

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional procedures consultation document

### Permanent His-bundle pacemaker implantation for treating heart failure

Heart failure is when your heart is not able to pump blood around your body well enough. In this procedure, a wire is inserted through a vein into the heart and attached to its specialised electrical conduction pathway (His bundle). This differs from traditional pacemaker placement, when the wire is attached to heart muscle. The wire is then connected to a pacemaker placed under the skin of the chest, which delivers electrical pulses. The aim is to help the heart pump blood more efficiently.

NICE is looking at permanent His-bundle pacemaker implantation for treating 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This document contains the [draft guidance for consultation](#).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 The draft guidance may change after this consultation.**

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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 17 December 2020

Target date for publication of guidance: April 2021

## 1 Draft recommendations

- 1.1 Evidence on the safety and efficacy of permanent His-Bundle pacemaker implantation for treating heart failure is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out [what only in research means on the NICE interventional procedures guidance page](#).
- 1.2 This is a technically challenging procedure and experience in cardiac electrophysiology is needed. It should only be done in specialist centres with experience of cardiac pacing.
- 1.3 Further research should be in the form of randomised controlled trials or registry data. It should report details of patient selection. Outcomes should include quality of life using relevant and validated measures, including the New York Heart Association classification, survival and the need for hospital admissions.

## **2 The condition, current treatments and procedure**

### **The condition**

- 2.1 Heart failure is a complex clinical syndrome of symptoms and signs that happen when the heart is not working well enough. It leads to reduced blood flow to body tissues and can cause oedema in the lungs (causing breathlessness) and swelling of the legs. Other symptoms include reduced ability to exercise, fatigue and malaise. Heart failure can be caused by structural or functional abnormalities of the heart.

### **Current treatments**

- 2.2 Treatments for heart failure are described in [NICE's guideline on diagnosing and managing chronic heart failure in adults](#). They initially include drugs to improve heart function. However, as heart failure becomes more severe, it becomes unresponsive to drugs alone. Implantation of specific devices to sense and stimulate the heart chambers might then be recommended as an adjunctive treatment. This is known as cardiac resynchronisation therapy (CRT) which may also include insertion of a defibrillator (CRT-D) or pacing (CRT-P).
- 2.3 Other treatments include cardiac rehabilitation, coronary revascularisation (when there is coronary artery narrowing), a heart transplant and palliative care. Permanent His-bundle pacemaker implantation may be another option for people with advanced heart failure.

### **The procedure**

- 2.4 The aim of implanting a permanent pacemaker at the His bundle is to produce normal physiological ventricular activation via the His-Purkinje system.

- 2.5 The procedure is done under local anaesthesia, with or without sedation, in a cardiac catheterisation laboratory. A pacemaker generator is implanted under the skin near the collarbone, usually on the left side of the chest (although the right side is possible). A pacing lead is inserted through the subclavian, cephalic or axillary vein into the heart. This is done under fluoroscopic guidance and continuous electrocardiogram monitoring or mapping, and using a specially designed His-delivery sheath. It is then positioned and secured to the His bundle, where it can directly stimulate the His-bundle fibres. An electrogram from the tip of the lead is used to ensure a His signal and that the pacing lead is correctly placed. The pacemaker generator is securely connected to the His-bundle lead. The generator can be adjusted transcutaneously to ensure optimum His-bundle pacing.

### **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 5 sources, which was discussed by the committee. The evidence included 1 systematic review, 1 randomised controlled trial, 1 case control study and 2 case series. 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: quality of life using relevant and validated measures such as the New York Heart Association classification, survival, improved cardiac function, and the need for hospital admissions.

- 3.3 The professional experts and the committee considered the key safety outcomes to be: cardiac perforation, cardiac arrhythmia, infection, lead breakage and lead displacement.
- 3.4 One commentary from a patient who has had this procedure was discussed by the committee.

### **Committee comments**

- 3.5 The procedure may have a role in preventing pacemaker-induced cardiomyopathy, which can occur with standard right ventricle pacing techniques.
- 3.6 In contrast to conventional right ventricular pacing, in this procedure, the pacemaker lead does not usually need to be passed through the tricuspid valve and into the right ventricle.
- 3.7 The recommendation for further research is based on the potential for this procedure to be a treatment option for heart failure.

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Chair, interventional procedures advisory committee

November 2020

ISBN: