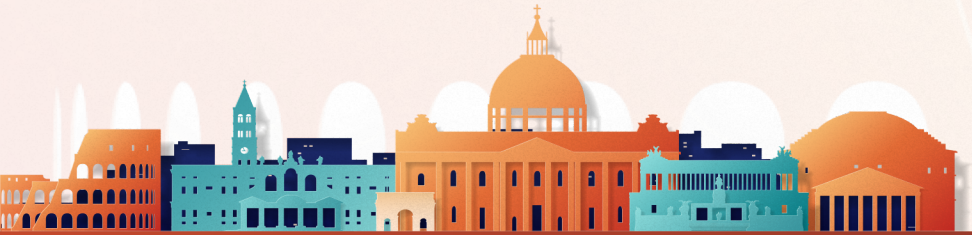
PLACE 2026
PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

CONGRESSO
ROMA, 25 - 27 Giugno 2026

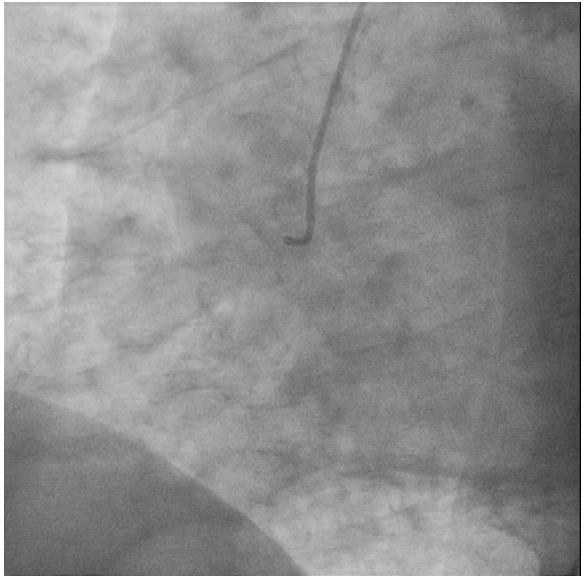
MANAGING COMPLEXITY: MCS IN HIGH RISK PCI & CARDIOGENIC SHOCK

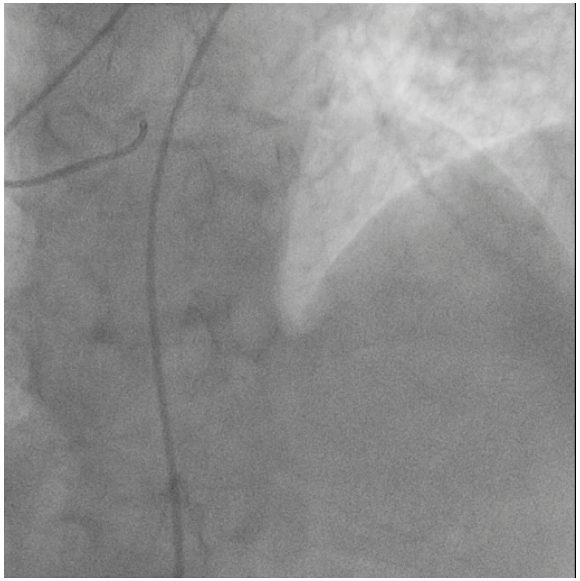
Indicazioni alla PCI protetta

Giuliani Livio
L'Aquila



INVASIVE CORONARY ANGIOGRAPHY

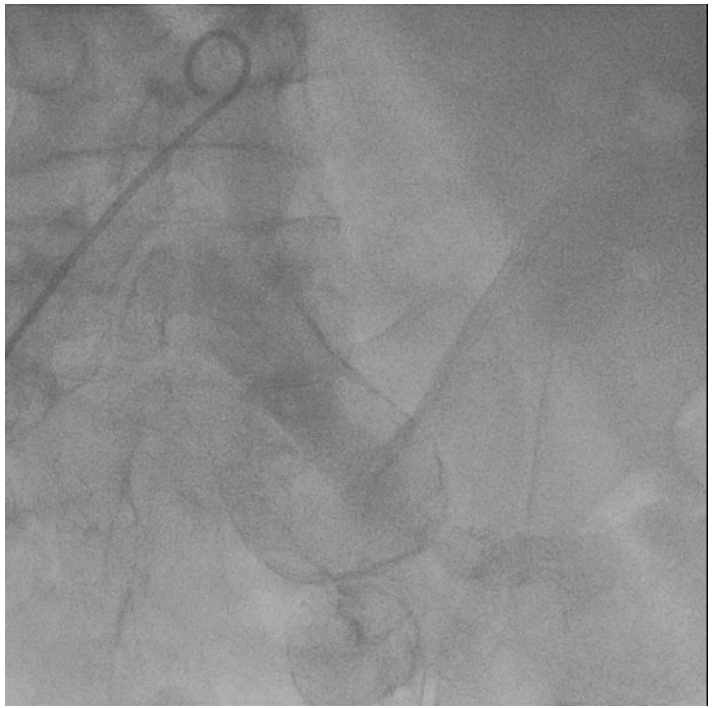


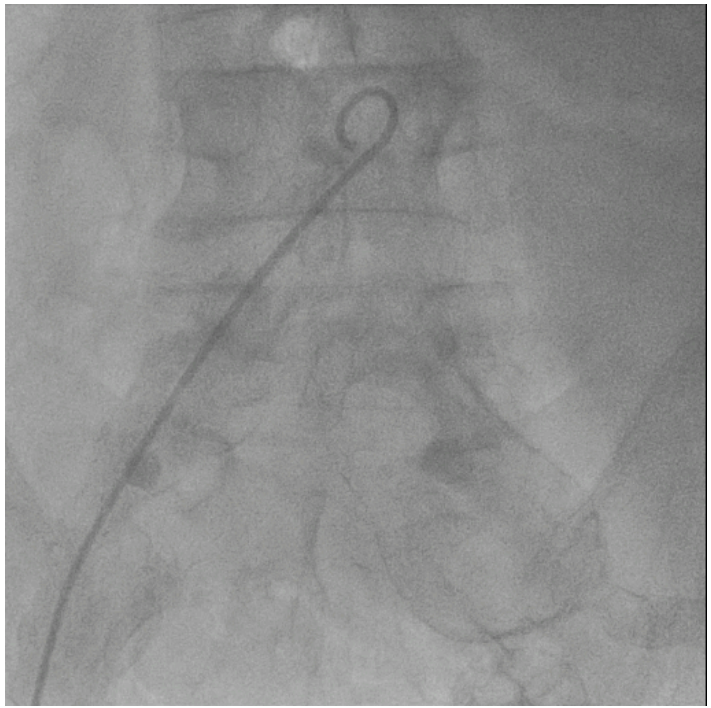


72-year-old male patient

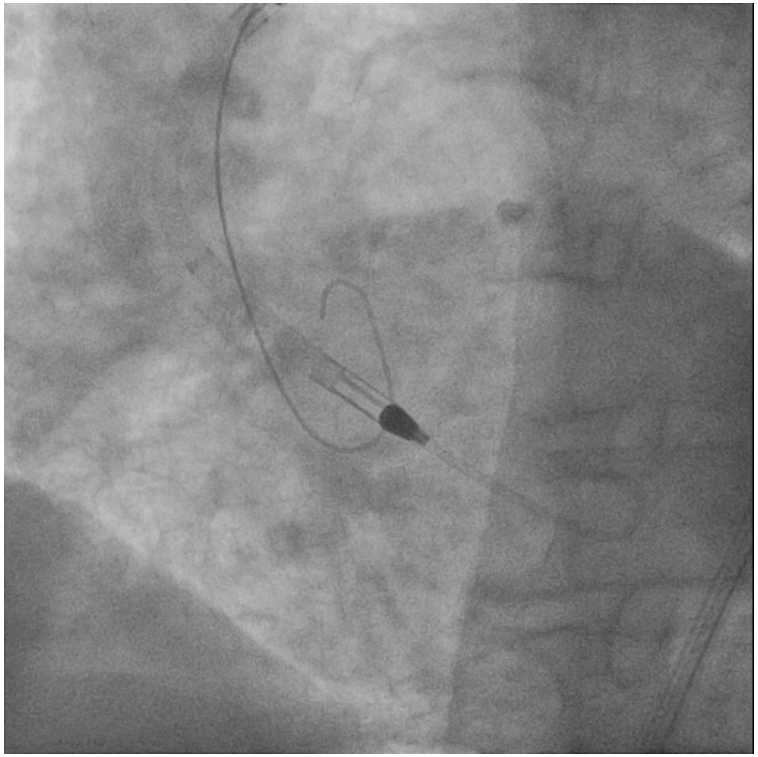
admitted for ACS, with 20% LVEF and acute heart failure at presentation

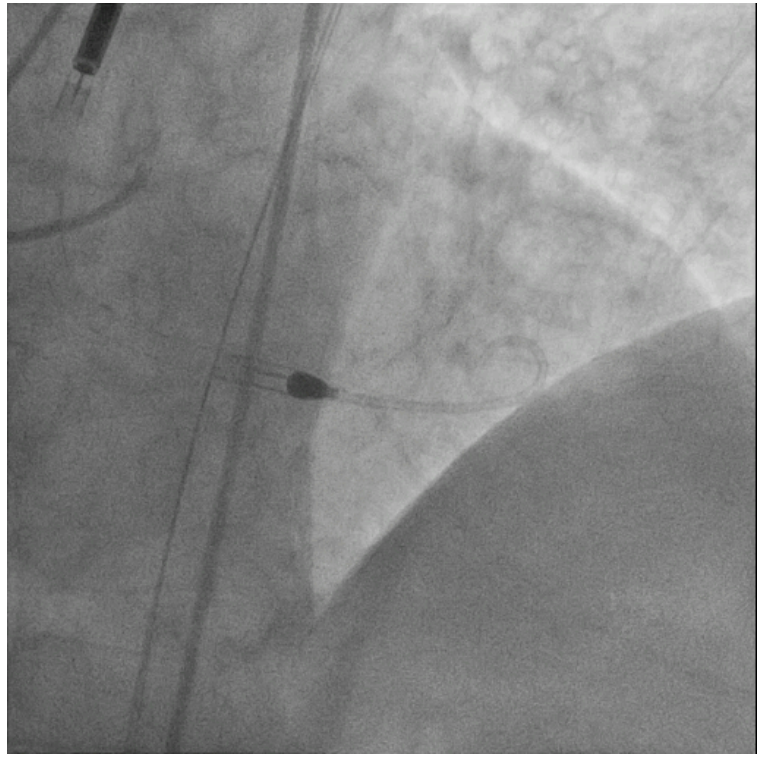

BBC NEWS
FIRST REACTION



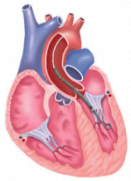


ultrasound-guided access





CENTRAL ILLUSTRATION Randomized Clinical Trials of the Percutaneous Microaxial Flow Pump Device



Percutaneous Microaxial Flow Pump Devices

	High Risk PCI	Role in AMI-CS	Role in Unloading	Role in Protection of Kidneys
Mechanism of Action	• Reduce myocardial oxygen consumption • Improve myocardial blood flow • Maintain systemic perfusion	• Improve cardiac output • Decrease LVEDP • Improve systemic perfusion and BP • Prevent progressive systemic inflammation response syndrome	• Reduce myocardial oxygen-demand • Decrease LVEDP and improve collateral flow • Enhance activity of kinases limiting ischemia reperfusion injury and promote recovery • Preserve mitochondrial integrity	• Improve renal perfusion by increasing cardiac output • Decrease LVEDP resulting in renal venous decongestion
Clinical Trials	• PROTECT II *Future Trials* - PROTECT IV	• ISAR-Shock • IMPRESS • IMPELLA-STIC *Future Trials* - Dan-Ger Shock - REVERSE - RECOVER-IV	• DTU *Future Trials* - DTU-STEMI - UNLOAD-AMI - HERACLES	*Future Trials* - PROTECT KIDNEY

Pahuja M, et al. J Am Coll Cardiol. 2022;80(21):2028-2049.

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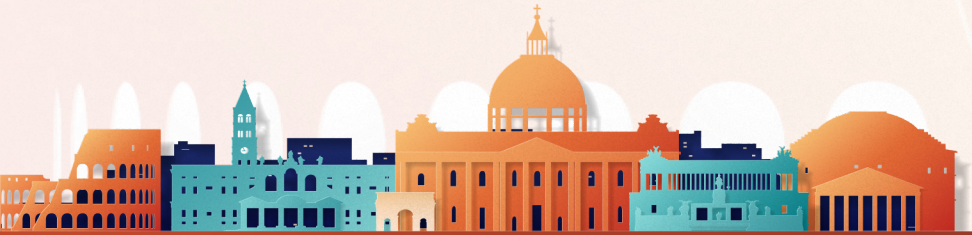

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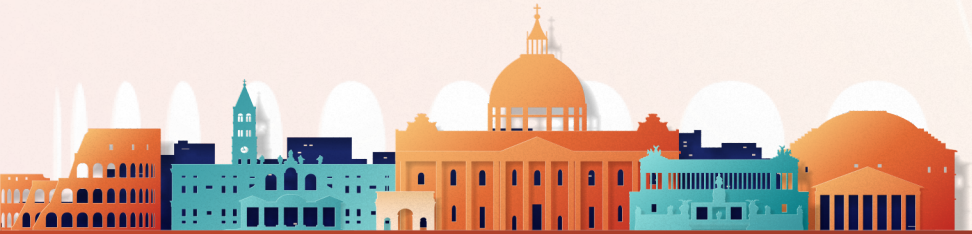
PROTECTED PCI IN HIGH-RISK PATIENTS

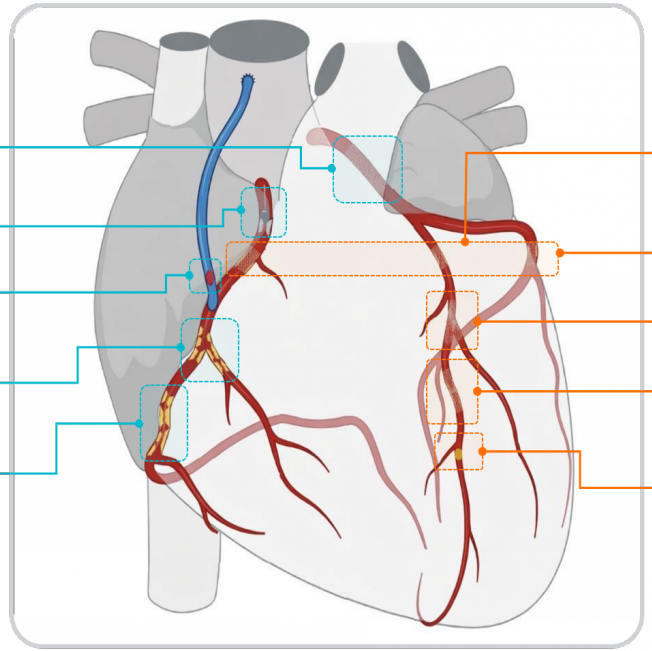
After CHIP-BCIS3: from routine support to precision strategy

Giuliani Livio
L'Aquila



Additional criteria for complex PCI

- Left main PCI
- Use of atherectomy device
- Saphenous vein graft PCI
- Bifurcation with side branch diameter ≥2.5 mm
- Lesion length ≥30 mm



Common criteria for complex PCI

- 3 vessels or ≥3 lesions
- ≥3 stents
- Bifurcation with 2-stent technique
- Total stent length ≥60 mm
- Treatment of chronic total occlusion

CHIP-BCIS3: the trial that changed the conversation

Randomized UK trial: elective microaxial-flow-pump unloading vs standard care during planned complex PCI.

300 patients randomized 148 mAFP / 152 standard care	**22 mo** median follow-up IQR 16–30	**27%** median LVEF	**38** median SYNTAX score	**12** median BCIS-JS

A VERY HIGH-RISK, BUT ATYPICAL, COHORT

Interpretation starts with phenotype: severe LV dysfunction + extensive CAD + high urgent/ACS/HF burden.

Perera et al. CHIP-BCIS3, NEJM 2026; baseline characteristics and trial design.

CHIP-BCIS3: the

Randomized UK trial: electiv **nplex PCI.**

300
patients randomized
148 mAFP / 152
standard care

TAX

12
median BCIS-JS

A VERY HIGH-RISK, BUT ATYPICAL, C

Urgent indication for PCI

Intended left main PCI

Calcium modification

Retrograde CTO

retation starts with
otype: severe LV
ion + extensive CAD
gent/ACS/HF burden.

Perera et al. CHIP-BCIS3, NEJM 2026; baseline characteristics and

Table 1. Demographic and Clinical Characteristics of the Patients at Baseline.*

	Microaxial Flow Pump (N=148)	Standard Care (N=152)
Age — yr	72.2±10.1	73.3±9.3
Male sex — no. (%)	125 (84.5)	123 (80.9)
Race or ethnic group — no. (%)†		
White	124 (83.8)	131 (86.2)
Black	3 (2.0)	2 (1.3)
Asian	21 (14.2)	16 (10.5)
Other ethnic group or missing data	0	3/152 (2.0)
Body-mass index‡	26.9±4.6	27.2±5.3

Table 1. (Continued.)

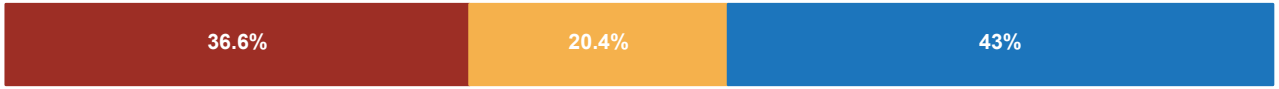
	Microaxial Flow Pump (N=148)	Standard Care (N=152)
Medical history — no. (%)		
Hypertension	105 (70.9)	106 (69.7)
Diabetes	83 (56.1)	73 (48.0)
Current or previous smoker	88 (59.5)	92 (60.5)
Previous PCI	33 (22.3)	34 (22.4)
Previous CABG	11 (7.4)	5 (3.3)
Peripheral vascular disease	21 (14.2)	28 (18.4)
Median left ventricular ejection fraction (IQR) — %	26 (20–31)	28 (20–32)
Median pre-PCI high-sensitivity cardiac troponin level (IQR) — × ULN§	5 (1–26)	13 (3–55)
CCS angina severity class — no./total no. (%)¶		
0	32/137 (23.4)	30/136 (22.1)
1	15/137 (10.9)	20/136 (14.7)
2	32/137 (23.4)	30/136 (22.1)
3	39/137 (28.5)	35/136 (25.7)
4	19/137 (13.9)	21/136 (15.4)
NYHA functional class — no./total no. (%)‖		
I	21/141 (14.9)	17/135 (12.6)
II	56/141 (39.7)	55/135 (40.7)
III	51/141 (36.2)	52/135 (38.5)
IV	13/141 (9.2)	11/135 (8.1)
Median BCIS-JS (IQR)**	12 (10–12)	12 (10–12)
Median SYNTAX score (IQR)††	38 (28–47)	38 (31–49)
Urgent indication for PCI — no. (%)	107 (72.3)	121 (79.6)
Predicted PCI complexity — no. (%)		
Intended calcium modification	118 (79.7)	126 (82.9)
Intended left mainstem procedure	105 (70.9)	111 (73.0)
Intended retrograde procedure for chronic total occlusion	43 (29.1)	39 (25.7)

* Plus–minus values are mean ±SD. CABG denotes coronary-artery bypass grafting, IQR interquartile range, PCI percutaneous coronary intervention, and ULN upper limit of normal range.
† Race or ethnic group was reported by the patient. The categories were Asian or Asian British, Black or Black British, White, other ethnic group, or not provided.
‡ The body-mass index is the weight in kilograms divided by the square of the height in meters.
§ All high-sensitivity cardiac troponin levels were normalized to the ULN for the assay used.
¶ The Canadian Cardiovascular Society (CCS) grade classifies angina severity from 0 (no angina) to 4 (symptoms at rest or on minimal exertion).
‖ The New York Heart Association (NYHA) Functional Class records functional limitation caused by heart failure. Scores range from I (no limitation of physical activity) to IV (symptoms at rest or during minimal exertion).
** The British Cardiovascular Intervention Society Jeopardy Score (BCIS-JS) is used to assess the extent of myocardium jeopardized by coronary artery disease. Scores range from 0 to 12, with higher values indicating a greater extent of disease.
†† The Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery (SYNTAX) score is used to assess the complexity of coronary artery disease. Each score for coronary stenosis is based on multiple factors relating to lesion complexity, with individual lesion scores summed to calculate an overall score. Scores start at 0 with no upper limit. Higher scores indicate more complex disease, with a score of 0 to 22 generally considered to represent low complexity, a score of 23 to 32 indicating intermediate complexity, and a score of 33 or greater indicating high complexity.

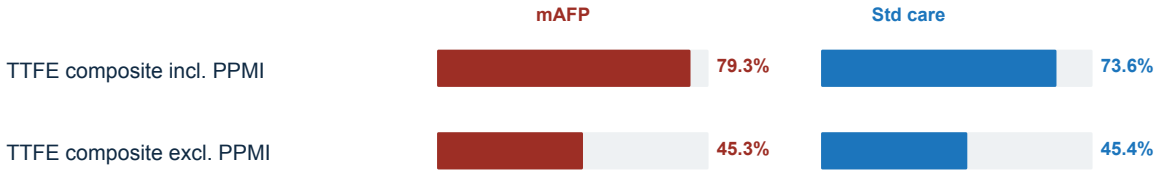
CHIP-BCIS3 primary endpoint: neutral — not even a signal of benefit

Hierarchical composite win ratio: death, disabling stroke, spontaneous MI, CV hospitalization, PPMI

Overall pairwise comparisons



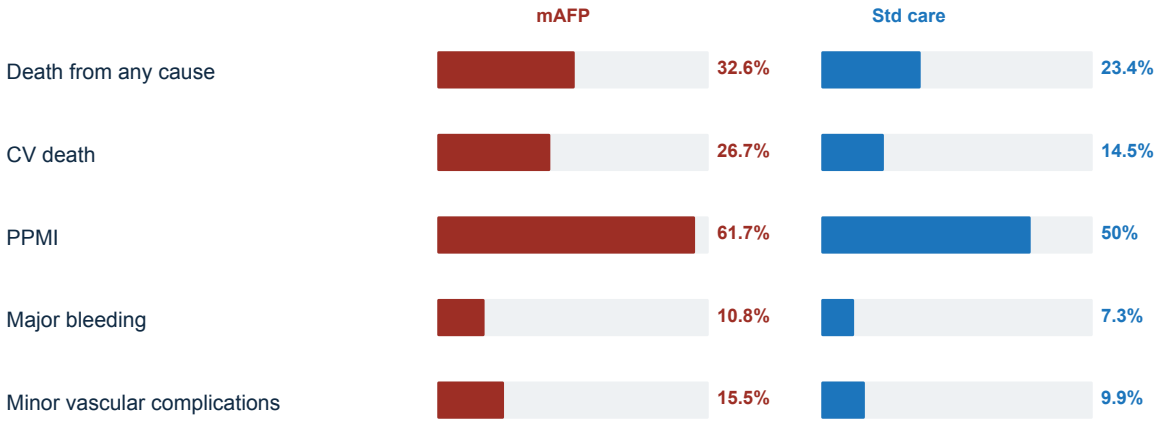
Win Ratio 0.85
95% CI 0.63–1.15
P=0.30



Excluding biomarker-defined PPMI, curves were flat: HR 1.06 (95% CI 0.75–1.49).

Perera et al. CHIP-BCIS3, NEJM 2026; primary outcome and time-to-first-event sensitivity analyses.

Secondary outcomes and safety: where caution is required



Death components were not powered and CIs were not multiplicity-adjusted — but the direction of effect cannot be ignored.

Revascularization completeness was not improved
CRI 67% vs 67%; residual SYNTAX 14 vs 13

Baseline hs-troponin imbalance complicates PPMI interpretation
5× vs 13× ULN

Perera et al. CHIP-BCIS3, NEJM 2026; Table 2, adverse events, procedural endpoints.


92

Why protected PCI still matters

High-risk PCI is not one risk: it is anatomy + myocardium + procedure + comorbidity

RISK DOMAINS

Anatomical risk
LM / MV-CAD
SYNTAX ↑
calcification / CTO

→

Hemodynamic risk
LVEF ↓
LVEDP ↑
BP reserve ↓

→

Procedural risk
long PCI
atherectomy
large ischemic territory

→

Clinical risk
CKD / diabetes
age / frailty
CABG-ineligible

The clinical goal is not simply to "survive the PCI", but to enable safe, complete-enough, ischemia-driven revascularization and recovery.

Source: user-provided protected PCI strategy deck; SCAI/ESC/ACC-AHA guideline synthesis.

What CHIP-BCIS3 should — and should not — tell us

WHAT THE TRIAL CLEARLY SAYS

Routine elective unloading for this broad, HF-enriched high-risk PCI phenotype did not improve major outcomes.

Support did not translate into more complete revascularization.

Signals toward higher mortality demand reflection.

WHAT IT DOES NOT CLOSE

It does not invalidate selective protected PCI in carefully chosen, CABG-ineligible, complex CAD patients.

It does not answer the “right patient / right timing / right endpoint” question.

It does not replace individualized Heart Team decision-making and HF recovery planning.

The trial is best read as a warning against routine use — not as a ban on precision use.

Interpretation based on CHIP-BCIS3 NEJM paper and the uploaded Medscape commentary.

- CHIP-BCIS3 demonstrated a **statistically neutral primary endpoint.**[1]
- Although classified as elective HRPCI, the baseline profile was more **consistent with urgent, advanced decompensated heart failure and Non-STEMI** in the setting of **highly complex multivessel coronary disease**—patients who typically **warrant heart team evaluation and shared clinical decision-making.**[2]
- **Advancing HRPCI research with PROTECT IV -** PROTECT IV is an upcoming **randomized trial (1,252 patients) designed to evaluate Impella™ in a truly elective high-risk PCI population** using contemporary best-practice supported-PCI strategy.[3]

AGIK Position Statement: CHIP-BCIS3

CHIP-BCIS3 Trial: Left Ventricular Unloading in High-Risk PCI

AGIK is the Working Group for Interventional Cardiology within the DGK (German Cardiac Society).

They:

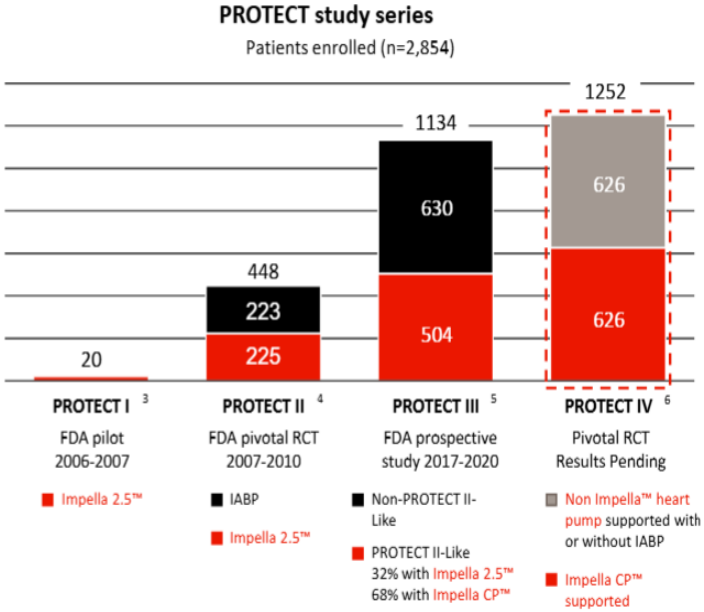
- Provide expert interpretations of clinical trials
- Develop practice-oriented guidance and recommendations
- Support education, training, and scientific exchange
- Help translate evidence into real-world clinical practice

Key Highlights from the paper:

- CHIP-BCIS3 is a neutral trial (no proven benefit of routine Impella use).
- Key limitation: ~2/3 ACS patients → not true elective CHIP.
- Mortality signal = exploratory, not conclusive.
- More aggressive PCI in Impella arm → potential bias.
- Bottom line: no routine use, but selective use in expert centers remains valid.
- PROTECT IV is the study that will provide the real answer.

What is different between CHIP-BCIS3 and PROTECT IV?

- Both trials seek to improve hemodynamic stability and procedural safety in high-risk PCI.
- The BCIS3 study team intended to demonstrate a **relative risk reduction of 38% (hazard ratio: 0.62) or more with 300 patients enrolled.**[1]
- PROTECT IV, we are looking for **25% similar composite at 90% power** with **1252 patients.**[2]



Journal Pre-proof

The Win Ratio in Contemporary Clinical Trials: Growing Adoption and Challenges — A Meta-epidemiological Study

Qize Li, MSc, Yingxuan Zhu, MD, Yanyan Zhao, MSc, Chilie Danzeng Wang, MSc, Ru Jiang, MSc, FeiLong Chen, MD, Xiaoying Lin, MSc, L MSc, Yang Wang, PhD

PII: S0895-4356(26)00190-3

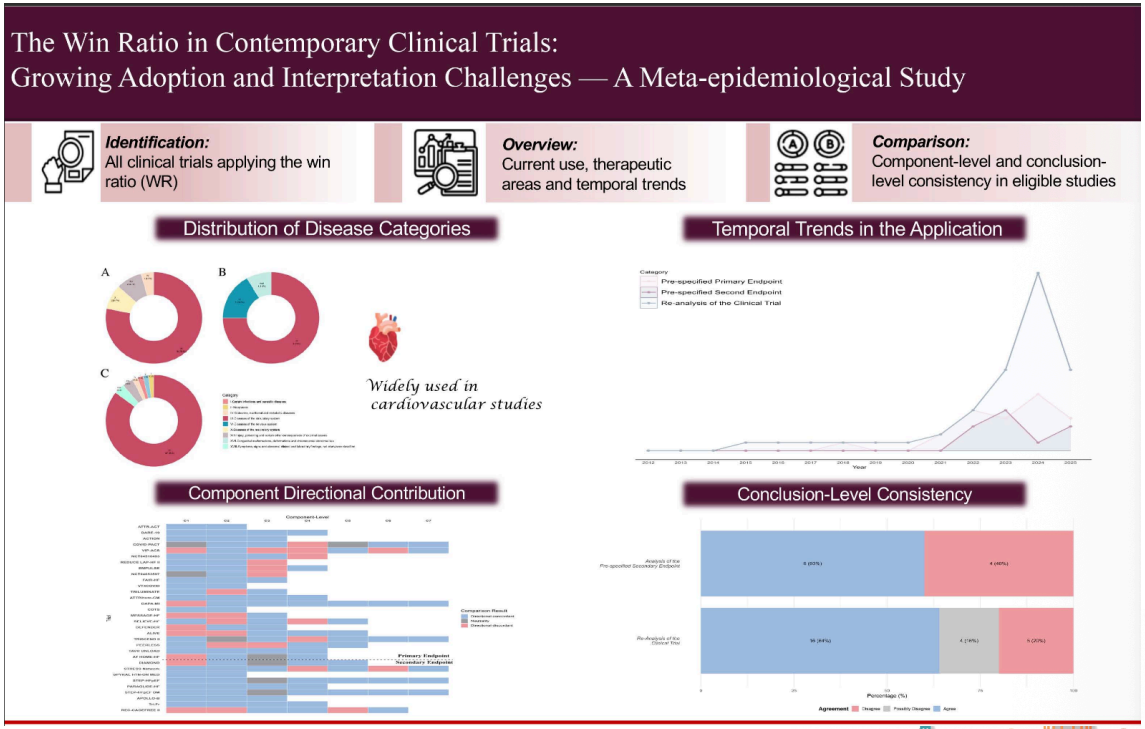
DOI: https://doi.org/10.1016/j.jclinepi.2026.112315

Reference: JCE 112315

To appear in: *Journal of Clinical Epidemiology*

Received Date: 17 October 2025

Revised Date: 28 April 2026



Protected PCI is a strategy — not a pump reflex

Heart Team selection
ischaemia / viability
CABG risk

Pre-PCI optimization
GDMT / volume
access planning

Elective support
right patient
right timing

Better PCI
imaging / physiology
stage when needed

Recovery plan
HF team
CICU if needed

Follow-up
EF / symptoms
GDMT, ICD/CRT

Message after CHIP-BCIS3: no routine “complete revascularization + pump” pathway. Use support to create a window for better decisions.

Contemporary CHIP strategy framework adapted from the uploaded presentation and guideline synthesis.

From BCIS3 to PROTECT IV: the balanced message

ONGOING EVIDENCE GAP

PROTECT IV: randomized Impella-supported PCI vs non-Impella PCI
N≈1252; LVEF ≤40%; complex CAD; follow-up to 36 months

PRACTICAL TAKE-HOME

CHIP-BCIS3: no routine protected PCI for all-comers with severe LV dysfunction.
Impella remains a potentially useful tool in selected patients, especially when it changes feasibility and safety of PCI.
The winning strategy is precision selection + elective support + imaging/physiology-guided PCI + HF recovery.

Protected PCI after CHIP-BCIS3: less enthusiasm, more precision.

PROTECT IV design and strategy synthesis from the uploaded presentation; CHIP-BCIS3 NEJM 2026.

Patient selection after CHIP-BCIS3: find the “right-risk” patient

High risk ≠ right risk. The question is whether support changes the achievable PCI strategy and recovery trajectory.

CONSIDER PROTECTED PCI WHEN THERE IS CONVERGENCE OF

- Severe LV dysfunction / low reserve
- Large ischemic territory / LM-MV CAD
- Complex PCI requiring time and stability
- CABG-ineligible or prohibitive surgical risk
- Potential for meaningful symptom/EF recovery
- Experienced center + bailout/ recovery capability

Avoid reflexive use when the main driver is decompensated HF biology without a clear revascularization-mediated benefit.

Selection framework derived from CHIP-BCIS3 phenotype, guideline recommendations, and the uploaded strategy deck.

Thanks for your attention!!