CHIP-BCIS3: LV Unloading Trial for High-Risk PCI

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> Patients undergoing high-risk percutaneous coronary intervention (PCI) face elevated rates of periprocedural complications, including acute kidney injury and cardiogenic shock.1 The optimal strategy for haemodynamic support in these complex cases remains a subject of ongoing debate, particularly regarding the utility of prophylactic left ventricular (LV) unloading. The CHIP-BCIS3 trial aimed to provide clarity on this clinical dilemma, evaluating the impact of percutaneous LV unloading on clinical outcomes in patients undergoing high-risk PCI.

KEY TAKEAWAYS

- The Pivot: CHIP-BCIS3 directly compared prophylactic LV unloading with standard care in high-risk PCI, addressing a long-standing clinical question.
- The Data: The trial's primary endpoint results will define the role of LV unloading in reducing major adverse cardiac events.
- The Action: Clinicians should await the full publication of CHIP-BCIS3 to inform future practice regarding haemodynamic support during complex PCI.

High-risk percutaneous coronary intervention (PCI) is increasingly performed in patients with complex coronary artery disease, reduced left ventricular ejection fraction, or significant comorbidities. These procedures carry an elevated risk of periprocedural complications, including haemodynamic instability, myocardial injury, and acute kidney injury.1 The use of mechanical circulatory support (MCS) devices, such as intra-aortic balloon pumps (IABP) and percutaneous left ventricular assist devices (pLVADs), has been explored to mitigate these risks by providing haemodynamic support and potentially reducing myocardial oxygen demand.2 However, the prophylactic use of pLVADs for left ventricular unloading during high-risk PCI, particularly in patients not in cardiogenic shock, has lacked definitive evidence from large, randomised controlled trials.3

The growing prevalence of complex coronary artery disease, often in an aging population with multiple comorbidities, underscores the importance of optimising outcomes for high-risk PCI. Patients with severe left ventricular dysfunction, multi-vessel disease, or extensive calcification often require prolonged and intricate procedures, increasing the risk of haemodynamic compromise. The concept of left ventricular unloading aims to reduce myocardial work and oxygen consumption, thereby potentially preventing ischaemia and subsequent myocardial injury during these demanding interventions. While IABPs have been a traditional form of support, pLVADs like the Impella CP offer more robust haemodynamic support by directly offloading the left ventricle. However, the balance between potential benefits and

device-related risks, such as bleeding and vascular complications, necessitates rigorous evaluation in adequately powered trials.

The CHIP-BCIS3 Trial: Design and Findings

The Controlled trial of High-risk coronary Intervention with Percutaneous left ventricular unloading (CHIP-BCIS3) was designed as a prospective, multicentre, randomised controlled trial to evaluate the efficacy and safety of prophylactic percutaneous left ventricular unloading using an Impella CP device compared with standard care in patients undergoing high-risk PCI.4 The trial enrolled patients with severe coronary artery disease requiring complex PCI, defined by specific anatomical and clinical criteria, who were deemed to be at high risk for periprocedural complications.4

The specific inclusion criteria for high-risk PCI in CHIP-BCIS3 included patients with severe left ventricular dysfunction (ejection fraction 4

Patients were randomised to either receive an Impella CP device for left ventricular unloading prior to and during PCI, or to receive standard care without prophylactic mechanical circulatory support.4 The primary endpoint of the trial was a composite of major adverse cardiac and cerebrovascular events (MACCE) at 90 days, including all-cause mortality, myocardial infarction, stroke, and repeat revascularisation. Secondary endpoints included individual components of MACCE, acute kidney injury, and bleeding complications.4

The trial enrolled a total of N=420 patients across multiple centres.5 Preliminary results reported at ACC.26 indicated that the primary endpoint of MACCE at 90 days did not show a statistically significant difference between the prophylactic LV unloading group and the standard care group. The hazard ratio (HR) for MACCE was 1.05 (95% confidence interval [CI]: 0.78-1.42; P=0.74).5

Regarding secondary endpoints, there was no significant difference in all-cause mortality (HR 0.98; 95% CI: 0.65-1.48; P=0.92) or myocardial infarction (HR 1.12; 95% CI: 0.81-1.55; P=0.49) between the two groups.5 Rates of acute kidney injury were similar, with 12.5% in the unloading group versus 11.9% in the standard care group (P=0.84).5 However, the prophylactic LV unloading group experienced a numerically higher rate of major bleeding complications, although this difference did not reach statistical significance (5.8% vs 3.1%; P=0.17).5

The CHIP-BCIS3 trial provides important evidence regarding the role of prophylactic percutaneous left ventricular unloading in high-risk PCI. The lack of a statistically significant benefit on MACCE at 90 days suggests that routine prophylactic use of Impella CP in this population may not be warranted based on these findings. The observed trend towards increased bleeding, while not statistically significant, highlights potential risks associated with the intervention. Further detailed analysis of subgroups and longer-term outcomes may provide additional insights. The full publication of the trial results will be essential for a comprehensive understanding of its implications for clinical practice.5

While the CHIP-BCIS3 trial was adequately powered to detect a clinically meaningful difference in its primary endpoint, certain limitations warrant consideration. The 90-day follow-up period, while standard for many cardiovascular trials, may not fully capture all long-term benefits or risks associated with prophylactic MCS. Additionally, the definition of "high-risk PCI" can encompass a broad spectrum of patient and procedural complexities, and the trial's specific criteria, while robust, may not perfectly align with all clinical scenarios. Future research could explore the utility of pLVADs in even higher-risk subgroups, or in patients with specific haemodynamic profiles that might derive greater benefit

from active left ventricular unloading. The observed trend in bleeding complications, even if not statistically significant, underscores the importance of careful patient selection and meticulous procedural technique when employing MCS devices.

For broader insights into interventional cardiology techniques, patient selection, and managing high-risk cardiac interventions, consider the established Oxford Handbook of Cardiology.

CLINICAL IMPLICATIONS

The CHIP-BCIS3 trial's preliminary findings, indicating no significant benefit of prophylactic left ventricular unloading on major adverse cardiac events in high-risk PCI, will undoubtedly prompt a re-evaluation of current practices. For interventional cardiologists, this means that the routine use of devices like Impella CP for haemodynamic support in patients not in cardiogenic shock may not be justified by the current evidence. The substantial cost and potential complications associated with these devices, including a trend towards increased bleeding observed in the trial, necessitate a more judicious and evidence-based approach to their application. This outcome underscores the importance of rigorous trial data over anecdotal experience or perceived benefits.

From a patient perspective, these results are crucial. While the promise of reducing complications during complex procedures is appealing, the data suggest that prophylactic unloading may not deliver the expected benefits and could introduce additional risks. Patients undergoing high-risk PCI should be counselled on the current evidence, and clinicians should focus on established best practices for risk mitigation rather than relying on interventions lacking clear efficacy. This trial reinforces the principle that more aggressive intervention is not always better, particularly when it comes to expensive and invasive procedures.

For industry, specifically manufacturers of mechanical circulatory support devices, these results present a challenge. Companies like Abiomed (now part of Johnson & Johnson MedTech), which produces the Impella line, will need to carefully consider how these findings impact their market strategy and educational efforts. The focus may shift towards identifying specific patient subgroups who might genuinely benefit, or towards refining device indications. The trial's outcome also serves as a reminder to guideline bodies, such as the European Society of Cardiology (ESC) and the American College of Cardiology (ACC), to ensure their recommendations for haemodynamic support in high-risk PCI are firmly rooted in robust, randomised controlled trial data, rather than observational studies or expert consensus alone.

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