

Permanent His-bundle pacemaker implantation for treating heart failure

Interventional procedures guidance

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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.

1 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](#). Initial treatments include drugs to improve heart function. However, as heart failure becomes more severe, it can become 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 inserting 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 usually 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 standard or dedicated 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 standard or 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, and where conventional cardiac resynchronisation therapy (CRT) is clinically

contraindicated or unsuccessful.

3.6 The recommendation for further research is based on the potential for this procedure to be a treatment option for heart failure.

3.7 The committee was informed that there is a trend in clinical practice towards bundle branch pacing.

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Endorsing organisation

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