

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Leadless cardiac pacemaker implantation for bradyarrhythmias

Bradyarrhythmias (abnormal heart rhythms) can cause a slow heartbeat, usually because of a problem with the electrical system of the heart. In this procedure, a leadless cardiac pacemaker is inserted into the heart using a thin tube (catheter) through a large blood vessel in the groin (at the top of the leg). It is attached directly to the heart wall where it stimulates the heart to beat more quickly. This avoids the need for a pacemaker box under the skin with leads passing into the heart. The aim is to help the heart beat at a normal rate and reduce symptoms such as dizziness, shortness of breath, tiredness and chest pain.

The National Institute for Health and Care Excellence (NICE) is looking at leadless cardiac pacemaker implantation for bradyarrhythmias. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

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

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations 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: 24 May 2018

Target date for publication of guidance: August 2018

1 Draft recommendations

- 1.1 Evidence on the safety of leadless cardiac pacemaker implantation for bradyarrhythmias shows that there are serious but well recognised complications. The evidence on efficacy is inadequate in quantity and quality. For people who cannot have conventional cardiac pacemaker implantation, leadless cardiac pacemakers should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to do leadless cardiac pacemaker implantation for bradyarrhythmias in people who cannot have conventional cardiac pacemaker implantation should:

- Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's [information for the public](#) *[[URL to be added at publication]]* is recommended.
- 1.3 For people who could have conventional pacemaker implantation, leadless cardiac pacemakers should only be used in the context of research. Further research should report the patient selection criteria and compare leadless cardiac pacemakers with conventional pacemakers. Follow-up should be for at least 5 year and outcomes should include adverse events, symptom relief, quality of life and device durability in the long term.
- 1.4 Clinicians should enter details about all patients having leadless cardiac pacemaker implantation for bradyarrhythmias onto the [National Institute for Cardiovascular Outcomes Research database](#) and review local clinical outcomes.
- 1.5 The procedure should only be done in specialist centres by clinicians with specific training on, and supervised experience in, inserting the device. Centres where this procedure is done should have both cardiac and vascular surgical support for emergency treatment of complications.
- 1.6 NICE advises clinicians to follow the [MHRA Expert Advisory Group recommendations on leadless cardiac pacemaker therapy](#).
- 1.7 NICE may review this procedure on publication of further evidence.

2 The condition, current treatments and procedure

The condition

- 2.1 Bradyarrhythmias are abnormal heart rhythms that can result in a slow heart rate (bradycardia), usually defined as less than 60 beats per minute. There are a range of causes including diseases such as sick sinus syndrome or atrioventricular block. The most common causes are natural ageing process, ischaemic heart disease, heart valve disorders and heart failure. If untreated, bradycardia may lead to fatigue, fainting, palpitations, dizziness, heart failure and an increased risk of death.

Current treatments

- 2.2 Bradyarrhythmias are managed with pacemakers as described in NICE's technology appraisal guidance on dual-chamber pacemakers for symptomatic bradycardia caused by sick sinus syndrome [and/or atrioventricular block](#) and [without atrioventricular block](#). Dual-chamber pacing is recommended for symptomatic bradycardia caused by sick sinus syndrome, atrioventricular block, or a combination of sick sinus syndrome and atrioventricular block, and also for sick sinus syndrome in people without atrioventricular block. Single-chamber ventricular pacemakers may be used for atrioventricular block alone or with sick sinus syndrome in people with continuous atrial fibrillation, or people who have specific factors such as frailty or comorbidities that influence the balance of risks and benefits in favour of single-chamber pacing.

The procedure

- 2.3 The aim of implanting a leadless cardiac pacemaker is to detect cardiac bradyarrhythmias and deliver electric pulses to the heart to increase the heart rate. The leadless pacemaker has a built-in pulse generator, battery and electrodes. The procedure is done under local anaesthesia, with or without sedation, in a cardiac catheterisation laboratory. Under fluoroscopic guidance, the proximal end of the pacemaker is attached to a deflectable delivery catheter and inserted percutaneously through the femoral vein using a dedicated introducer sheath. It is then advanced into the right atrium through the tricuspid valve, into the right ventricle and positioned near the apex or lower septum. Contrast may be injected into the right ventricle to visualise the desired location. Once positioned, the pacemaker is deployed and securely implanted into the endocardium at the apex of the right ventricle wall using a fixation mechanism (a screw-in helix or nitinol tines). An electrode at the distal end of the pacemaker delivers electrical impulses that pace the heart. Electrical measurements are taken and, if satisfactory, the pacemaker is released from the catheter and the catheter is removed.
- 2.4 The pacemaker can be adjusted using an external programmer that transmits signals to it. If the position is suboptimal, the pacemaker can be detached from the endocardium and repositioned or retrieved using a catheter retrieval system.
- 2.5 The device can only detect and pace the right ventricle (single chamber) in contrast to some conventional pacemakers that can provide dual-chamber (right atrium and right ventricle) detection

and pacing. It is therefore suitable for people who only need single-chamber ventricular pacing.

3 Committee considerations

The evidence

- 3.1 To inform the committee, 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 6 case series and 2 retrospective matched case control studies and is presented in table 2 of the [interventional procedures overview](#). There is an overlap of patients in the included studies. Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: adequate pacing performance and quality of life.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: cardiac perforation, cardiac tamponade, pericardial effusion, device dislodgement, battery failure, revision rates and duration of device function.
- 3.4 Three submissions were received from patient organisations and were discussed by the committee.

Committee comments

- 3.5 Leadless cardiac pacemakers are only used for right ventricular pacing and are not suitable for people who need sequential pacing or dual-chamber pacing.
- 3.6 Device problems related to battery life have been reported in the literature.
- 3.7 Different devices are available for use in this procedure, and the technology and their attachment mechanisms are evolving.

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Chairman, interventional procedures advisory committee

April 2018