

# Insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg463](http://www.nice.org.uk/guidance/ipg463)

## 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. However, 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.

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.

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 and efficacy of the insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure is limited in both quality and quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to insert and use implantable pulmonary artery pressure monitors in chronic heart failure should take the following actions.
- Inform the clinical governance leads in their Trusts.
  - Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and safety and provide them with clear written information. In addition, the use of NICE's [information for the public](#) is recommended.
  - Audit and review clinical outcomes of all patients having pulmonary artery pressure monitors inserted (see [section 7.1](#)).
- 1.3 NICE encourages further research into the insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure, particularly studies that look at their long-term effects on hospital admissions and quality of life and that record adverse events.

# 2 Indications and current treatments

- 2.1 Heart failure occurs 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, which causes congestion and oedema in the lungs (causing breathlessness) and/or the body (causing swelling in the legs). Symptoms include breathlessness, reduced exercise tolerance, oedema, fatigue and malaise.
- 2.2 Treatment for chronic heart failure involves lifestyle changes and pharmacological treatments such as angiotensin-converting enzyme inhibitors, beta-blockers, aldosterone antagonists, angiotensin II receptor antagonists, diuretics, hydralazine in combination with nitrate, and digoxin (see [Chronic](#)

heart failure: management of chronic heart failure in adults in primary and secondary care [NICE clinical guideline 108]). Cardiac resynchronisation therapy is used in some patients.

- 2.3 Patients with chronic heart failure are monitored to identify signs of deterioration in order to modify treatment, with the aims of improving their quality of life and avoiding admission to hospital. This monitoring typically includes clinical assessment of functional capacity, fluid status (for example by body weight), cardiac rhythm, and cognitive and nutritional status. Clinical monitoring and treatment in the community, usually by nurses, may reduce the incidence of complications and subsequent hospitalisation.

## 3 The procedure

- 3.1 Insertion of implantable pulmonary artery pressure monitors is usually done under local anaesthesia. Using a percutaneous approach, commonly via the femoral vein, a passive radiofrequency sensor without batteries or leads is implanted into a distal branch of the pulmonary artery, with radiological guidance. The sensor is anchored within the artery.
- 3.2 Data are downloaded in a secure format via an antenna linked to a computer in the patient's home. The antenna can be housed in a pillow on which the patient lies for this purpose. Data are then forwarded daily by the patient to a remote secure database from where the information can be accessed by the heart failure team.

## 4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 4.1 A randomised controlled trial (RCT) of 550 patients whose condition was managed by either pulmonary artery pressure monitoring or standard monitoring reported 84 and 120 heart failure-related hospitalisations respectively at 6-month follow-up ( $p < 0.0001$ ). By the end of the trial (mean follow-up 15 months) there were 158 heart failure-related hospitalisations in

the pressure monitor group versus 254 in the control group ( $p < 0.0001$ ).

- 4.2 The RCT of 550 patients reported 174 and 172 mean days alive outside hospital in the pressure monitor and control groups respectively at 6-month follow-up ( $p = 0.02$ ).
- 4.3 The RCT of 550 patients reported mean scores of 45 and 51 on the Minnesota Living with Heart Failure Questionnaire (lower scores indicate a better quality of life, and a 5-point difference is considered clinically significant) in the pressure monitor and control groups respectively at 6-month follow-up ( $p = 0.02$ ).
- 4.4 The specialist advisers listed efficacy outcomes as reduction in heart failure-related hospitalisations, improved quality of life, and mortality.

## 5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 5.1 Failure of the delivery system and the need for a snare to remove it was reported in 1 patient in the RCT of 550 patients. Pressure sensor failure was reported in 1 patient in a case series of 40 patients at 6-month follow-up.
- 5.2 Cardiogenic shock was reported in 1 patient in the RCT of 550 patients, the timing of which was not reported. Exacerbation of pre-existing atrial arrhythmias during right-heart catheterisation was reported in less than 1% (2/550) of patients in the same study.
- 5.3 The specialist advisers listed anecdotal adverse events including excessive reduction in blood pressure and renal dysfunction caused by aggressive treatment of raised pulmonary artery pressure.
- 5.4 The specialist advisers listed theoretical adverse events including embolism of the device into the peripheral pulmonary tree, infection, pulmonary embolism, rupture of branch pulmonary artery, movement of the device, faulty communication of data, and errors in clinical decision-making based on

measurements (even if the measurements are accurate).

## 6 Committee comments

- 6.1 The Committee noted that most of the evidence for efficacy came from 1 single-blind RCT with its primary end point at 6-month follow-up. Given the prevalence and chronicity of chronic heart failure in the population the Committee considered that more and longer-term data were necessary to better understand the role of pressure monitoring in its management; this underpinned the recommendation for further research.
- 6.2 The Committee noted that other interventional procedures and implantable devices have been used for the direct or indirect monitoring of intracardiac pressure in heart failure. These monitor pressure at other sites, including the left atrium and right ventricular outflow tract, and various procedures are used for their insertion.

## 7 Further information

- 7.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an [audit tool](#) (which is for use at local discretion).
- 7.2 For related NICE guidance see [the NICE website](#).

## Information for patients

NICE has produced information on this procedure for patients and carers ([Information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

## About this guidance

NICE interventional procedures guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the

procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedures guidance process](#).

We have produced a [summary of this guidance for patients and carers](#). Tools to help you put the guidance into practice and information about the evidence it is based on are also [available](#).

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their 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.

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## Endorsing organisation

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

## Accreditation

