

Percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

1 Recommendations

- 1.1 Current evidence on the safety of percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions shows there are serious, infrequent but well-recognised safety concerns. Evidence on efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out [what special arrangements mean on the NICE interventional procedures guidance page](#).
- 1.2 Clinicians wishing to do percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions should:
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information to support [shared decision-making](#). In addition, the use of [NICE's information for the public on percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support](#) is recommended.

- Details of all patients should be entered into the [British Cardiovascular Intervention Society percutaneous coronary interventions database \(BCIS PCI database\)](#).
- 1.3 Patient selection should be done by an experienced multidisciplinary team, when the urgency of the clinical situation allows.
- 1.4 The procedure should only be done in specialised centres by clinicians and teams with specialised training in the use of this technology and experience in complex percutaneous coronary interventions.
- 1.5 Further research should report details of patient selection and subsequent management.

2 The condition, current treatments and procedure

The condition

- 2.1 Additional support for the heart is not usually needed with angioplasty or percutaneous coronary intervention. However, a subset of high-risk patients may benefit from some form of heart support during their angioplasty procedure. This includes those with extensive or complex coronary artery disease (unprotected left main disease, last remaining vessel or multi-vessel disease), poor left ventricular function, ongoing myocardial ischemia, cardiogenic shock and comorbidity, in whom revascularisation may not otherwise be possible.

Current treatments

- 2.2 Temporary percutaneous mechanical haemodynamic support can be used prophylactically in some elective high-risk angioplasty procedures or in urgent procedures. The aim is to support the patient's circulatory system, provide blood flow to increase cardiac output, unload the ventricle and improve blood flow to maintain haemodynamic stability. This minimises myocardial ischemia and reduces the risk of

haemodynamic collapse during the procedure. Intra-aortic balloon pumps or extra-corporeal pumps may be used for temporary percutaneous mechanical haemodynamic support. Percutaneous left ventricular-assist devices for haemodynamic support are sometimes used instead of intra-aortic balloon pumps or extra-corporeal pumps.

The procedure

- 2.3 Inserting a temporary percutaneous mechanical haemodynamic support device may be done before or during percutaneous coronary intervention in selected high-risk patients, and is then taken out when the patient is stable.
- 2.4 The procedure is done under local anaesthesia. An introducer sheath is inserted into a large artery (usually the femoral or axillary artery) and a guidewire is passed into the left ventricle. A catheter with an integrated pump at its distal end is passed over the guidewire, into the large vessel and into the left ventricle. Fluoroscopic imaging is used during the procedure. The catheter is then attached to an automated external console, which controls the pump speed and monitors its function, allowing blood to be taken from the left ventricle and pumped into the ascending aorta.
- 2.5 Different miniature, catheter-based, intravascular devices are available and the precise implantation technique varies according to the device.

3 Committee considerations

The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 10 sources, which was discussed by the committee. The evidence included 4 systematic reviews, 3 case series, 1 randomised controlled trial and 2 case reports, and is presented in [table 2 of the interventional](#)

procedures overview. Other relevant literature is in appendix A of the overview.

- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: procedural success and completeness of revascularisation, haemodynamic stability, survival to hospital discharge, survival at 30 days, and rate of major adverse cardiac events.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: vascular damage, bleeding, haemolysis and left ventricle damage.
- 3.4 Four commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

Committee comments

- 3.5 The committee noted that:
- Evidence of benefit for patients with cardiogenic shock is limited. In the evidence reviewed, there were only a small number of patients with cardiogenic shock who could not have percutaneous coronary intervention and the outcomes of these patients are poor.
 - The use of the procedure may allow intervention in patients who would otherwise be unable to have percutaneous coronary intervention. This may include patients who have had previous coronary artery surgery.
 - The risks of bleeding has reduced with improvement in the design of the technology.
 - More than 1 device is available for use in this procedure and the technology is evolving.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).