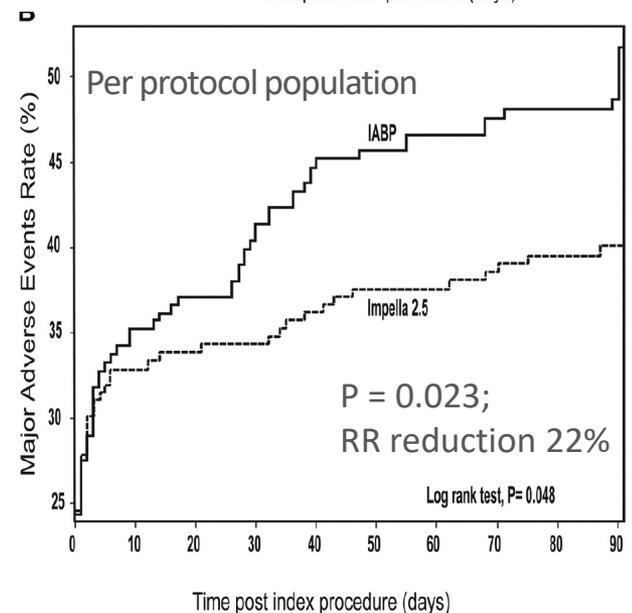
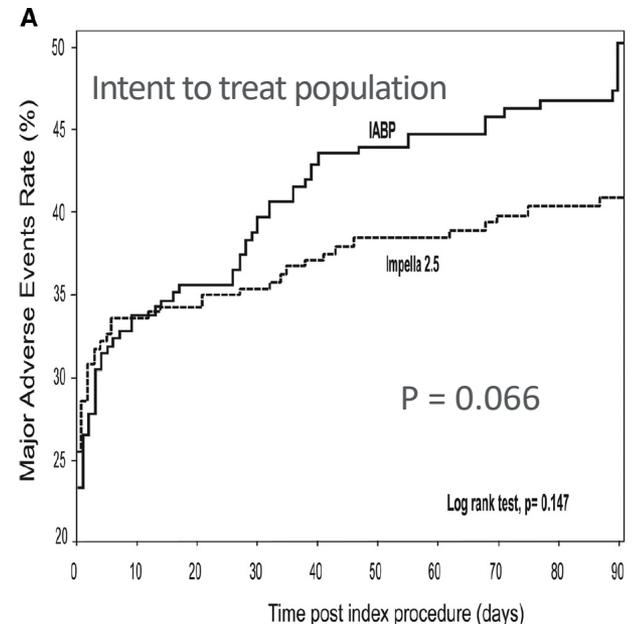


A Prospective, Randomized Clinical Trial of Hemodynamic Support With Impella 2.5 Versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention

The PROTECT II Study

William W. O'Neill, MD; Neal S. Kleiman, MD; Jeffrey Moses, MD;
Jose P.S. Henriques, MD, PhD; Simon Dixon, MBChB; Joseph Massaro, PhD; Igor Palacios, MD;
Brijeshwar Maini, MD; Suresh Mulukutla, MD; Vladimír Džavík, MD; Jeffrey Popma, MD;
Pamela S. Douglas, MD; Magnus Ohman, MD

- 452 pts with complex CAD (3V or LMCA)
AND severe LV dysfunction
- Randomized to IAPB vs Impella 2.5 during PCI
- Primary endpoint was 30 day incidence of major adverse events

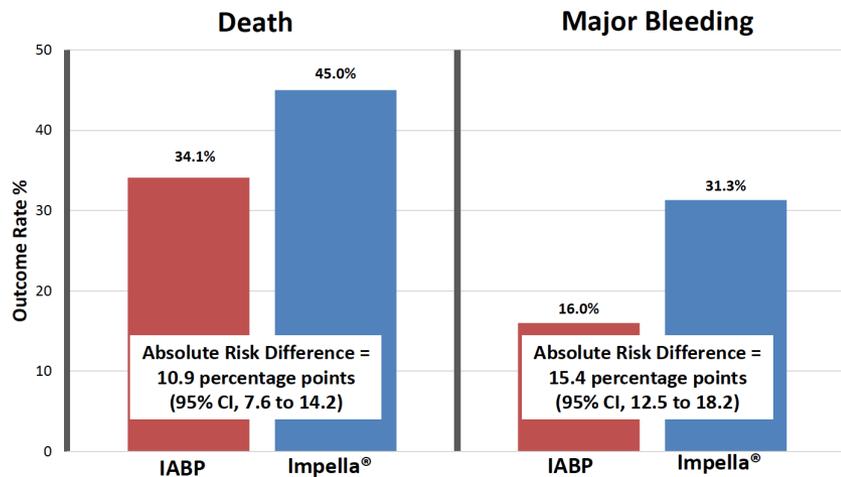


	Utilization and Outcomes of Impella vs. IABP Among Patients with AMI Complicated by Cardiogenic Shock Undergoing PCI Dhruva et al.	The Comparative Effectiveness and Costs of Impella vs. Intra-Aortic Balloon Pump in the United States Amin et al.
What	AMI with shock and PCI needing MCS	PCI with MCS on same day shock 50% AMI 62%
Who	NCDR: Cath PCI (>1500 hospitals) and Chest pain MI™ Registries (>1000 hospitals) 28,304 patients	Premier® Healthcare Database 48,306 patients 432 hospitals
When	2015-2017	2004-2016
Treatment groups	IABP only Impella only Other (ECOM, Tandem heart, etc) None = Medical therapy	IABP only (90.1%) Impella only (9.9%) Comparing pre impella and impella era

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

The Comparative Effectiveness and Costs of Impella vs. Intra-Aortic Balloon Pump in the United States
Amin et al.

In-Hospital Clinical Outcomes



Comparative Effectiveness of Impella vs. IABP

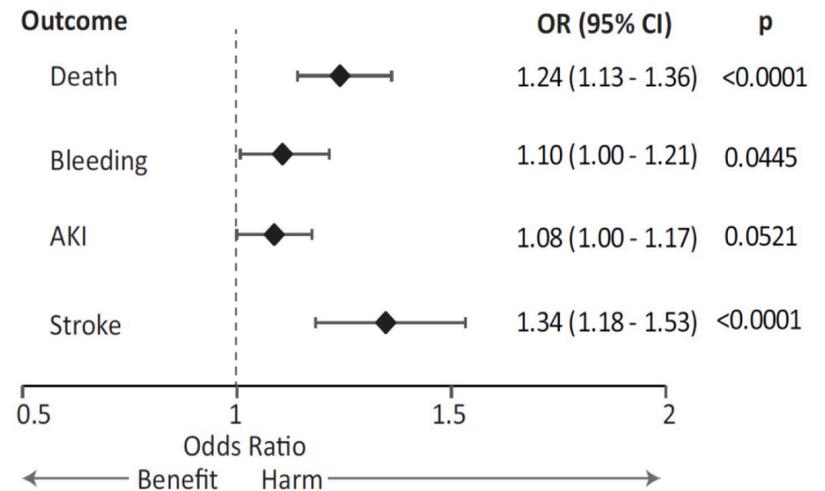


Table 2. Hospital-level variation in the study outcomes in patients who received Impella® device*.

Outcome	Variation across all hospitals (n = 4,782)
	Dichotomous outcomes (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)
	Continuous outcomes (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)

Study Conclusions

- Impella utilization has been increasing
- In both of these studies, higher utilization of Impella was found to be associated with higher risk of adverse outcomes
- There is substantial variability between hospitals in the risk of adverse outcomes associated with Impella use

Limitations

- Associations observed in registry and administrative datasets do not imply causation
- Non-standardized definitions of cardiogenic shock, bleeding, etc.
- Lack of nuance in characterization of the severity of patient condition
- Unable to determine which patients, if any, would not have undergone PCI if not for mechanical support.

Future Implications

- Prospective randomized studies are needed to clarify causative relationships between the use of mechanical support devices and outcomes in carefully defined patient populations.
- Future trials will be enhanced by:
 - Better understanding of patients' comprehensive risks
 - Standardized definitions of bleeding, subclassifications of shock, etc.
- Reduced variation in outcomes between hospitals should be pursued by careful attention to known strategies for optimizing outcomes such as bleeding avoidance strategies.

Thank you!



American Heart Association®

Scientific Sessions