NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

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

In chronic heart failure your heart muscle is weak and not able to pump blood around your body strongly enough. This causes pressure to increase in the pulmonary artery (the blood vessel that takes blood from the heart to the lungs). In this procedure, a small electronic pressure sensor is inserted through the skin (percutaneous) into a vein in the thigh or the neck and then into the pulmonary artery. The sensor sends daily blood pressure measurements to a monitor in your home. The monitor sends the measurements to your care team, who can assess whether your treatment needs adjusting. The aim is to manage treatment and reduce hospital admissions.

This is a review of NICE's interventional procedures guidance on insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

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

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

Issue date: July 2021

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

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

Closing date for comments: 19 August 2021

Target date for publication of guidance: December 2021

1 Draft 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 and treatment 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, are 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. Collection and transmission of data are usually done by the patient daily or more frequently if required by the heart failure team.

2.5 This procedure allows the provision of data to guide the management of chronic heart failure, with the aim of reducing 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 8 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial, 1 case control study, 5 case series and 1 review of US Food and Drug Administration 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 The committee noted that there is more than 1 device available for this procedure.

3.6 The committee noted that evidence on the efficacy of the procedure focuses primarily on the reduction in hospital admissions.

3.7 The committee noted that most of the evidence it 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 The committee noted that for 1 device for which it reviewed evidence, the patient was required 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.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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