



BRITISH CARDIOVASCULAR INTERVENTION SOCIETY

BCIS Officers:

President: Prof Daniel Blackman
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British Cardiovascular Intervention Society (BCIS) position statement on the role of temporary percutaneous mechanical circulatory support.

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This statement is intended to provide an update for the membership of BCIS, in relation to the use of micro axial flow pumps (mAFPs). We have taken into consideration recent evidence, in the context of existing guidelines and NICE guidance, on the use of mAFPs in high-risk PCI (HTG492, November 2018) and cardiogenic shock (HTG775, March 2026).

Although focused on the indications and appropriateness of mAFP use, this statement extends to provide guidance on the broader care of high-risk patients in the cathlab.

Defining high risk

Dependent upon the guidance or trial inclusion criteria, the definition of high-risk varies.

NICE guidance 2018 HTG492 (www.nice.org.uk/guidance/htg492)

- i. Extensive or complex CAD (unprotected left main stem (LMS) disease, last remaining vessel, or multi-vessel disease)
- ii. Poor left ventricular (LV) function
- iii. Ongoing myocardial ischaemia
- iv. Cardiogenic shock

PROTECT II¹

- i. Unprotected LMS with LV ejection fraction (LVEF) $\leq 35\%$
- ii. Last patent coronary vessel with LVEF $\leq 35\%$
- iii. 3-vessel disease with LVEF $\leq 30\%$

CHIP-BCIS^{3,2}

- i. LVEF $\leq 35\%$ (or LVEF $\leq 45\%$ with severe mitral regurgitation (MR))
- ii. Extensive coronary artery disease as indicated by BCIS-Jeopardy score ≥ 8 (<https://bcis-js.com/> - maximum score 12)
- iii. Complex planned PCI (target vessels include LMS bifurcation +/- multivessel calcium modification +/- chronic total occlusion (CTO) with primary retrograde approach)

For the purpose of this statement we will consider 3 separate ‘at-risk’ populations:

1. High-risk coronary anatomy in the context of severe LV dysfunction
2. Acute myocardial infarction
3. Cardiogenic shock

1. High-risk PCI in the context of severe LV dysfunction

Existing NICE guidance (HTG492) acknowledged the neutral result of Protect II¹, a study terminated prematurely due to likely futility and cautioned operators regarding infrequent but serious and well-recognised safety concerns associated with the use of mAFPs. A more contemporary European guideline supports the use of a mAFP in high-risk PCI for complex CAD in patients with heart failure with reduced EF³ with a class IIb, level of evidence C, recommendation.

Most recently, CHIP-BCIS3 compared an approach of elective LV unloading with a mAFP vs standard care during planned complex PCI in patients with severe LV dysfunction². The primary outcome was a hierarchical composite that included all-cause mortality, disabling stroke, spontaneous MI, hospitalisation for cardiovascular causes, or periprocedural myocardial injury, as analysed according to a win ratio. At a median of 22 months, 36.6% of pairwise comparisons favoured the mAFP, and 43.0% favoured standard care (win ratio, 0.85; 95% CI 0.63 to 1.15 p=0.30). Death from any cause occurred in 47 patients in the mAFP group and 33 in the standard-care group (HR 1.54; 95% CI 0.99 to 2.41). Even when considered as a time to first event (rather than hierarchical) composite outcome, elective LV unloading failed to reduce the risk of major adverse clinical outcomes. Completeness of revascularisation was balanced between groups; however, the standard care group more frequently underwent staged PCI. Major vascular complications were infrequent in both groups (1.4% vs 0.7% with mAFP & standard care, respectively). A pre-specified haemodynamic sub-study demonstrated use of a mAFP resulted in less use of vasopressors/inotropes but a greater frequency of loss of pulse pressure, associated with periprocedural myocardial injury⁴. This sub-study also showed that patients selected by CHIP-BCIS3 clinical inclusion criteria had severely reduced haemodynamic reserve and so fulfilled criteria for SCAI Cardiogenic Shock Classification Level A (at risk of shock).

BCIS Recommendations for high-risk PCI

- i. The combination of extensive coronary artery disease, severely impaired LV systolic function, and high expected procedural complexity (as encapsulated in the CHIP-BCIS3 inclusion criteria) identifies a population at high risk of death following PCI. Risk stratification according to these metrics may be useful for heart teams and when counselling patients
- ii. Routine use of a mAFP in high-risk PCI is not supported by current evidence
- iii. Careful procedural planning, and staging of PCI, should be considered in complex cohorts
- iv. CT planning and ultrasound guidance of large-bore vascular access may positively impact the safe deployment of mAFPs, whether used as an elective or bail-out strategy
- v. If considered appropriate for selected patients, mAFPs should only be used in PCI centres with the requisite skills and experience, including large bore access management, device implantation, trouble-shooting expertise, and appropriate in-dwelling device management services (including a trained intensive care unit for patients who may require mAFP support after the PCI procedure).
- vi. All patients undergoing mAFP-supported intervention must be entered into the British Cardiovascular Intervention Society percutaneous coronary interventions database

2. Acute Myocardial Infarction

Mechanical revascularisation has transformed the management of ST elevation myocardial infarction. However, the incidence of STEMI and the substantial associated morbidity and mortality drive ongoing efforts to enhance outcomes. In line with current evidence, we consider the role of mAFP in uncomplicated anterior STEMI in this section & will evaluate acute myocardial infarction-related cardiogenic shock (AMICS) in section 3.

The ST-segment elevation myocardial infarction door to unload randomised controlled trial reported at ACC 2026⁵, and hypothesised that unloading the LV before reperfusion may reduce infarct size and improve clinical outcomes. A total of 527 patients presenting with uncomplicated anterior STEMI, within 1-6 hrs of symptom onset, were recruited between December 2019 and September 2024 with 262 patients randomised to the investigational arm. Treatment involved placement of a mAFP and 30minute delay to PCI, with maintenance of the device for a minimum of 4hours. The primary outcome was infarct size normalised to LV mass (IS/LVM) evaluated by CMR 3-5 days after PCI. Use of a mAFP with delay to reperfusion did not reduce infarct size compared with immediate PCI in patients with acute anterior myocardial infarction uncomplicated by cardiogenic shock (Infarct size/LV mass was 30.8% +/-16.2% vs 31.9% +/-16.9% in control (mean diff -1.1%; 95%CI: -4.2-2.0, p=0.50). A post-hoc analysis comparing mAFP treatment with standard care demonstrated significantly more occurrence of major bleeding or vascular complications in the treatment group (34.0% vs 6.0%, p<0.01).

BCIS Recommendation for acute STEMI

- i. The upfront use of mAFP in the treatment of acute STEMI is not indicated

3. Cardiogenic Shock

The shock to survival framework document (<https://ics.ac.uk/static/8d541809-af1e-4e46-89c0d4382fd41bc6/Shock-to-Survival-Reportfinal.pdf>) identifies cardiogenic shock (CS) as a complex illness with effective treatment requiring early identification, classification of severity, escalation of treatment, intervention, and ideally with input from a network CS centre. A role for mechanical circulatory support (MCS) is acknowledged in deteriorating patients; however, criteria for escalation have not been agreed. Instead, it is acknowledged that treatment is best delivered through involvement of a CS-MDT, ideally comprising an interventional cardiologist, intensivist/cardiac intensivist, cardiac critical care nursing staff, heart failure cardiologist, and cardiac surgeon. Temporary MCS should be available in all CS-centres and be considered in select patients as a bridge to decision, bridge to recovery, or bridge to candidacy for either long-term MCS or urgent heart transplantation.

The recent NICE HTG775 for the 'percutaneous insertion of a catheter-based left ventricular microaxial flow pump for cardiogenic shock' (www.nice.org.uk/guidance/htg775) acknowledges that mAFP can be used to provide temporary short-term cardiac support

when the shock state has not responded to other forms of treatment, while more evidence is generated. It recognised recent positive data specific to the role of mAFP in the management of a subgroup of patients with acute myocardial infarction-related CS (AMICS)⁶.

3.1 AMICS

It is acknowledged that AMICS, which comprises nearly half of CS cases, is associated with high mortality rates ranging between 40-60%. Studies investigating the role of MCS with extracorporeal life support (ECLS) or a mAFP have provided mixed results. Importantly, the populations treated with these MCS devices differed significantly, as illustrated in the table below.

Shock Definition	ECLS-SHOCK ⁷	Dan-Ger SHOCK ⁶
Lactate	>3mmol/L	≥2.5mmol/L
Systolic blood pressure	<90mmHg or vasopressor requirement	<100mmHg or vasopressor requirement
LVEF	Not required	<45%
Additional signs of hypoperfusion	At least one of: confusion, oliguria, cold or clammy skin	Not required
Exclusion Criteria		
Out of hospital cardiac arrest (OHCA)	CPR >45minutes before randomisation	Comatosed OHCA
Other	Mechanical cause for shock	Overt right ventricular failure
	Severe PAD	Severe valvular disease

Dan-Ger-Shock randomised patients presenting with STEMI and CS to receive mAFP plus standard care or standard care alone. The primary endpoint was death from any cause at 180 days. A composite safety endpoint included severe bleeding, limb ischaemia, haemolysis, device failure, or worsening aortic regurgitation (AR). Routine use of a mAFP in parallel with standard care in the management of AMICS led to lower risk of all-cause death

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at 180 days (45.8% vs 58.5%, HR 0.74; 95% CI 0.55-0.99; $p=0.04$). Importantly, the incidence of the composite safety endpoint was higher with the use of mAFP (24.0% vs 6.2%, RR 4.74; 95% CI 2.36-9.55). Subsequent analyses have suggested that the benefit of mAFP may be with earliest implantation⁸ but limited to patients with systolic blood pressure ≤ 82 mmHg⁹ and below 77yrs of age¹⁰.

BCIS Recommendations

- i. Early recognition of CS expedites treatment
- ii. SCAI staging of CS should be adopted (to standardise the description of CS thereby facilitating triage) and the underlying aetiology considered.
- iii. Whenever feasible, a CS-MDT should be engaged to support the management and escalation of treatment
- iv. mAFPs should be considered for selected patients with suitable indications in PPCI centres with on-site intensive care expertise and by healthcare professionals with specific training in this procedure
- v. All patients must be entered into the British Cardiovascular Intervention Society percutaneous coronary interventions database

References

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