

Percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg711

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.

This guidance replaces IPG463.

1 Recommendations

- 1.1 Evidence on the safety and efficacy of percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what [standard arrangements mean on the NICE interventional procedures guidance page](#).
- 1.2 Patient selection, continuing monitoring and management should be done by a multidisciplinary team. This should include healthcare professionals (both a doctor and a nurse) experienced in managing chronic heart failure, and interventional specialists experienced in right-heart catheterisation and inserting this device.

2 The condition, current treatments and procedure

The condition

- 2.1 Heart failure happens when the pumping action of the heart is impaired by structural or functional abnormalities. It can lead to reduced blood flow to the body tissues and increased filling pressure in the heart. This causes congestion and oedema in the lungs (causing breathlessness) and the body (causing swelling in the legs). Symptoms include breathlessness, reduced exercise tolerance, oedema, fatigue and malaise.

Current treatments

- 2.2 Diagnosis and management of chronic heart failure is described in [NICE's guideline on chronic heart failure in adults](#). Treatments include lifestyle changes, medicines, device implantation (to help control heart rhythm) and heart surgery (such as a bypass operation or a heart transplant).
- 2.3 Chronic heart failure needs regular monitoring to identify signs of deterioration and modify treatment, with the aim of improving the patient's quality of life and avoiding hospital admissions. Monitoring includes assessment of functional capacity, fluid status, blood pressure, cardiac rhythm, renal function, and cognitive and nutritional status. Medication is reviewed and adjusted if necessary. Implantable devices to monitor haemodynamic changes may assist heart failure monitoring.

The procedure

- 2.4 A delivery catheter is introduced into a large vein (usually the femoral vein) under local anaesthesia. Under radiological guidance, the catheter is used to pass a small pressure sensor through the heart and into a suitable branch of the

pulmonary artery. The pressure sensor is deployed and the delivery catheter removed. Data on pulmonary artery pressure (PAP), such as pressure trend information and PAP waveforms, is transmitted from the sensor to an external monitor in the patient's home. The monitor securely transmits the data to a remote database that can be accessed by the heart failure team. The patient usually collects and transmits data daily, or more often if needed by the heart failure team.

- 2.5 This procedure makes data available that can be used to guide the ongoing monitoring and management of chronic heart failure. The aim is to reduce hospitalisations caused by heart failure.

3 Committee considerations

The evidence

- 3.1 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 9 sources, which was discussed by the committee. The evidence included 2 randomised controlled trials, 1 case control study, 5 case series and 1 review of US Food and Drug Administration MAUDE (Manufacturer and User Facility Device Experience) database. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduction in hospital admissions for heart failure, improvement in heart failure symptoms and improvement in quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: device failure, malfunction or migration, cardiac perforation, pulmonary artery injury and infection.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 There is more than 1 device available for this procedure.
- 3.6 Evidence on the efficacy of the procedure focuses primarily on reducing hospital admissions.
- 3.7 Most of the evidence the committee considered was for patients with New York Heart Association class 3 heart failure. The clinical expert confirmed that this reflects current clinical practice.
- 3.8 One device for which the committee reviewed evidence required the patient to lie on a special pillow for 18 seconds every day.
- 3.9 The committee encourages data entry to a suitable registry with a commitment to publish all outcomes.

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Endorsing organisation

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