NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

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

Some people having elective or urgent high-risk procedures to their heart arteries (percutaneous coronary interventions) may need support with circulatory blood flow support devices to reduce the risk of their heart and circulation failing during the operation. In this procedure, a catheter (a thin tube) with a pump in the end is inserted into the left ventricle in the heart through a large artery (usually in the groin or arm pit). The aim is to help the heart pump blood round the body during a heart operation.

The National Institute for Health and Care Excellence (NICE) is looking at percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.

Issue date: [month year]

- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide.

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 23 August 2018

Target date for publication of guidance: November 2018

1 Draft 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.

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 *[[URL to be added at publication]]* is recommended.
- Details of all patients should be entered into the National Audit of Cardiac Rhythm Management database at the UK National Institute for Cardiovascular Outcomes Research (NICOR).

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 special training 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 (PCI). However, a subset of high-risk patients 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 co-morbidity may benefit from some form of heart support during their angioplasty procedure.

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

The procedure

2.3 Inserting a temporary percutaneous mechanical haemodynamic support device can be done before, during or after PCI 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 ascending aorta and across the aortic valve 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. One device needs a trans-septal puncture to be done.

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 8 sources, which was discussed by the committee. The evidence included 4 systematic reviews, 2 retrospective studies, one randomised controlled trial and 1 case

report, 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: 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, left ventricle damage and acute procedure-related mitral regurgitation.

3.4 Three commentaries from patients who had experience of this procedure was received, which was discussed by the committee.

Committee comments

3.5 The committee noted that:

- Evidence of benefit for patients with cardiogenic shock is limited.
- More than 1 device is available for use.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
July 2018